BCIT™ Research Ethics Board

APPLICATION FOR AMENDMENT, ANNUAL RENEWAL, UNANTICIPATED PROBLEMS, AND STUDY COMPLETION

Complete the relevant sections of the form and email it and all attachments to the REB chair at research_ethics@bcit.ca. The chair will acknowledge receipt and let you know if they have everything they need for review. Minimal-risk studies are reviewed on an ongoing basis. Minimal risk research is defined in TCPS2 as "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research."

AMENDMENTS

Amendments are changes to an ongoing study. If you are changing any part of the study (e.g. co-investigators, title, agency, documentation) you must submit an amendment. Amendments should be changes within the scope of the original study, not new studies that are simply related to the original study. Please submit a new application if it is a new study. Any changes in the co-investigators (as opposed to research staff) must be accompanied by appropriately updated recruitment, consent, and any other materials given to subjects. Any changes to documents should be clearly explained in the form and highlighted on the attached, revised document.

Where the amendment is limited to an 'administrative change' (e.g. changes in granting status, staff personnel, contact person, etc.), please include an explicit statement to the effect that the research procedures (including recruitment, consent, etc.) have not been changed in any way.

The following questions should be considered when proposing an amendment:

1. Does the amendment affect the risk/benefit ratio?
2. Does the amendment affect recruitment? If so, is a revised recruitment ad or letter attached?
3. Does the amendment affect what the subject is asked to do or confidentiality of the data? If so, is a revised consent form attached?
4. Does the consent form adequately reflect the change in time, risk, or confidentiality?
5. When reviewed initially did the BREB have any significant concerns about this study that should be considered when reviewing the amendment?

Please complete sections 1-8 of the application. Your application for an amendment will usually be reviewed for completeness, usually within 3-5 days, and the chair will let you know if anything else is required. Relatively minor amendments are often approved within 5 business days.

ANNUAL RENEWAL

Application for annual renewal should be submitted within two weeks of expiration. Expired studies will generally require a new application. Annual renewal is not required if the researcher will have no further contact with participants for the purpose of data collection or research (e.g. for follow-up or verification). Renewal is not required to analyze data or write a paper. TCPS2 Article 6.14 states, "At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year)" (http://www.ger.ethique.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#14).

Please complete sections 1-8 of the application. If you have not started to collect data, please explain and describe your plans to begin the study in Box 6. If there are no amendments to your study please certify the absence of changes in each section. Your application will be reviewed for completeness, usually within 3-5 days, and the chair will let you know if anything else is required. Renewals with no amendments are often approved within 5 business days.

UNANTICIPATED PROBLEMS AND PROTOCOL DEVIATIONS

An unanticipated problem is any incident, experience, or outcome that meets all of the following: Unexpected (in terms of nature, severity, or frequency); Related or possibly related to participation in the research; Suggests that the research places research participants or others at a greater risk of harm than was previously known or recognized. For example, the theft of a laptop containing confidential information about participants, or unanticipated incidental findings would constitute an unanticipated problem.

For clinical trials, under the Food and Drug Act, a clinical trial sponsor is legally required to report serious unexpected adverse drug reactions to the Minister (Health Canada) either within 15 days (not fatal or life-threatening) or within 7 days (fatal or life threatening) of becoming aware of the information. The ICH Good Clinical Practice Guidelines stipulate that Research Ethics Boards must establish, document in writing and follow procedures for: determining the frequency of continuing review as appropriate (including adverse drug reactions and adverse events) and requiring that the Investigator should promptly report to the REB 1) changes increasing the risk to subjects and/or affecting significantly the conduct of the trial, 2) all adverse drug reactions that are both serious and unexpected, 3) new information may affect adversely, the safety of the subjects or the conduct of the trial.

Please complete sections 1-4 and 7-8 of the application. Your report will be reviewed for completeness, usually within 3-5 days, and the chair will let you know if anything else is required.

STUDY COMPLETION

Before your certificate expires, please complete the Study Completion sections of the application (1-4 and 9) to state that the remaining research no longer requires certification because all data collection procedures described in the project have been completed. TCPS states that "At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year)" (http://www.ger.ethique.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#14).

Your report will be reviewed for completeness, usually within 3-5 days, and the chair will let you know if anything else is required.

DETAILED INSTRUCTIONS FOR THE APPLICATION

The following table can be used as a template to write and edit your form in Microsoft Word or compatible word processing application.

