WPRO - MEMORANDUM

From WPRO-ERC

To WR, Laos

Date 27 February 2020

Our ref. 2019.6.LAO.2.MVP

Attention Chitsavang Chanthavisouk
Responsible Technical Officer

Your ref.

Subject REQUEST FOR EXTENSION OF APPROVAL OF RESEARCH PROPOSAL ID: 2019.6.LAO.2.MVP

Originator

This refers to your memo dated 19 February 2020 requesting extension of approval for research proposal titled "***Evaluation of the efficacy and safety of Artemether+Lumefantrine (Coartem®) with low-dose Primaquine for the treatment of uncomplicated Plasmodium falciparum and Plasmodium vivax malaria in three sites of Savanakhet, Champasack, and Salavanh province, Lao***", '**approved**' by the WPRO-ERC based on expedited review on 4 March 2019.

Based on the justification you provided, I am pleased to notify you that WPRO-ERC approves the extension of this research proposal. Please find the details below:

Basic Proposal information:

Principal Investigator (PI): Dr Bouasy Hongvanthong, Director, Center for Malariology, Parasitology and Entomology, Ministy of Public Health.

Responsible WPRO staff member: Chitsavang Chanthavisouk, Technical Officer, Malaria, WHO Country Office in Lao PDR.

WPRO role in research: Funder for the proposed research (USD 223,800); technical assistance/collaboration

Protocol Title: Evaluation of the efficacy and safety of Artemether+Lumefantrine (Coartem®) with low-dose Primaquine for the treatment of uncomplicated Plasmodium falciparum and Plasmodium vivax malaria in three sites of Savanakhet, Champasack, and Salavanh province, Lao

Unique Proposal ID assigned: 2019.6.LAO.2.MVP

Type of review: Expedited review

Reason for expedited review:
On initial screening, the proposal was assessed to have minimal risk and considered eligible for expedited review by Secretariat of WPRO-ERC.

Protocol Summary:
The research proposal aims to assess the efficacy and safety of artemether-lumefantrine for the treatment of uncomplicated P.falciparum and P. vivax malaria infections. The surveillance is a one-arm prospective evaluation of clinical and parasitological responses to directly observed treatment for uncomplicated malaria.

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Ethical considerations. Appropriate safeguards will be provided to ensure privacy and confidentiality of data. The information provided to the participant and their guardians and the consent documentation considered adequate.

Local Ethics Review and approval: The study has been approved by the National Ethics Committee for Health Research, Ministry of Health in Lao People's Democratic Republic No 098/NECHR, dated 31 December 2019.

Decision on expedited review: The proposal is **approved** on expedited review by WPRO-ERC. This approval is valid for twelve months from the date of the latest local ethics approval obtained. The responsible technical officer for the research project shall submit the following documents electronically via WPRO health research portal at http://researchportal.wpro.who.int or by an email to the Secretariat of WPRO-ERC (wproethicsreviewcomm@wpro.who.int):

- Annual progress report (if applicable and if the duration of the research goes beyond one year after approval)
- A copy of final data file without personal identifiers for archiving
- Final scientific Report
- Immediate notification of serious adverse events (if any)
- Patient/participant feedback (if any).

Dr Gao Jun
Secretary, WPRO-ERC