



**UNIVERSITY OF ZAMBIA  
BIOMEDICAL RESEARCH ETHICS COMMITTEE**

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**IRB00001131 of IORG0000774**

28<sup>th</sup> May, 2020.

Your REF. No. 933-2020.

Dr. Ketty Mwansa Lubeya,  
University of Zambia,  
School of Medicine,  
Department of Obstetrics and Gynaecology,  
Women and Newborn Hospital,  
P.O. Box 50110,  
**Lusaka.**

Dear Dr. Lubeya,

**RE: “A RANDOMISED CONTROLLED TRIAL TO ASSESS THE PHARMACOKINETICS AND PHARMACODYNAMICS OF INTRAMUSCULAR, INTRAVENOUS AND ORAL ADMINISTRATION OF TRANEXAMIC ACID IN WOMEN GIVING BIRTH BY CAESAREAN SECTION” (VERSION 1.2) (REF. NO. 933-2020)**

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 27<sup>th</sup> May, 2020. The proposal is **approved**. The approval is based on the following documents that were submitted for review:

- a) **Study proposal**
- b) **Questionnaires**
- c) **Participant Consent Form**

**APPROVAL NUMBER : REF. 933-2020**

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

- **APPROVAL DATE : 27<sup>th</sup> May 2020**
- **TYPE OF APPROVAL : Standard**
- **EXPIRATION DATE OF APPROVAL : 26<sup>th</sup> May 2021**

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

- **SERIOUS ADVERSE EVENT REPORTING:** All SAEs and any other serious challenges/problems having to do with participant welfare, participant safety and study integrity must be reported to UNZABREC within 3 working days using standard forms obtainable from UNZABREC.

- **MODIFICATIONS:** Prior UNZABREC approval using standard forms obtainable from the UNZABREC 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 must be submitted to the UNZABREC using standard forms obtainable from the UNZABREC Offices.
- **NHRA:** You are advised to obtain final study clearance and approval to conduct research in Zambia from the National Health Research Authority (NHRA) before commencing the research project.
- **QUESTIONS:** Please contact the UNZABREC on Telephone No.256067 or by e-mail on [unzarec@unza.zm](mailto:unzarec@unza.zm).
- **OTHER:** Please be reminded to send in copies of your research findings/results for our records. You're also required to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study. Use the online portal: [unza.rhinno.net](http://unza.rhinno.net) for further submissions.

Yours sincerely,



Sody Mweetwa Munsaka, BSc., MSc., PhD

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