The form and additional instructions incorporate wording from TCPS2 and the UBC Office of Research Ethics guidelines and application forms for Behavioral (BREB) and Clinical REBs (CREB), with their permission, found at:

- https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes/guidance-notes-behavioural-application
- https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes
- http://www.ger.ethique.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

FORM SECTION	INFORMATION AND ADDITIONAL INSTRUCTIONS

1. Select all that apply: □ Amendment (complete Sections 1-8) □ Annual Renewal (complete Sections 1-8) □ Unanticipated Problems or Protocol Deviation (complete Sections 1-4 and 7-8) □ Study Completion (complete Sections 1-4 and 9)	See information above and include all required attachments.
2. BCIT study number (YYYY-NN)	This number can be found on your approval letter and certificate.
3. Principal Investigator (Name) Institution Phone Email	
4. Current title of project	If considering a change to title, include new title in Box 5.4 and remember to update the study documents.
5. Amendments 5.1 New Principle Investigator (Name) Degree(s)/Position Institution Faculty/Department Mailing Address Phone Email □ Current PI will remain as co-investigator on the study □ I will be removed from the study. Signature of current PI (submission will serve as signature if emailed) □ I do not have any conflicts of interest. □ I have a conflict of interest and have attached a description. Signature of new PI (scan and email or email Chair directly) Signature of Direct Supervisor (Serves as Principle Investigator if student Project; Attests that investigator has the expertise and resources to carry out the study)	Ensure that any study documents (e.g. consent or assent documents) are updated and attached to reflect the new Principal Investigator. An updated Certificate of Approval will be issued to the newly designated Principal Investigator only. Signature or supervisor. 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 (https://www.bcit.ca/files/pdf/policies/6600.pdf). If the project is intended to fulfill a course or degree requirement then enter your name as the primary contact for correspondence. Your faculty advisor will be responsible for ensuring that you, as a student, conduct your study to the same standards. 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. Please have the supervisor send an email directly to the REB chair (research_ethics@bcit.ca) to attest that you have the expertise and resources to carry out the study. Alternatively, print this page, collect signatures, then scan and email. NOTE: Using Adobe digital signature feature for PDFs will lock your application from editing and make revisions more difficult. Use a separate copy, named and marked "signatures" for digital signatures if you choose to use this PDF feature.
5.2 What are the research qualifications of all new investigators, co-investigators, or research assistants conducting the study? Describe relevant training, experience, and/or courses.	Explain in brief what each person will do on the research team and what experience they bring to it. Describe relevant training, experience, degrees, and/or courses.
5.3 New co-investigator or research	List any others who will assist in collecting or analyzing data. If

assistant (Name). If more than one, include same information in an attachment. Degree(s)/Position Institution Faculty/Department Role in project Mailing Address Phone Email	more than one, please include these same details for each in Box 5.2 or attachment, followed by their research qualifications.
5.4 Proposed changes to study	Briefly describe the nature of the proposed change(s) and explain the reason why you want to make the proposed change(s). Changes may be to study design such as study objectives or procedures, or administrative changes such as study personnel, project title, sponsor, start or end dates, or any other similar changes. Explain why each change was made (e.g. the previous PI has left the institution; interim results indicate a need to change the study objectives, etc.). If no changes, state "None"
5.5 New estimated end date if requesting renewal. Please note that approval will be for a period of one year from the end of the current approval period.	Please note that approval will be for a period of one year from the end of the current approval period.
5.6 Any change in risk to participants? □ Yes □ No If yes, please explain.	Indicate whether or not the proposed changes will result in any increase in risk for the study participants beyond what was originally anticipated. If so, please explain what the increased risks are and why they are necessary. TCPS2 defines minimal risk research as "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research." Minimal risk research is normally eligible for review on an ongoing basis by a subset of REB members (i.e., "delegated review"). Applications are reviewed as they are received. Research considered above-minimal risk will be reviewed at a meeting of the full board. Please submit your application at least two weeks in advance of the next meeting (see FAQ on our website for meeting dates: https://www.bcit.ca/appliedresearch/ethics/faq.shtml) Risks of research include physical risk (harm through bodily contact or administration of any substance, device or other intervention), psychological or emotional harm (harm due to feeling embarrassed, uncomfortable, anxious or upset), social risk (harm due to loss of status, privacy, or reputation, and includes legal, financial or employment risk). Vulnerability to harm exists along a continuum and is influenced by many factors such as participant capacity (mental, emotional, cognitive), age, wellness or health status, institutionalization, power relationships, gender and gender identity, setting and

