Australian Government
Department of Defence

Australian Defence Human Research Ethics Committee
CP3-6-036, Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

2016/1188880

ADHREC/OUT/2016/R28058103

30 November 2016

Dr Michael Edstein
Australian Army Malaria Institute
Weary Dunlop Drive
Gallipolli Barracks
Enoggera Brisbane QLD 4051

Copy: Prof Dennis Shanks, Director Army Malaria Institute

Dear Dr Edstein

Protocol 841-16 'Efficacy and tolerability of pyronaridine-artesunate in treating uncomplicated mono-infections of falciparum, vivax and malaria or mixed infections in Vietnam'

Thank you for resubmitting the above research project for ethical review. This project was considered by the Chair of Australian Defence Human Research Ethics Committee (ADHREC) and I am pleased to advise you that the Chair has granted ethical approval of this research project.

The nominated participating site in this project is Dak Drong Commune, Cu Jut District, Dak Nong Province, Vietnam.

Note: *If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify ADHREC. Notification of withdrawn sites should also be provided to the ADHREC in a timely fashion.*

The approved documents include:

Document	**Version**	**Date**
National Ethics Application Form		Received (30 Sep 16)
Adult information and consent form	1.0	15 Jul 2016
Parent/Guardian permission form for children to be in the study	1.0	15 Jul 2016
Parent/Guardian permission for children (age up to 14 years)	1.0	15 Jul 2016
Statement of assent for children (age 10 to 14 years)	1.0	15 Jul 2016
Statement of consent for pregnancy test for adults	1.0	15 Jul 2016

Schedule of activities	1.0	15 Jul 2016

Approval of this project from ADHREC is valid from 30 November 2016 to 29 November 2019 subject to the following conditions being met:

- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the ADHREC of any event that requires an amendment/modification to the protocol or other project documents and submit any required amendments.
- The Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with ADHREC policy and procedures.
- The Principal Investigator will report to the ADHREC six monthly and notify ADHREC when the project is completed at all sites in the specified formats.
- The Principal Investigator will notify the ADHREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Principal Investigator will notify the ADHREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Principal Investigator will notify the ADHREC of their inability to continue and indicate the name of and contact information for a replacement.
- The return of the Principal Investigators Assurance (Attachment A) signed by all Principal Investigators.
- Prior to commencement of the clinical phase of the research the trial is to be registered in a publicly accessible register.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

Should you have any queries about the ADHREC's consideration of your project please contact the ADHREC Secretariat on (02) 6266 3807 or adhrec@defence.gov.au.

The ADHREC wishes you every success in your research.

Yours sincerely

Georgina Gill
Research Administration Officer

For
Mr Ian Tindall
Chair, Australian Defence Human Research Ethics Committee

Attachments:

A. Principal Investigator's Assurance
B. ADHREC Guidelines for Volunteers