CONSENT FORM PROTOCOL

Regimental Number: _____ Volunteers Initials: _____
You have been asked to take part in this research study. The purpose of this form is to explain this research study to you and to obtain your consent to take part in this study.

PURPOSE / BENEFITS OF THE STUDY

As you are deploying to an area where Malaria is known to occur, the decision has been taken by Land Command Health Services to provide you with drugs to protect you against this potentially life-threatening disease. The purpose of this study is to observe a less commonly used drug, Mefloquine, under field conditions.
The benefit of taking part in the study is that you will be monitored for the development of malaria following your deployment and treated promptly. In addition, the study results may provide a better understanding on how to prevent malaria infection from overseas deployments in the future.

WHAT IS THE MEDICINE?

Mefloquine one tablet weekly in the AO and for two weeks after return to Australia. You will initially be given at least six tablets prior to deployment. The usual medicine is Doxycycline one tablet daily through deployment and for two weeks after. You are initially given two tablets prior to deployment.

WHAT IS THE STUDY?

The study is looking at how satisfactory Mefloquine is under field conditions. You will be provided with one tablet weekly through the standard supply system in the field. Supply and use of each tablet weekly will be recorded. You will be asked immediately prior to deployment, several times throughout the deployment and on return to Australia, whether you had any problems you thought were due to the antimalarial tablet. A small group will be (randomly) selected to additionally give blood on two occasions during deployment.

LENGTH OF THE STUDY

The study will begin 4 weeks prior to your redeployment and will be continued until 12 months after your deployment is completed. Your only involvement after redeployment will be if you develop malaria.

STUDY TESTS

All volunteers will be asked to complete a questionnaire immediately prior to deployment, during deployment and prior to returning to Australia. As the investigators are looking at baseline drug levels in blood, and measuring biochemistry and haematology levels to monitor safety, a small group will be requested to donate two samples of blood from your arm. The amount of blood collected for the study amounts to no more than about 20mls, or the equivalent of 4 teaspoons.

RISKS / DISCOMFORTS

There may be some bruising with blood taken from the veins in your arm.

When Mefloquine is used to treat people ill with malaria especially children less than 45kg, side effects have been reported and recorded. These include over 1% reporting sleepiness, insomnia, abnormal dreams, dizziness, loss of balance, headache, nausea and vomiting, diarrhoea or abdominal pain. Less than 1% had episodes of anxiety, confusion, depression, restlessness, forgetfulness, hallucinations and psychotic or paranoid reactions, nerve damage, convulsions, tiredness, fever, chills, loss of appetite, rash, itchiness, hair loss, visual disturbances, muscle weakness, cramps, muscle and joint pain, ringing in the ears, hearing disorders, low or high blood pressure, fainting, palpitations, extra heart beats, slow heart rate, or lowering of the clotting cells in the blood, or white cells (used for fighting infection) and fewer than 0.1% had brain damage, psychotic events, severe hypersensitivity reactions in the skin and heart block.

Overall, Mefloquine has fewer side effects than Doxycycline in trials among travellers (including Australians).

PRECAUTIONS

If you have had a significant response to any medications in the past, or have experienced urticaria (hives) or anaphylaxis (a significant allergic reaction involving collapse, swelling of the face and mouth, difficulty breathing) you may not be able to take part in the study. If you have had any anxiety attacks or serious depression in the past you also may not be able to use Mefloquine. If you have experienced this type of reaction, or if you think (females only) that you may be pregnant, please discuss this with the study Medical Officer.

CONFIDENTIALITY

In all reports only a number will identify you. The investigators will have your contact details and full name to allow them to make sure you can be contacted if necessary. This information will not be passed on to anyone else. Your medical records will be kept confidential and only released to medical personnel to assist in any care that you may need. Your name will not appear on any reports about this study.

COMPENSATION

Mefloquine is authorised to use as an antimalarial by civilian authorities in Australia in addition to being directed for use as an alternative to Doxycycline by the Director General, Defence Health Services in HPD215. This trial has also been approved by the Australian Defence Medical Ethics Committee.

All necessary medical care for injury or disease caused by your participation in this study will be provided at no cost to yourself. In the event that you believe that injury or illness has resulted from your participation in the study, you should seek immediate assistance from your nearest medical facility, and the study investigators should be advised by calling the RMO or AMI (0407 150384).

YOUR RIGHTS

If during the course of the study you have any questions, or believe you have sustained a research-related injury or illness you can contact the RMO or study investigators. Additionally, any concerns can be raised with the Executive Secretary of the Australian Defence Medical Ethics Committee as detailed below:

Executive Secretary
Australian Defence Medical Ethics Committee
CP2-7-66
Department of Defence
Canberra, ACT, 2600
Phone: (02) 6266 3925

VOLUNTARY PARTICIPATION

Your decision to participate in this study is entirely voluntary and refusal to participate will involve no penalty or loss of benefits to which you might otherwise have been entitled. You may withdraw from the study at any time without detriment, but if you choose to leave the study you should advise the study investigators. Should you not wish to participate in the study, you will receive the normal antimalarial course of Doxycycline daily and an eradication course of Primaquine and will still have all the required blood samples taken for redeployment and post deployment screening.

INFORMED WRITTEN CONSENT

I have carefully read the information provided to me and understand all the points. All questions raised by me have been answered to my satisfaction. I have been given a copy of this consent form/information sheet. I understand that I am free to withdraw from the study at any time without incurring any disadvantage to me in the future.

I consent to my participation in the study

VOLUNTEER'S SIGNATURE _____

Printed Name: _____**Date:**_____

INVESTIGATOR'S SIGNATURE _____**Date:**_____