An amendment is a change to an ORE/REB Approved and ongoing study. If you are changing any part of the study (e.g. consent forms, procedures, co-investigators, title, funding, documentation) you must submit an amendment request. Amendments to studies should be changes within the scope of the original study, not new studies that are simply related to the original study. Amendments to previously approved research studies must be reviewed and approved by the SFU REB before any change to the protocol/study details, consent forms, research instruments, or any other change is implemented.

To request an amendment to a previously approved study, send this completed document to dore@sfu.ca citing your study number in square brackets in the subject line (e.g. [2008s0679]) and attach your revised documents in PDF format. Only highlight the sections in the revised document(s) showing where the current change(s) occur. Remove any highlighting or track changes markings previously approved (e.g. with a prior amendment). Include an updated version date and number in the footer of the document. Supervisor Approval is also required in the case of a Graduate Student, Staff, or Postdoctoral Researcher.

If the Associate Director of Research Ethics (ADORE) or Director of Research Ethics (DORE) deems the amendment to be more than a minor amendment, you may be asked to complete a new application. Examples of minor and major amendments are provided below.

Please note the following when submitting an amendment:

- Amendments that involve adding procedures that are Above Minimal Risk must be referred to the Full Board for review and approval;
- Any changes to documents should be clearly explained and highlighted, and include a version date, on the attached, revised ORE Amendment Request Form;
- Where the amendment is limited to an 'administrative change' (e.g. changes in granting status, staff personnel, contact person, change in supervisor, etc.), please include an explicit statement to the effect that the research procedures (including recruitment, consent, etc.) have not been changed in any way, and
- Briefly explain the rationale behind any changes in the protocol.

The following questions should be considered when proposing an amendment:

- Does the amendment affect the risk/benefit ratio?
- Does the amendment affect recruitment? If so, is a revised recruitment ad or letter attached?
- Does the amendment affect what the participant is asked to do or confidentiality of the data? If so, is a revised consent form attached?
- Does the consent form adequately reflect the change in time, risk, or confidentiality?

You may find the following concepts and definitions useful when completing this form:

**A minor amendment:**

Any changes that do not involve Above Minimal Risk for participants or the conduct of the trial. Examples include:

- Minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications;
Office of Research Ethics
Amendment Request Guidance Form

- Updates of the Investigator’s Brochure (IB) (unless there is a change to the risk/benefit assessment for the trial);
- Changes to the research team at particular trial sites (other than appointment of a new PI);
- Changes to contact details for the sponsor, PI, or other study staff member;
- Changes in funding arrangements. Note, when this is the case, ensure if application, consent documents are updated to include the addition of funding;
- Changes in the documentation used by the research team for recording study data;
- Changes in the logistical arrangements for storing or transporting samples;
- Inclusion of new sites and investigators in a clinical trial of investigational medicinal product;
- Extension of the study beyond the period specified in the application form.

A **major amendment**:
Any changes that affect the safety or physical or mental integrity of the participants for the conduct or management of the trial. Examples include:

- Changes to the design or methodology of the study, or to background information affecting its scientific value;
- Changes to the procedures undertaken by participants;
- Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
- Significant changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or careers;
- A change of sponsor(s) or sponsor’s legal representative;
- Appointment of a new PI or key collaborator, unless the newly appointed PI was already deemed a sub-PI for the study as noted on the site delegation log (to be treated as a minor amendment);
- A change to the insurance or indemnity arrangements for the study;
- Inclusion of a new trial site (not listed in the original application) in a clinical trial of investigational medicinal product;
- Appointment of a new principal investigator at a trial site in a clinical trial of investigational medicinal product;
- Temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt;
- A change to the definition of the end of the study;
- Any other significant change to the protocol or the terms of the REB application.

### Specific Guidance per Question

| Section 1 Question 4 | If this amendment requires Health Canada approval, then it requires Full Board REB review. |
The PI must update the Clinical Trial Registry record promptly and also verify your record on the Registry at a minimum every 6 months to ensure publication of the study data will be accepted at a later date.

<table>
<thead>
<tr>
<th>Section 2</th>
<th>Question 2</th>
<th>If your study is limited to an existing data set or naturalistic observation where no active recruitment is involved, your response to this question would be “no”.</th>
</tr>
</thead>
</table>

| Section 2  | Question 4 | If this study received REB Approval from other institutions or authorities, these bodies must also receive any revised study documentation associated with this Amendment.  
If another REB is the Board of Record for this study and has already approved this Amendment, please include this documentation. The Board of Record is the REB that assumes responsibly for the study in question. |
|-----------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

<table>
<thead>
<tr>
<th>Section 4</th>
<th>Question 1</th>
<th>The N/A category in this question would apply to studies involving no consent processes (e.g., some types of secondary use of data or naturalistic observation).</th>
</tr>
</thead>
</table>

| Section 4  | Question 3 | An unanticipated problem is any incident, experience, or outcome that meets all of the following criteria:  
- 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 would constitute an unanticipated problem; an outbreak, war or insurrection in the area of the research might constitute an unanticipated problem.  
Unanticipated Problems should be reported to the ORE/REB using the Unanticipated Problem Form.  
*Please note that an Adverse Event should be reported to the ORE/REB immediately using the Unanticipated Problem Form.* |
|-----------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|