Application Form for Amendment

APPLICATION FOR APPROVAL OF:

- ☐ **CHANGES IN INVESTIGATOR(S) AT APPROVED SITE (includes additional investigators)**
- ☐ **ADDITIONAL SITE(S)**

Title of the study:

Protocol number:

Date:

1. APPLICANT

Name
Address
Telephone
Fax number

2. TRIAL PARTICULARS (original application)

Trial approval number:

Date of approval of original protocol:

Principal investigator(s) approved for this trial:

Number of local sites approved for this trial:

Number of participants approved for this trial:

3. INVESTIGATOR'S DETAILS

3.1 Name and address of additional Investigator(s)/Changes to Investigators: [Proof of ICH - GCP training must be provided for investigators who have not previously participated in clinical trials]

3.2 Summarise other ongoing/planned studies at the site involving the investigator: [Provide details of studies, including numbers of study participants, whether the investigator is involved in research in a full-time or part-time capacity, and any other details that may affect the capacity of the site at any one time]

3.3 Date of application to Ethics Committee:

3.4 Date of approval by Ethics Committee:

3.5 Is CV for additional investigator(s) attached?

Yes ☐
No ☐

3.6 Is the declaration of Intent attached?

Yes ☐
No ☐

(If yes, attach declaration)

4. CAPACITY OF THE SITE

Describe how the site is structured so as to be able to take on the work for which this application is being made: [Give details of support staff, facilities, back up and any other relevant infrastructure].

5. RATIONALE FOR APPLICATION

5.1 Briefly explain the reason for the new investigator/s or site(s):

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**