

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

**OFFICE OF THE DIRECTOR - RESEARCH AND
PUBLICATIONS**



In reply quote;

Ref. No.DA.282/298/01.C/453

Date: 11/01/2021

MUHAS-REC-12-2020-453

Dr. Emmanuel Balandya
Principal Investigator-SPARCO)-Tanzania,
MUHAS

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED:
SICKLE PAN-AFRICAN RESEARCH CONSORTIUM (SPARCO) –
TANZANIA: IMPROVING SICKLE CELL DISEASE CARE, RESEARCH
AND TRAINING**

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 11/01/2021

EXPIRATION DATE OF APPROVAL: 10/01/2022

STUDY DESCRIPTION:

Purpose:

The purpose of this implementation science project is to enhance the quality and quantity of longitudinal data in SPARCO sickle cell disease (SCD) database, promote use of SCD standards of care guidelines among clinicians and enhance skills of researchers in conducting research on SCD

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:

<https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20427.pdf> and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
8. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website <https://drp.muhas.ac.tz/>.



Dr. Bruno Sunguya
Chairman, MUHAS Research and Ethics Committee