	recruitment, dependency). Please consider participant vulnerability and include justification for your choice in research plan (Appendix E). Common examples of above minimal risk studies include: • Projects involving any moderate to serious physical, emotional, psychological, legal, social, or economic risk to participants. • Potential disadvantage due to experimental design (e.g., randomization in an intervention study). • Projects involving sensitive questions or invasive procedures. • Projects involving vulnerable populations where participants' capacity to consent may be affected (e.g., infants and young children, individuals with cognitive or intellectual disabilities). • Projects where there is a possibility of coercion (e.g., studies involving "captive" groups such as employees, students, members of the military, prisoners). • Projects involving partial disclosure or deception (e.g., some information which may affect participants' decision to participate is withheld at time of initial consent). (From https://research.uottawa.ca/ethics/submission-and-review/types-review)
5.7 Any change to institutions or locations taking part? □ Yes □ No If yes, please explain and provide documentation of approval from these additional sites.	Please include documentation of REB approval from the other institutions as an attachment.
5.8 Any change to funding? □ Yes □ No If yes, please explain and provide documentation.	Applied Research is allowed to release limited amounts of grant funding to researchers for "initial" research work that doesn't involve human participants.
5.9 Changes in conflict of interest of Principal Investigator and/or other members of the study team? □ Yes □ No If yes, please explain and provide documentation.	Please provide details of any changes in relation to conflict of interest status of the Principal Investigator and/or other members of the study team. The REB needs to be satisfied that participants are informed of conflict of interest matters in the consent process. Note that patent/property rights or holdings of immediate family members also constitute a conflict of interest for the PI and/or other members of the study team. "Immediate family members" includes partners and children (whether living in the household or not). The REB does not require that the investigator identify holdings in managed mutual funds to be declared in the conflict of interest statements.
5.10 Summary of document changes Any change to informed consent process? □ Yes □ No Revised proposal?	For amendments that change conditions described in the consent form, please include updated recruitment materials and consent form. If "Yes," list each document(s) name and provide a brief summary describing the changes being made to that document (identify where the change(s) are in each document with reference

□ Yes □ No Other revised or new document(s)? □ Yes □ No If yes to any of these, please explain and list each document with changes highlighted.	to the section and page). Ensure that the changes in the documents are identifiable by either using highlights or track changes.
6. Progress to date	Provide a brief summary of the overall progress of the study and results, if known. The summary of progress to date should include information on whether participants are still being recruited. For ongoing studies, remarks about the ability to recruit participants are also appropriate, as is any information about the results from any interim analyses. Please include the number of participants taking part in the study. If there have there been any participant withdrawals please explain. If space on this form is insufficient, attach separate sheet(s).
7. Unanticipated problems and Serious Adverse events 7.1 Unanticipated problems? □ Yes □ No If yes, please explain.	An unanticipated problem is any incident, experience, or outcome that meets all of the following: Unexpected (in terms of nature, severity, or frequency); Related or possibly related to participation in the research; Suggests that the research places research participants or others at a greater risk of harm than was previously known or recognized. Please include a description of the incident, experience or outcome if applicable, a summary of the new information if applicable, a description of any changes to the protocol or other corrective actions that have been taken or are proposed to be taken in response to the new information, unanticipated problem or new documentation. Include, for example, • Site of unanticipated problem • Date & time of unanticipated problem • Date research team became aware of the problem • How the research team became aware of the problem • Is it a serious unanticipated problem? • Has any member of your study team had any communication with the participant and if so, please describe and include this communication as an attachment. • Was the participant discontinued from the study as a result of the unanticipated problem? • Was medical or other intervention provided to the participant? • What action (if any) has been taken, or will be taken, by the research team and by whom, to reduce the likelihood of a future unanticipated problem? • What adverse outcome has occurred or can be expected for the participant (for example, the participant's reputation will be harmed)? • Describe the current status of the participant. For example, is the participant experiencing any ongoing problems, have they

	recovered completely?
	• Describe what follow-up action for study participants you recommend, such as
	  o Re-consenting current participants with an amended consent form
	  o Informing current study participants ASAP
	  o Revising consent/assent forms
	  o Protocol revisions/amendment
	  o Updating investigator's brochure
	  o Temporarily suspending study

