

Office Use Only

Protocol Number:

Office of Research Ethics

Request to Revise an Application to Involve Human Participants in Research

This form is to be submitted with amendments to previously cleared protocols. Please ensure that all revised documents are included with this request.

Revised procedures should not be implemented until ethics clearance has been received.

Submit one **(1 signed copy)** of this form to the Office of Research Ethics: **ethics@uwindsor.ca**.

### 1. TITLE OF RESEARCH PROJECT

|  |
| --- |
|  |

Date**:**

Protocol Reference #: Original Clearance Date:

Previous Renewal Date:

### 2. INVESTIGATOR INFORMATION

**Investigator:**

|  |  |
| --- | --- |
| Title:  | Name:  |
| Department (or organization if not affiliated with U of Windsor):  |
| Mailing address:       |
| Phone:        | Email:       |

**Level of Project**

|  |
| --- |
| Faculty Research [ ]   |
| Post-Doctoral Research [ ]   |
| Student Research: Doctoral [ ]  Masters [ ]   |

 **Faculty Supervisor/Sponsor:**

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department (or organization if not affiliated with U of Windsor):       |
| Mailing address:       |
| Phone:        | Email:       |

The headings below correspond to sections of the University of Windsor Application to Involve Human Subjects in Research.

* Please check all boxes that apply to the sections you wish to revise or modify. On a separate sheet please explain these changes in detail.
* If the revision is related to a questionnaire or interview protocol, please submit the entire revised document and highlight the sections that are being revised or added.

### 3. OTHER RESEARCH ETHICS BOARD APPROVAL(S)

 a) Does the research involve another institution or site? Yes [ ]  No [ ]

 b) Has any other REB renewed the ethics approval for this project? Yes [ ]  No [ ]

If **Yes**, please provide a copy of the approval letter with this application.

### 4. PROPOSED CHANGES

* 1. Please describe the proposed study amendment or modification in the space provided below. Please specify if it is a **minor** (e.g., administrative change, including funding status) or **major** (e.g., addition of study method, participants involved in the study, recruitment process, risks, procedures, etc.) change:

[ ]  Minor [ ]  Major

If you are requesting an extension of your protocol date, please add the following details:

Number of participants that have completed the study:

Number of participants currently enrolled in the study:

Number of additional participants still required for the study:

Number of participants that have voluntarily withdrawn from the study:

b) Would you also like to extend your annual renewal date to a year from now?

[ ] Yes [ ]  No

c) Will the proposed amendment change the overall purpose or objective of the study?

[ ] Yes [ ]  No

If **Yes**, a new protocol may be requested by the REB.

d) Will the proposed amendment affect the vulnerability of the participant group or the research risk?

[ ] Yes  [ ]  No

If **Yes**, please indicate the **new** overall risk level on the Risk Matrix below.

e) What follow-up action do you recommend for study participants who are already enrolled in the study?

[ ]  Inform study participants

[ ]  Revise consent/assent forms (please attach a copy with the changes)

[ ]  Other (please describe)

[ ]  No action required

### 5. RISK MATRIX:

By locating a protocol on the matrix, researchers can determine both the review type (i.e. delegated expedited or full) and level of continuing review (e.g. annual renewal or small possibility of site visit) appropriate to a project.

 **Research Risk**

**Group Vulnerability Low Medium High**

**Low** **1** [ ]  **1** [ ]  **2** [ ]

**Medium** **1** [ ]  **2** [ ]  **3** [ ]

**High** **2** [ ]  **3** [ ]  **3** [ ]

**6. SIGNATURES**

**My signature certifies that the above information is correct and that no unapproved procedures will be used on this study.**

|  |
| --- |
|  Signature of Investigator:       Date:        |

AND (if applicable)

|  |
| --- |
|  Signature of Faculty Supervisor/Sponsor:       Date:       (for student or supervised research only) |