Ethics and Medical Research Committee

### ELM PARK, DUBLIN 4

## Tel. (01) 2214117 Fax (01) 2214428

## email: svhgethics@ucd.ie

## 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.

**Principal Investigator:** ………………………………

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

**Title of Research Project**:

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**Amendment No: \_\_\_\_\_\_\_\_\_\_\_\_ Date: - - - - - - - -**

* 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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Signed: …………………………………………… Date: - - - - - - - -

# Principal Investigator