The Government of the Republic of the Union of Myanmar
Ministry of Health and Sports
Department of Medical Research
No. 5, Ziwaka Road, Dagon Township, Yangon 11191
Tel : 95-1-375447, 95-1-375457, 95-1-375459 Fax : 95-1-251514

ERC Number: 002716
Approval Number: Ethics/DMR/2016/032EAA/2019
Date of Approval: 14 May 2019 (valid up to 13 May 2020)

Project Title: **Efficacy and safety of (a) Artemether-Lumefantrine (b) Dihydroartemisinin piperaquine phosphate for the treatment of uncomplicated Plasmodium falciparum in Tamu Township, Sagaing Region**

Principal Investigator: **Dr. Moe Kyaw Myint, Dr Khin Linn**

Items Approved:

1. Request for extension and amendment of the proposal Dated 4 April 2019
2. Progress report Dated 4 April 2019
3. Study area(s)- Tamu Township, Sagaing Region

The Ethics Review Committee on Medical Research Involving Human Subjects, Department of Medical Research, Ministry of Health and Sports approves **Extension and Amendment** of proposed research project as it is in full compliance with the Declaration of Helsinki, Council for International Organizations of Medical Sciences guidelines and International Conference on Harmonisation in Good Clinical Practice guidelines.

The principal investigator should be aware that there might be site monitoring visits at any time from ERC team during project implementation and should provide full cooperation to the team.

Prof. Pe Thet Khin
Chairperson
Ethics Review Committee
Department of Medical Research

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Approval is subject to following conditions:

- The principal investigator (PI) must notify immediately to the ERC of any changes or deviation in the conduct of the research activity. Only with the ERC's approval such changes in the study must be pursued. The PI must also make a prompt report to the ERC of any new and significant information that may impact a research subject's safety or willingness to continue in the study and any anticipated problems involving risks to the participants or other.

- PI is responsible for submitting the progress report at least 6 weeks prior to the expiry of the approved date to allow adequate time for the ERC for substantive and meaningful review and for assuring that the research is not conducted beyond the approved date.

- Final report is to be provided to ERC at the end of the study.

- Random site visits may be carried out to ensure that informed consent procedures are appropriate.