

RESEARCH ETHICS BOARD ON HUMAN SUBJECTS

REQUEST FOR ETHIC APPROVAL MODIFICATION

SECTION 1 – IDENTIFICATION

1.1 Date of request:	Click here to add date
1.2 Short title (if applicable) :	Short title
1.3 Complete project title :	Complete project title
1.4 Case number :	Case number
1.5 Principal investigator	Principal investigator
Establishment :	Establishment
Postal code :	Postal code
Telephone :	Telephone
Email :	Email
1.6 Project support person (e.g., student, post-doctorat)	First and last name
Establishment :	Establishment
Telephone :	Telephone
Email :	Email
1.7 Approval date :	Click here to enter the date
1.8 Approval end date :	Click here to enter the date
1.9 Project end date :	Click here to enter the date

SECTION 2 – INFORMATION ON THE CURRENT STATUS OF THE PROJECT

2.1 Indicate the current status of the project:

- Ongoing / Recruitment not started
- Ongoing / Actively recruiting
- Ongoing / Recruitment finished
- Project currently interrupted

SECTION 3 – INFORMATION PERTAINING TO MODIFICATIONS

3.1 Check all the elements that apply:

PLEASE NOTE: Add the modified documents and explain the reasoning for each necessary modification.

Changes requested	Date and version	Reasoning
<input type="checkbox"/> Modification to the research protocol	Answer	Answer
<input type="checkbox"/> Modification to the consent process/form	Answer	Answer
<input type="checkbox"/> Addition of a new consent form	Answer	Answer
<input type="checkbox"/> Modification to materials used for the recruitment of research subjects (e.g., publicity)	Answer	Answer
<input type="checkbox"/> Addition of materials used for the recruitment of research subjects (e.g., publicity)	Answer	Answer
<input type="checkbox"/> Modification to questionnaires or other research documents (including documents given to research subjects)	Answer	Answer
<input type="checkbox"/> Addition of questionnaires or other research documents (including documents given to research subjects)	Answer	Answer
<input type="checkbox"/> Modification to the project budget	Answer	Answer
<input type="checkbox"/> Other, indicate : Answer	Answer	Answer

3.2 Do these modifications need to be approved by Health Canada (e.g., no objection letter from Health Canada)?

- Yes
- No
- NA

If yes, please append the no objection letter from Health Canada.

3.3 Do the new modifications require renewed consent from the already enrolled research subjects?

- Yes
- No
- NA (recruitment finished)

If yes, how will you go about renewing the consent (contact with subjects)?

Answer

SIGNATURE

By signing this form, I agree that:

- all information in this form was written truthfully and at the best of my knowledge;
- all researchers implicated in this submission has revised the form and approved its content;
- I assume the role and responsibilities incurred by this research project for the duration of the project;
- I will not put into effect major changes to the project without the authorization of the Research Ethics Board for human subjects.

Signature of Principal Investigator

Date

Name (printed)

I confirm that if the ethics approval submission was written by a student, research student or postdoctoral student, I revised the form before submission to the Research Ethics Board.

Signature of supportive Investigator
(if Principal Investigator is a student)

Date

Name (printed)