PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

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

1.1 Name/address/telephone/fax number of Applicant wishing to conduct trial

1.2 Name/address/telephone/fax number of CRO representing sponsor as Applicant or Local Sponsor Company details (if applicable)

1.3 Name, designation and qualifications of person representing the Applicant (*Local Contact Person for all further correspondence*)

1.4 National Coordinator name, address, telephone/fax number

1.5 International Principal Investigator name, address, telephone/fax number

1.6 Name of sponsor

2. TRIAL PARTICULARS (original application)

2.1 Trial Approval Number:

2.2 Date of Approval of original protocol:

2.3 Number of local investigators approved for this trial:

2.4 Number of local sites approved for this trial:

2.5 Number of participants approved for this trial:

3. INVESTIGATOR DETAILS

3.1 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]*

3.2 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 affect the capacity of the site at any one time]*

3.3 Details of Ethics Committee(s) who will approve investigator(s):

3.4 Date of application to Ethics Committee:

3.5 Date of approval by Ethics Committee:

3.6 Is CV for additional Investigator(s) attached? YES / NO

3.7 Is the Declaration of Intent attached? YES / NO

4. CAPACITY OF THE SITE

4.1 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]*

5. RATIONALE FOR APPLICATION

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

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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