# Instructions

1. Complete all sections. Please write “N/A” if a section is not applicable to your research/training protocol.
2. Attach a copy of all relevant permits, questionnaires, interview schedules, tests, informed consent forms, project budget, and/or other items required for a complete review of your amendment request form.
3. Submit this form to the Chair of the Research Ethics Committee via email – chairREC@auroracollege.nt.ca

Please note that unapproved changes to the protocol cannot be carried out until they have been approved by the REC. If an unapproved change has already been made to the protocol, please submit an Unanticipated Event Report.

# Project Identification

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator Name | Click or tap here to enter text. | REC Protocol # | Click or tap here to enter text. |
| Affiliation | Click or tap here to enter text. |
| Division/Faculty | Click or tap here to enter text. |
| Mailing Address | Click or tap here to enter text. |
| E-Mail Address | Click or tap here to enter text. | Phone Number | Click or tap here to enter text. |
| Project Title | Click or tap here to enter text. |

# Proposed Changes

1. Please check all applicable boxes to indicate which sections of the study protocol may be changed

1. **Principal Investigator Information**

[ ]  Principal Investigator (PI)

[ ]  PI Affiliation

1. **Project Details**

[ ]  Title of Project

[ ]  Study dates

[ ]  Study locations

[ ]  Study dates

[ ]  Study objectives

[ ]  Research design or methodology

1. **Risks and Benefits**

[ ]  Estimation of risks

[ ]  Risk mitigation plan

[ ]  Potential benefits

[ ]  Compensation and reimbursement

1. **Recruitment**

[ ]  Study population

[ ]  Recruitment process

[ ]  Sample size

[ ]  Accommodation for participant cultural/language needs

1. **Informed Consent**

[ ]  Consent process
[ ]  Assent process

[ ]  Community consultation

[ ]  Deception (including partial disclosures)

[ ]  Participant withdrawal process

[ ]  Follow-up/debriefing

1. **Privacy and Confidentiality**

[ ]  Data management protocol

[ ]  Persons with access to study data

[ ]  Privacy and confidentiality protocols

[ ]  Data retention/disposal

[ ]  Secondary use

1. **Dissemination**

[ ]  Plan for dissemination

[ ]  Research products

[ ]  Community-level dissemination

1. **Research Instruments
(questionnaire, interview guide, etc.)**

[ ]  Changes to any research instruments

1. **Consent Form and Information Sheet**[ ]  Changes to information sheet
[ ]  Changes to consent form

2. Please describe the proposed study amendment and its rationale:

Click or tap here to enter text.

3. Will the proposed amendment affect the rights and interests of the study participants? Will the proposed amendment affect the potential risks associated with participating in the study?

[ ]  **Yes** [ ]  **No**

a. If YES, please explain:

Click or tap here to enter text.

4. Do you plan to re-contact participants who are already enrolled in the study?

[ ]  **Yes** [ ]  **No, there is no follow-up required**

a. If YES, please indicate which follow-up is planned:

[ ]  Informing the study participants of the changes to the study as soon as possible

[ ]  Seeking new informed consent from participants

[ ]  Other (please specify):

 Click or tap here to enter text.

5. Please indicate which, if any, of the study documents will require revision and attach copies with revisions **emboldened,** CAPITALIZED or otherwise highlighted:

[ ]  Information sheet

[ ]  Consent form

[ ]  Research instruments

[ ]  Interview question list

[ ]  Other (please specify):

# Signatures

Principal Investigator Name:

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_