**Ethics and Medical Research Committee**

### ELM PARK, DUBLIN 4

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**AMENDMENT NOTIFICATION FORM**

When any revision to an approved research protocol, patient information leaflet/consent form and/or advertisement for subject recruitment is desired, an amendment must be filed with the Research Ethics Committee. The amendment notification form must be completed indicating the changes; revisions may be within the protocol itself, the patient information leaflet/consent form or the advertisement. The form should explain what changes have been made and the rationale for the change. A revised copy of the pertinent original documents (protocol, patient information leaflet/consent form and/or advertisement) should also be submitted with the particular changes identified. A cover letter or additional information may also be attached, as necessary.

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator: Dr / Mr / Ms / Prof \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Ethics Committee Reference Number: RS\_\_\_\_\_\_-\_\_\_\_\_\_\_\_**

**Protocol No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title of Research Project:**

**Date of Amendment: \_\_\_\_\_\_\_\_\_\_\_**

**Amendment No: \_\_\_\_\_\_\_\_\_\_**

Dear Chairperson,

I would like to make an amendment to the above-named application to {change / add / extend etc.}

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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www.stvincents.ie

* Is a revised protocol necessary as a result of this amendment? YES NO

If YES, please attach a copy and highlight the changes.

* Is a revised patient information leaflet/consent form necessary YES NO

as a result of this amendment?

If YES, please attach a copy and highlight the changes.

* Is a revised advert necessary as a result of this amendment? YES NO

If YES, please attach a copy and highlight the changes.

* Does the amendment affect the safety or the conduct of

the participants of the study? YES NO

If YES, give details

**Please list the specific changes from the previously approved protocol and provide sufficient rationale** **for each change to allow the Committee to make a decision**.

* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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I enclose the following {revised / new} documents for review. I confirm that any changes to revised documents have been highlighted for ease of review, and that version number of revised documents have been changed as required.

**Enclosures[[1]](#footnote-1)**

1. \_\_\_\_
2. \_\_\_\_
3. \_\_\_\_
4. \_\_\_\_

**Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

#  **Principal Investigator**

1. Highlight or track changes in enclosed documents, as opposed to originally approved documents, and update the version numbering as required. [↑](#footnote-ref-1)