

Uganda National Council for Science and Technology

(Established by Act of Parliament of the Republic of Uganda)

Our Ref: SS 4679

8th August 2018

Ms. Susan Nayiga Infectious Diseases Research Collaboration Kampala

Re: Research Approval: The Antimicrobials in Society (AMIS) Uganda Project.

Understanding the Role of Antimicrobials in Daily Life in Tororo, Wakiso and Kampala Districts of Uganda through Three Entry

Points: Health Care, Farming and Urban Work

I am pleased to inform you that on 13/07/2018, the Uganda National Council for Science and Technology (UNCST) approved the above referenced research project. The Approval of the research project is for the period of 13/07/2018 to 13/07/2022.

Your research registration number with the UNCST is SS 4679. Please, cite this number in all your future correspondences with UNCST in respect of the above research project.

As Principal Investigator of the research project, 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 research protocol or the consent form (where applicable) must be submitted to the designated Research Ethics Committee (REC) or Lead Agency for re-review and approval prior to the activation of the changes. UNCST must be notified of the approved changes within five working days.
- 3. For clinical trials, all serious adverse events must be reported promptly to the designated local IRC for review with copies to the National Drug Authority.
- 4. Unanticipated problems involving risks to research subjects/participants or other must be reported promptly to the UNCST. New information that becomes available which could change the risk/benefit ratio must be submitted promptly for UNCST review.
- 5. Only approved study procedures are to be implemented. The UNCST may conduct impromptu audits of all study records.
- 6. An annual progress report and approval letter of continuation from the REC must be submitted electronically to UNCST. Failure to do so may result in termination of the research project.

LOCATION/CORRESPONDENCE

COMMUNICATION

Plot 6 Kimera Road, Ntinda P. O. Box 6884 KAMPALA, UGANDA

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Below is a list of documents approved with this application:

		Document Title	Language	Version	Version Date
1	1.	Research proposal	English	8.0	May 2018
. 2	2.	Informed consent forms	English, Luganda and Japadhola	1.1	May 2018
3	3.	Interview guides	English	1.0	February 2018
4	4.	Observation checklist	English	1.0	February 2018
	5.	Questionnaires	English	8.0	May 2018

Yours sincerely,

Isaac Makhuwa

For: Executive Secretary

UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Copied to: Chair, Makerere School of Biomedical Sciences, Research Ethics Committee

WEBSITE: http://www.uncst.go.ug