7.2 Clinical Serious Adverse Events (SAEs) Please indicate the type of SAE you are submitting and details of the event (*see instructions*).	Include the following information: • The status of the study (i.e. open or closed to enrolment or on-hold, etc.) • Summary of the status of participants enrolled • A detailed description of the local event (include the date, whether this is an initial or follow-up report, and whether the event reaction was mild, moderate or severe) • An opinion expressed by the local investigator that the event is both serious and unexpected and a justification of that opinion • An opinion expressed by the local investigator that the event is related or potentially related to the study drug/procedure/device and an explanation of that opinion • An opinion expressed by the local investigator regarding the implications of the SAE on the continuation of the study and any further actions that may be required such as changes to the study procedures, informed consent or protocol • A statement of the study team response to the event and the participant's outcome of the SAE Individual Local or non-local (external) Serious Adverse Events must meet the definition of an Unanticipated Problem (unexpected, related and involving greater risk - see definition) and must be reported within Seven (7) days of the occurrence of the event/ receipt of the notice of the reportable individual event. Events that do not meet the above criteria are NOT acceptable as an individual report and instead must be reported to the REB in the form of a quarterly or six monthly periodic safety update report provided by the sponsor, which must include a meaningful interpretation of the events and a position statement as to whether these warrant a change (these reports should be submitted within Fifteen (15) days of receipt from the sponsor). **Adverse Event (AE):** Any untoward medical occurrence in a research participant administered an investigational product including an occurrence which does not have a causal relationship with this product. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of an investigational product, whether or not related to the investigational product.

	Local (Internal) Adverse Event: Those adverse events experienced by research participants enrolled by the investigator(s) at one or more centres under the jurisdiction of the REB of Record. In the context of a single-centre clinical trial, all adverse events would be considered local adverse events. **Non-Local (External) Adverse Event (EAE):** From the perspective of the REB overseeing one of more centres engaged in a multi-centre clinical trial, external adverse events are those adverse events experienced by research participants enrolled by investigator(s) at other centres/institutions outside the REB's jurisdiction. **Adverse Drug Reaction (ADR):** Any response to a drug, biologic, or natural health product which is noxious and unintended, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function. A reaction, as opposed to an adverse event, is characterized by the fact that a causal relationship between the product and the occurrence is suspected (i.e. judged to be at least a reasonably possibility). **Serious Adverse Event (SAE):** Any untoward medical occurrence at any dose that: • Results in death • Is life-threatening • Requires inpatient hospitalization or prolongation of existing hospitalization • Results in persistent or significant disability/incapacity • Results in a congenital anomaly/birth defect • Based upon appropriate medical judgement, is an important medical event that may jeopardize the patient or may require medical intervention to prevent one of the outcomes listed above. **Unexpected Adverse Drug Reaction (UADR):** An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. the Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product). **Medical Device Serious Adverse Event (MDSAE):** An adverse event associated with a medical device complaint meets the criteria of a medical device SAE when both of the following are fulfilled: • The event involves contact with the medical device and • The event results in death or serious deterioration in state of health. This includes: o Life-threatening illness or injury

	○ Permanent impairment of a body function ○ Permanent damage to a body structure ○ A condition that requires medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure
8. Protocol deviations? □ Yes □ No If yes, please explain.	Please include the following: • The status of the study (i.e. open or closed to enrolment or on-hold, etc.) • Summary of the status of participants enrolled • A description of the deviation that occurred with an explanation of the circumstances that led to the deviation and the resulting problem • An explanation as to whether or not the deviation compromised the scientific integrity of the study • An explanation of whether or not the deviation increased the risk or the possibility of risk for the research participant(s) • If applicable, an explanation of whether and how participants affected by a protocol deviation will be informed • A description of steps taken or that will be taken to correct/address the problem resulting from the deviation; and • A plan for ensuring that similar deviation does not occur in the future. • Confirm whether any previous protocol deviation(s) have occurred that have been previously reported to the REB.
9. Completion of Study 9.1 How many research participants were proposed for the study? 9.2 How many research participants were involved in this study? 9.3 Did any research participants actively withdraw from the study? □ Yes □ No If Yes, how many? Please describe circumstances. 9.4 How many research participants completed the study? 9.5 Please provide a brief summary of the findings of your study (100-200 words). 9.6 Since receiving original ethics approval, have there been any adverse or unanticipated events? □ Yes □ No If Yes, please complete the Adverse or	Your submission certifies that: • The information you have provided is correct and that no unapproved procedures were used in study • Proper safeguards to confidentiality and security of data will be maintained until all data are destroyed. • You will not use the data for other research purposes without application to and approval by the Research Ethics Board

Unanticipated Event Report section) 9.7 Please give the reason and provide explanation for closing the study (i.e., end of study, accrual met, not enough participants, etc.). 9.8 DATA AND CONFIDENTIALITY Please describe how study-related documents will be stored and/or retained after the completion of the study, explaining privacy protection and supporting security. Will this be different from what you described in your original submission to the REB? □ Yes □ No Your submission certifies that: • The information you have provided is correct and that no unapproved procedures were used in study • Proper safeguards to confidentiality and security of data will be maintained until all data are destroyed. • You will not use the data for other research purposes without application to and approval by the Research Ethics Board	
END OF FORM	