

Lao People's Democratic Republic Peace Independence Democracy Unity Prosperity ===== 000 ======

Ministry of Health National Ethics Committee for Health Research (NECHR)

No 061 /NECHR Vientiane Capital 20/.6/.2018

Approval Notice

Dr Bouasy Hongvanthong

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RE: Ethical Approval for Health Research

Title: "Efficacy and safety of Artesunate-mefloquine with low dose primaquine for the treatment of uncomplicated Plasmodium falciparum and Plasmodium vivax malaria in Champasack province, Lao PDR" (Submission ID: 2018.19.Cha)

Dear Dr Bouasy Hongvanthong,

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: March 2018 – March 2019 Approved Subject Enrollment: 10 districts

Study Site: Champasak province

Sponsor: WHO;

Budget: 63,623USD

Implementing Panel/Project Investigator: Dr Bouasy Hongvanthong

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:

- 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 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 National Ethics Committee for Health Research