Sickle Haemoglobinopathy ReseArch in Zimbabwe and Zambia (SHAZ) IRB Approval Year 1

In Zimbabwe an initial approval and annual continued review of the research project will be done until completion of study. In Zambia initial study review and approval will be done. Thereafter, 6 monthly and annual reviewing of the study will be done. Find attached the IRB approvals for both PTH and UTH sites for year 1.

a. Zimbabwe IRB Approval

University of Zimbabwe
Faculty of Medicine
& Health Sciences

Faculty of Medicine and Health Sciences(FMHS) &
Parirenyatwa Group of Hospitals(PGH)

JREC Office No.4, 5th Floor, Faculty of Medicine and Health Sciences Building
Telephone: +263 242 708140/791631 Extns 2241/2242
Email: jrec.office@gmail.com - website: www.jrec.uz.ac.zw

Parirenyatwa
Group of Hospitals

APPROVAL LETTER

Date: 24 May 2021

JREC Ref: 202/2021

Names of Researcher **Patience Kuona**
Address: UZ – Department of Primary HealthCare Sciences, Adolescent and Child Health Care

RE: SICKLE HAEMAGLOBINOPATHY RESEARCH IN ZIMBABWE AND ZAMBIA.

Thank you for your application for ethical review of the above mentioned research to the Joint Research Ethics Committee. Please be advised that the Joint Research Ethics Committee has reviewed and approved your application to conduct the above named study. You are still required to obtain MRCZ and RCZ approval before you commence the study if required by the nature of your study.

- **APPROVAL NUMBER:** **JREC/202/2021**
- **APPROVAL DATE:** **24 May 2021**
- **EXPIRY DATE:** **23 May 2022**

This approval is based on the review and approval of the following documents that were submitted to the Joint Ethics Committee:

a) Completed Application Form
b) Full Study Protocol
c) Informed Consent in English and/or appropriate local language

After this date the study may only continue upon renewal. For purposes of renewal please submit a completed renewal form (obtainable from the JREC office) and the following documents before the expiry date:

a. Progress Report
b. A Summary of Adverse Events
c. A DSMB Report

Telephone: 08644073772/791193
E-mail: mrcz@mrcz.org.zw
Website: http://www.mrcz.org.zw

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

APPROVAL

MRCZ/A/2747 **29 June, 2021**

Dr Patience Kuona
UZ - Dept of Primary Health Sciences
Box A178,
Avondale
Harare

RE: - Sickle Hemoglobinopathy Research in Zimbabwe and Zambia (SHAZ)

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 conduct the above titled study.

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

1. Protocol v1.3 dated 7 June 2021
2. Adult consent form English v1.3 dated 7 June 2021
3. Parental Consent form English v1.3 dated 7 June 2021
4. Assent form 7-17years English v1.3 dated 7 June 2021
5. Shona Adult consent form v1.3 dated 7 June 2021
6. Shona Parental consent form v1.3 dated 7 June 2021
7. Shona Assent form 7-17 years dated 7 June 2021

- **APPROVAL NUMBER : MRCZ/A/2747**

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

- **TYPE OF MEETING : EXPEDITED**
- **APPROVAL DATE : 29 June, 2021**
- **EXPIRATION DATE : 28 June, 2022**

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. (0242) 791193, 0864407377203 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.
- **In addition to this approval, all clinical trials involving drugs, devices and biologics (including other studies focusing on registered drugs) require approval of Medicines Control Authority of Zimbabwe (MCAZ) before commencement**

Yours Faithfully

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MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

MEDICAL RESEARCH COUNCIL OF ZIMBABWE
2021 -06- 29
APPROVED
P.O. BOX CY 573 CAUSEWAY, HARARE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

B. Zambia IRB Approval

B1.0 Initial Approval

NATIONAL HEALTH RESEARCH AUTHORITY
Paediatric Centre of Excellence, University Teaching Hospital, P.O. Box 30075, LUSAKA
Tell: +260211 250309 | Email: znhrasec@gmail.com | www.nhra.org.zm

Ref No:……. **Date: 14th July, 2021**

The Principal Investigator
Dr. Catherine Chunda Liyoka
Ministry of Health
University Teaching Hospitals – Childrens Hospital
P/Bag RW IX,
Lusaka.

Dear Dr. Liyoka,

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 **"Sickle Haemoglobinopathy research in Zimbabwe and Zambia (SHAZ)."**

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,

For Prof. Patrick Musonda
Chairperson
National Health Research Ethics Board

Zambia 6-Month Review Approval

Plot No. 1, Cnr Joseph Mwilwa & Great East Road
Rhodes Park, Lusaka - Zambia
Tel: +260 955 155 633
+260 955 155 634
Cell: +260 977 493220
Email: eresconvergeltd@gmail.com

I.R.B. No. 00005948
F.W.A. No. 00011697

31st may, 2021.

Ref. No. 2021- May- 092

The Principal Investigator
Dr. Patience Kuona
Department of Paediatrics and child health facility of medicines and health sciences
University of Zimbabwe
Harare, Zimbabwe

Dear Dr. Kuona

REF: SICKLE HAEMOGLOBINOPATHY RESE ARCH IN ZIMBABWE AND ZAMBIA(SHAZ)

Reference is made to your protocol resubmission. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

Review Type	**Fast Track**	Approval No. **2021-May-099**
Approval and Expiry Date	Approval Date: 31st May, 2021	Expiry Date: 30th May, 2022
Protocol Version and Date	Version - Nil.	30th May, 2022
Information Sheet, Consent Forms and Dates	• English.	30th May, 2022
Consent form ID and Date	Version - Nil	30th May, 2022
Recruitment Materials	Nil	30th May,2022
Other Study Documents	Questionnaire.	30th May, 2022
Number of participants approved for study	-	30th may, 2022

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- A reprint of this letter shall be done at a fee.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB

Dr. Jason Mwanza
Dip. Clin. Med. Sc., BA., M.Sc., PhD
CHAIRPERSON

B1.1 Zambia 6-month IRB Approval

ERES CONVERGE

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Lusaka - Zambia
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Cell: +260 977 493 220
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I.R.B. No. 00005948
F.W.A. No. 00011697

17th January, 2022.

Ref. No. 2021- may- 092

The Principal Investigator
Dr. Patience Kuona
Department of Paediatrics and child health facility of medicines and health sciences
University of Zimbabwe
Harare, Zimbabwe

Dear Dr. Kuona

RE: 6 MONTHS PROGRESS REPORT: SICKLE HAEMOGLOBINOPATHY RESEARCH IN ZIMBABWE AND ZAMBIA(SHAZ)

We would like to acknowledge receipt of your 6 months progress report dated 14th January, 2022.

This study is to proceed.

Yours faithfully,
ERES CONVERGE IRB

Dr. Jason Mwanza
Dip. Clin. Med. Sc., BA., M.Sc., PhD
CHAIRPERSON