

14/12/2021

To: Sarah Kiguli

Type: Initial Review

**Re: Mak-SOMREC-2021-170: Sickle Pan-African Research Consortium (SPARCO) Uganda:
Strengthening Capacity for Clinical Care, Research and Training in Sickle Cell Disease - SCRT Project., 1.1,
2021-11-18**

I am pleased to inform you that at the **122** convened meeting on **07/09/2021**, the MAK School of Medicine REC (Mak-SOMREC), committee meeting, etc voted to approve the above referenced application. Approval of the research is for the period of **14/12/2021** to **14/12/2022**.

As Principal Investigator of the research, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the research.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the REC for re-review and approval **prior** to the activation of the changes.
3. Reports of unanticipated problems involving risks to participants or any new information which could change the risk benefit: ratio must be submitted to the REC.
4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by participants and/or witnesses should be retained on file. The REC may conduct audits of all study records, and consent documentation may be part of such audits.
5. Continuing review application must be submitted to the REC **eight weeks** prior to the expiration date of **14/12/2022** in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion may result in suspension or termination of the study.
6. The REC application number assigned to the research should be cited in any correspondence with the REC of record.
7. You are required to register the research protocol with the Uganda National Council for Science and Technology (UNCST) for final clearance to undertake the study in Uganda.

The following is the list of all documents approved in this application by MAK School of Medicine REC (Mak-SOMREC):

No.	Document Title	Language	Version Number	Version Date
1	Informed Consent forms	Langi	1.0	2021-09-29
2	Informed Consent forms	Langi	1.0	2021-09-29
3	Informed Consent forms	Langi	1.0	2021-09-29
4	Informed Consent forms	Langi	1.0	2021-09-29
5	Informed Consent forms	Langi	1.0	2021-09-29
6	Informed Consent forms	Langi	1.0	2021-09-29
7	Informed Consent forms	Lumasaba	1.0	2021-09-29
8	Informed Consent forms	Lumasaba	1.0	2021-09-29
9	Informed Consent forms	Lumasaba	1.0	2021-09-29
10	Informed Consent forms	Lumasaba	1.0	2021-09-29
11	Informed Consent forms	Lumasaba	1.0	2021-09-29
12	Protocol	English	1.1	2021-11-18
13	Informed Consent forms	Lusoga	1.1	2021-11-21
14	Informed Consent forms	English	1.1	2021-11-21
15	Informed Consent forms	luganda	1.1	2021-11-21
16	Informed Consent forms	English	1.1	2021-11-17
17	Informed Consent forms	lusoga	1.1	2021-11-17
18	Informed Consent forms	Lusoga	1.1	2021-11-17
19	Informed Consent forms	luganda	1.1	2021-11-17
20	Informed Consent forms	English	1.1	2021--17
21	Informed Consent forms	Lusoga	1.1	2021--17
22	Informed Consent forms	luganda	1.1	2021-11-17
23	Informed Consent forms	English	1.1	2021-11-17
24	Data collection tools	English	1.0	2021-08-01
25	Data collection tools	English	1.0	2021-08-01
26	Data collection tools	English	1.0	2021-08-01

Yours Sincerely



Ponsiano Ocama
For: MAK School of Medicine REC (Mak-SOMREC)