



Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity
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Ministry of Health
National Ethics Committee for Health Research (NECHR)

No 062 /NECHR
Vientiane Capital 10 / 08 / 2022

Approval Notice

Dr. Keobouphaphone Chindavongsa
Email: Chinda07@gmail.com

RE: Ethical Approval for Health Research

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 Savanakheth, Salavanh, and Attopue province, Lao PDR."(Submission ID: 2022.22)

Dear Dr. Keobouphaphone Chindavongsa,

The National Ethics Committee for Health Research of the Lao People's Democratic Republic have reviewed and approved your research. Please note the following information about your approved research protocol:

Approval period	AUGUST 2022 – AUGUST 2023
Approved Subject Enrollment	300
Study Site	Savanakheth Salavanh and Attopue Provinces
Sponsor	World Health Organization
Budget	120,000 USD
Implementing Panel/Project Investigator	Dr. Keobouphaphone Chindavongsa
Please note that the Ethics Committee reserves the right to ask for further questions, seek additional or monitor the conduct of your research and consent process. Principle Investigator is required to notify the Secretary of the National Ethic Committee for Health Research	
<ul style="list-style-type: none">• Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);• Serious adverse effects on participants and the action taken to address those effects;• Any other unforeseen events or unexpected developments that merit notification;• The inability of the Principal Investigator to continue in that role, or any other change in research personnel involved in the project;• Any other unforeseen events or unexpected developments that merit notification;• The inability of the Principal Investigator to continue in that role, or any other change in research personnel involved in the project;• Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;• A delay of more than 12 months in the commencement of the project; and,• Termination or closure of the project.	

Additionally, the Principal Investigator is required to submit a progress report on the anniversary of approval and on completion of the project.

President of NECHR

Dr. Sengchanh KOUNNAVONG