



## Uganda Virus Research Institute

Plot 51-59, Nakiwogo Road, Entebbe  
P.O. Box 49, Entebbe-Uganda  
Tel: +256 414 320 385 / 6  
Fax: +256 414 320 483  
Email: [directoruvri@uvri.go.ug](mailto:directoruvri@uvri.go.ug)



Our Ref: GC/127/19/06/717

Your Ref:

### UVRI REC APPROVAL NOTICE

To: Dr. Cally Tann, Principal Investigator

Re: Application Title: **“The OMWANA study: Operationalizing kangaroo mother care before stabilization among low birth weight Neonates in Africa: a multi-site randomized controlled trial to examine mortality impact in Uganda.”**

Type:  Initial Review

I am pleased to inform you that REC meeting 04 convened on May 30, 2019 the UVRI REC voted to approve the above referenced application.

Approval of research is for the period of June 12, 2019 to June 12, 2020.

This research is for considered minimal risk for pediatric risk category.  check box if not applicable

As principal investigator of the research, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators of the research must be kept informed of the status of research.
2. Changes, amendments and addenda to protocol or the consent form must be submitted to the REC for review and approval **prior** to activation of changes. The REC application number assigned to the research should be cited in any correspondence.
3. Reports of unanticipated problems involving risks to participants or other must be submitted to the REC. New information that becomes available which could change the risk: benefit ratio must be submitted to REC.
4. Only approved consent forms are to be used in enrollment of participants. All consent forms signed by subjects and/or witness should be retained on file. The REC may conduct audits of all study records, and consent documentation may be part of such audits.
5. Regulations require review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to REC eight weeks prior to the above expiration date of June 12, 2020 in order to continue with the study beyond the approved period.** Failure to submit a continuing review application in timely fashion may result in suspension of the study. At which point new participants may not be enrolled and currently enrolled participants must be taken off the study.



6. You are required to register the research protocol with the Uganda National Council of Science and Technology (UNCST) for final clearance to undertake the study in Uganda.

**NOTE:** This study, being considered high risk will be closely monitored by the REC.

The following is the list of all documents approved in this application by UVRI REC:

Document Title	Language	Version	Date
OMWaNA protocol	English	1.1	17 <sup>th</sup> May 2019
OMWaNA ICF (English, Luganda and Lusoga )	English, Luganda & Lusoga.	1.0	8 <sup>th</sup> February 2019
OMWaNA ICF Photography and medical images (English, Luganda and Lusoga )	English, Luganda & Lusoga.	1.0	8 <sup>th</sup> February 2019
OMWaNA ICF Qualitative ( English, Luganda and Lusoga )	English, Luganda & Lusoga.	1.0	8 <sup>th</sup> February 2019

Yours sincerely,



Dr. Tom Lutalo  
Chair, UVRI REC  
C.C Secretary, UVRI REC

