

NATIONAL HEALTH RESEARCH AUTHORITY

Paediatric Centre of Excellence, University of Hospital, P.O. Box 30075, LUSAKA

Tell: +260211 250309 | Email: znhrasec@gmail.com | www.nhra.org.zm

th October	, 2020
	October

The Principal Investigator
Dr Mwansa Ketty Lubeya
University Teaching Hospital
Woman and Newborn
P.O Box RW1X
Lusaka.

Dear Dr. Lubeya,

Re: Request for Authority to Conduct Research

The National Health Research Ethics Board (NHREB) is in receipt of your request for authority to conduct research titled "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."

I wish to inform you that following submission of your request to the Board, its review of the same and in view of the ethical clearance, this study has been **approved** on condition that:

- 1. A Material Transfer Agreement is obtained and cleared by the National Health Research Ethics Board should there be any need for samples to be sent outside the country for analysis.
- 2. The relevant Provincial and District Medical Officers where the study is being conducted are fully appraised;
- 3. Progress updates are provided to NHRA quarterly from the date of commencement of the study:
- 4. The final study report is cleared by the NHRA before any publication or dissemination within or outside the country;
- 5. After clearance for publication or dissemination by the NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, and all key respondents.

Yours sincerely,



Prof. Patrick Musonda Chairperson National Health Research Ethics Board