The Government of the Republic of the Union of Myanmar
Ministry of Health
Department of Medical Research
No. 5, Ziwaka Road, Dagon Township, Yangon 11191
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IRB Number: 002716
Approval Number: Ethics/DMR/2016-032 EA/2019E/2020E/2021E
Date of Approval: 31st December 2021 (valid up to 30th December 2022)
Project Title: **"Efficacy and safety of (a) Artemether-lumefantrine for the treatment of uncomplicated *Plasmodium falciparum* malaria and Chloroquine for *P.vivax* malaria in Homalin Township, Sagaing Region (b) Dihydroartemisinin-Piperaquine phosphate for the treatment of uncomplicated *Plasmodium falciparum* malaria in Moemeik District (Moemeik and Mabein Townships), Northern Shan State"**

Principal Investigators: **Dr. Moe Kyaw Myint**
Director, Department of Medical Research

Items Accepted:

1. Full Proposal Dated: 15th December 2021
2. Informed consent for participants (English & Myanmar version): 15th December 2021
3. Study area: Homalin Township, Sagaing Region and Moemeik and Mabein Townships, Moemeik District, Northern Shan State
4. Study population: Patients with uncomplicated *Plasmodium falciparum* malaria and *P.vivax* malaria

The Institutional Review Board, Department of Medical Research, Ministry of Health approves to conduct the 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 investigators should be aware that there might be a request for remote monitoring (through video call) at any time from the IRB team during project implementation and should provide full cooperation.

Dr Khin Thet Wai
Chairperson
Institutional Review Board
Department of Medical Research

Approval is subject to the following conditions:

- The principal investigator (PI) must notify immediately to the IRB of any changes or deviation in the conduct of the research activity. Only with the IRB's approval, such changes in the study must be pursued. The PI must also make a prompt report to the IRB 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 IRB 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 IRB at the end of the study.

- Random site visits may be carried out to ensure the research integrity and informed consent procedures are appropriate.