Telephone: 791792/791193
Telefax: (263) - 4 - 790715
E-mail: mrcz@mrcz.org.zw
Website: http://www.mrcz.org.zw

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

APPROVAL

REF: MRCZ/A/2144

04 April 2018

Collen Masimirembwa
AiBST-CTU
P.O Box 2294
Harare

RE:- 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. An Open Label Two Parallel Treatment ARMs non-Inferiority, Superiority And Cost Effective Analysis Clinical Trial.

Thank you for the application for review of Research Activity that you submitted to the Medical Research Council of Zimbabwe (MRCZ). Please be advised that the Medical Research Council of Zimbabwe has **reviewed** and **approved** your application to continue conducting the above titled study.

This approval is based on the review and approval of the following documents that were submitted to MRCZ for review:-

a) MRCZ Form 102
b) Progress Report
c) Full proposal version 1.4 dated October, 2017
d) Screening Informed Consent Form version 1.3 dated 31 January, 2018 (English and Shona)
e) Enrolment Informed Consent Form version 1.3 dated 31 January, 2018 (English and Shona)
f) Questionnaire

- **APPROVAL NUMBER : MRCZ/A/2144**

This number should be used on all correspondence, consent forms and documents as appropriate.

- **TYPE OF MEETING : Full Board**
- **EFFECTIVE APPROVAL DATE : 04 April 2018**
- **EXPIRATION DATE : 03 April 2019**

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Offices should be submitted three months before the expiration date for continuing review.

- **SERIOUS ADVERSE EVENT REPORTING**: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices or website.
- **MODIFICATIONS**: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the Protocol (including changes in the consent documents).
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices or website.
- **QUESTIONS**: Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw

Other

- Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
- You're also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.

Yours Faithfully

.....

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

MEDICAL RESEARCH COUNCIL OF ZIMBABWE
2018 -04- 04
APPROVED
P.O. BOX CY 573 CAUSEWAY, HARARE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

MCAZ Medicines Control Authority of Zimbabwe

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P.O. Box 10559
Harare
Zimbabwe

Ref: B/279/5/3/2018

8 January 2018

The Principal Investigator
CT147/2017
African Institute of Biomedical Science and Technology
Wilkins Hospital
P.O Box 2294
HARARE

ATTENTION: Professor Collen Masimirembwa

Dear Sir,

RE: Application for authorization to conduct a clinical trial protocol titled: "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 (EFV-PGX-01) Version 1.4 dated October 2017" MCAZ Reference: CT147/2017

It is hereby notified that the Medicines Control Authority of Zimbabwe has in terms of Section 18 (2) of the Medicines and Allied Substances Control Act *(Chapter 15:03)*, with the approval of the Secretary for Health and Child Care authorized you to conduct the above clinical trial subject to compliance with the approved protocol and consent forms, and MCAZ guidelines for good clinical trial practice in Zimbabwe. Please note that this includes the following:

a) Reporting all serious adverse events to MCAZ;
b) Submission of all amendments to the protocol for approval by MCAZ;
c) Submission of a progress report of the clinical trial annually;
d) Submission of the final report and copy of any publication of the clinical trial prior to publication of results.

Please find enclosed the indemnity forms for conducting the clinical trial, which must be completed and returned to the Director-General before commencement of the trial.

We draw your attention to the provisions of Sections 22 and 24 of the Medicines and Allied Substances Control Act (*Chapter 15:03)* and that it is an offence to disseminate or publish the clinical trial results without prior submission of the same results to the MCAZ.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

.....
G N Mahlangu (Ms)
DIRECTOR-GENERAL
/att