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Medical Research Council of Zimbabwe
Josiah Tongogara / Mazoe Street
P. O. Box CY 573
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Harare

MRCZ/A/2144

01 February 2018

Prof C Masimirembwa
AiBST
P.O Box 2294
Harare

RE: - Amendment Application: - Clinical validation of a CYP2B6 pharmacogenetics test and dosing algorithm in the safe and efficacious use of Efavirenz and its cost effective and benefit analysis in a public healthcare setting

We refer to your correspondence dated 01 February, 2018 on the above mentioned subject.

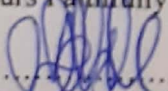
Please be advised that the MRCZ has **reviewed** and **approved** your requests to:-

1. Remove the Control Arm 1 (600mg EFV) from the study.
2. Change the study design to a two ARM open label study from a double blind three ARM study.
3. Reduce the total sample size from 460 to 260.
4. Reduce the PK study sample to 30 from 40 participants.
5. Add Dr. G. Kadzirange as a Co-Principal Investigator.
6. Replace Dr. Munyoro with Dr. Chitiyo as a study clinician.
7. Explicitly describe pregnancy as exclusion criteria.
8. Separate the I.C.F for screening participants for the pharmacokinetics from the ICF for the prospective study.

Correspondingly, the following has been approved:-

1. Protocol Version 1.4 dated October, 2017.
2. Screening Informed Consent Form Version 1.3 dated 31 January, 2018 (English and Shona).
3. Enrolment Informed Consent Form Version 1.3 dated 31 January, 2018 (English and Shona).
4. Study Initiation Questionnaire.
5. Study Follow Up Questionnaire.

Yours Faithfully


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MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE



PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH