WSU Health Research Ethics Committee (HREC) Medical School Sisson Street

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**Date**: 11 March 2024

**From**: HREC Chairperson

 Walter Sisulu university Health Research Ethics Committee (WSU HREC)

**To**: Dr AKM Alam

Protocol no: **073/2020**

Dear Dr Alam,

RE: Acknowledgement for receipt of **SAE Report**/Study Amendment/ Study Notification and Submission Progress Report

This serves to acknowledge receipt of submissions as stated on the subject line for the study titled **“INTENSIFIED TUBERCULOSIS TREATMENT WITH OR WITHOUT ASPIRIN TO REDUCE THE MORTALITY OF HIV-INFECTED AND HIV-UNINFECTED PATIENTS WITH TUBERCULOUS MENINGITIS: A PHASE III RANDOMIZED CONTROLLED TRIAL”.**

The report was reviewed, and the following recommendation were made:

1. **SAE report for Participant Number ((PID):** ZAF-DN-085, Female, 50 years old. **Type of report**: Final. **Reaction/ event/ diagnosis**: DILI. **Outcome**: Hospitalisation/ prolonged hospitalisation. Death.
2. The HREC made the following comments:
	1. The reviewer concurs with the PI that the SAE is possibly related to trial drugs.
	2. The outcome should be death and not hospitalisation or prolonged hospitalisation.

**Decision**: SAE closed.

WSU HREC formally acknowledges the above-mentioned submission. Feel free to contact WSU HREC office for any further study related queries.

Yours sincerely

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Prof EJ Ndebia: WSU HREC Chairperson

Date: 11.03.2024