Medicines Control Authority of Zimbabwe

**PVF 82**

# PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

APPLICATION FOR CLINICAL TRIAL PROTOCOL AMENDMENT

**MCAZ Reference Number: _____**

**Application for Approval of:**

☐ Protocol Amendment
☐ Increase in Number of Patients Participating
☐ Changes in Dose/Regiment of Study Drug

**Study title:**

_____
_____
_____

**Date: _____**

## 1. APPLICANT DETAILS

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. AMENDMENT PARTICULARS

(Please list requests for approval)

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

Yes ☐
No ☐

3.2 Does the applicant wish to change the dose/regimen of the study drug?

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.

3.4 Protocol Amendment Number:

3.5 Version Number and Date of Protocol Amendment: (*for each document submitted*)

3.6 General motivation for the proposed Amendment: *(List all of the issues included in the amendment and provide the rationale for each amendment)*

3.7 Details of the proposed Protocol Amendment: (*For each amendment, provide a brief motivation 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*)

3.8 Will this Amendment apply to all approved investigators/sites:

Yes ☐
No ☐

If NO: Specify the investigator(s)/site(s) for which the Amendment will apply:

## 4. 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 to sign this form).

| | |
|---|---|
| Principal Investigator | Date |