APPLICATION FOR ADDITIONAL INVESTIGATOR(S), CHANGE OF INVESTIGATOR(S) OR ADDITIONAL CLINICAL TRIAL SITES

**MCAZ Reference Number:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Application for Approval of:**

Changes in Investigator at Approved Site (includes additional investigators)

Additional Site(s)

**Study title:**

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

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

1. **APPLICANT DETAILS**
   1. Name/address/telephone/fax number of Applicant wishing to conduct trial
   2. Name/address/telephone/fax number of CRO representing sponsor as Applicant or Local Sponsor Company details (*if applicable*)
   3. Name, designation and qualifications of person representing the Applicant: (*Local Contact Person for all further correspondence*)
   4. National Coordinator name, address, telephone/fax number
   5. International Principal Investigator name, address, telephone/fax number
   6. Name of sponsor
2. **TRIAL PARTICULARS (original application)** 
   1. Trial Approval Number:
   2. Date of Approval of original protocol:
   3. Number of local investigators approved for this trial:
   4. Number of local sites approved for this trial:
   5. Number of participants approved for this trial:
3. **INVESTIGATOR DETAILS** 
   1. Name and address of additional Investigator(s)/Changes to Investigators: (*Proof of GCP training must be provided for investigators who have not previously participated in clinical trials*)
   2. Summarise other ongoing/planned studies at this site involving this investigator: (*Provide details of studies, including numbers of subjects, whether the investigator is involved in research in a full-time or part-time capacity, and any other detail that may effect the capacity of the site at any one time*)
   3. Details of Ethics Committee(s) who will approve investigator(s):
   4. Date of application to Ethics Committee:
   5. Date of approval by Ethics Committee:
   6. Is CV for additional Investigator(s) attached?

Yes

No

* 1. Is the Declaration of Intent attached?

Yes

No

1. **CAPACITY OF THE SITE** 
   1. 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*)
2. **RATIONALE FOR APPLICATION** 
   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 to sign this form).

\_\_\_ \_\_\_\_

(Principal Investigator) Date