MCAZ Medicines Control Authority of Zimbabwe

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REF: B/279/5/4/2019

8 January 2019

The Principal Investigator
CT171/2018 Study
African Institute of Biomedical Science & Technology (AiBST)
Wilkins Hospital
Cnr Tongogara/Rekai Tangwena
HARARE

ATTENTION: Dr Roslyn Stella Thelingwani

Dear Madam,

RE: Application for authorization to conduct a clinical trial titled: "Drug-Drug interaction in the co-administration of the antiretroviral drugs and the antischistomicide Praziquantel" (MCAZ Ref CT171/2018).

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 Welfare 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)* for clinical trials. The Authority further advises that it is a condition of authorisation of this trial that there will be no dissemination or publication of the clinical trial results without prior submission of the same results to the MCAZ.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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pp **Ms G N Mahlangu**
DIRECTOR-GENERAL
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