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

3700 Willingdon Avenue, Burnaby, BC, Canada V5G 3H2

The information collected on this form will be used to assess your request for amendment, annual renewal, unanticipated problems, and study completion in compliance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2) and will be shared with the BCIT Research Ethics Board, its administration, and consultants as described in BCIT Policy 6500 and procedures. Please contact the chair of the REB at **research_ethics@bcit.ca** for instructions on how to submit this form. The detailed instructions for this form, additional contact information, and guidelines are available at **bcit.ca/appliedresearch/ethics**

CLEAR FORM

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)	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	

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)	
For new PI, signature of Direct Supervisor (Serves as Principle Investigator if student project; attests that investigator has the expertise and resources to carry out the study)		
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.		
5.3 New co-investigator or research assistant (Name). If more than one, include same information in an attachment.	Degree(s)/Position	Institution
Faculty/Department	Mailing Address	
Phone	Email	
Role in Project		

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). 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.

5.6 Any change in risk to participants? ☐ Yes ☐ No

If yes, please explain.

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.

5.8 Any change to funding? ☐ Yes ☐ No

If yes, please explain and provide documentation.

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.

5.10 Summary of document changes

Any change to informed consent process? ☐ Yes ☐ No
Revised proposal? ☐ 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.

6. Progress to date. Provide a brief summary of the overall progress of the study and results, if known. 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.

7.2 Clinical Serious Adverse Events (SAEs)

Please indicate the type of SAE you are submitting and details of the event (see instructions).

8. PROTOCOL DEVIATIONS?

☐ Yes ☐ No

If yes, please explain.

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 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