APPLICATION FOR CLINICAL TRIAL PROTOCOL AMENDMENT

APPLICATION FOR APPROVAL OF:

☐ **PROTOCOL AMENDMENT**
☐ **INCREASE IN NUMBER OF STUDY PARTICIPANTS**
☐ **CHANGES IN DOSE/REGIMEN OF INVESTIGATIONAL MEDICINAL PRODUCT**

Title of the study:

Protocol Number:

Date:

1. APPLICANT

1.1 Name
1.2 Address
1.3 Telephone
1.4 Fax number

2. TRIAL PARTICULARS (original application)

2.1 Trial Approval Number:

2.2 Date of Approval of original protocol:

2.3 Principal Investigator(s) approved for this trial:

Number of local sites approved for this trial:

Number of participants approved for this trial:

3. AMENDMENT PARTICULARS

(Please list requests for approval)

3.1 Does the applicant wish to increase the number of local study participants participating in this trial?

Yes ☐
No ☐

3.2 Does the applicant wish to change the dose/regimen of the investigational medicinal product?

Yes ☐
No ☐

3.3 Does this amendment request require a new consent form to be signed by the participant?

Yes ☐
No ☐

If "Yes" please submit new PIL together with this application.

Protocol Amendment Number:
Version Number and Date of Protocol Amendment (for each document submitted):
General motivation for the proposed amendment: [List all of the issues included in the amendment and provide the rationale for each amendment]
Details of the proposed protocol amendment: [For each amendment, provide reasons for amendment and clearly highlight changes to the original protocol; this can be done either as "old text" replaced with "new text" or with the old text deleted with a line through it and the new text in bold and underlined]

3.4 Will this amendment apply to all approved site(s)?

Yes ☐
No ☐

If No: Specify the investigator(s)/site(s) for which the amendment will apply:

4.1 **ETHICS COMMITTEE APPROVAL**

4.1 Have the Research Ethics Committee(s) responsible for each centre to which this amendment applies been notified?

4.2 Research Ethics Committee(s) responsible:

4.3 Date of application to Ethics Committee:

4.4 Date of approval by Ethics Committee:

I/We, the undersigned, agree to conduct/manage the above-mentioned trial under the conditions as stated in this application. (The person(s) undertaking legal responsibility should sign this form).

Applicant	**Date**