**PARTICIPANT INFORMATION SHEET**

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| --- | --- |
| **Title** | Evaluation of the safety, tolerability and effectiveness of weekly tafenoquine in protecting Vietnam People’s Army personnel in South Sudan against malaria infections”. |
| **Short title** | Evaluation of weekly tafenoquine antimalarial prophylaxis in Vietnam People’s Army personnel in South Sudan |
| **Protocol number** | *To be provided by the Secretariat*  |
| **Project Sponsor**  | Australian Defence Organisation represented by ADFMIDI |
| **Principal Investigator** | Prof. Dr. Do Quyet | +84 983301839 |
| **Co- Principal Investigator** | Dr. Vu Minh Duong | +84 912134655 |
| **Co-Investigator** | Dr. Vu The Anh | +84 348970705 |

This Participant Information Sheet and Consent Form (PISCF) is for the research study “Evaluation of the safety, tolerability and effectiveness of weekly tafenoquine in protecting Vietnam People’s Army personnel in South Sudan against malaria infections” to be conducted by the Vietnam Military Medical University (VMMU). The study is funded by the Sponsor, the Australian Defence Organisation represented by Australian Defence Force Malaria and Infectious Disease Institute (ADFMIDI). The study will be ethically approved by the Vietnam Ministry of Health Institutional Review Boards in National Biomedical Research (MoH IRBNBR) and the Departments of Defence and Veterans’ Affairs Human Research Ethics Committee (DDVA HREC).

**Introduction for participation in this research study**

You and 62 other Vietnamese military personnel are invited to take part in this study because you are healthy, aged 18 to 55 years old (males and females) and will be assigned to the Level 2-Field Hospital (L2FH) No. 4 rotation on peacekeeping duties to South Sudan, a country of high malaria transmission. In 2019, South Sudan located in east-central Africa with a population of 11,062,114 had an estimated 3,009,338 malaria cases, with 4,873 reported malaria deaths (World Health Organization Malaria Report 2020). Most of the malaria transmission is exclusively due to *Plasmodium falciparum* malaria, the deadliest form of malaria infection. Thus, you will need to be protected from malaria infections, which will require you taking an antimalarial drug during your deployment, as well as other personnel protection measures such as the wearing of insecticide impregnated military uniforms and using mosquito repellents.

This study is designed to evaluate the safety (e.g. blood and urine tests), tolerability (i.e. types of adverse events such as stomach pain caused by the drug) and effectiveness of a new weekly antimalarial drug called tafenoquine to protect you from malaria infections in South Sudan. Malaria rapid diagnostic testing and blood film microscopy will be carried out on participant’s blood samples during the study. The effectiveness of tafenoquine will be determined by the number of participants who are malaria free at the end of the 26 weekly tafenoquine regimen. We will also check your blood for tafenoquine concentrations to make sure you have good drug exposure against malaria. The study is planned to start between March and April 2022 and will last for 26 weeks (6 months) after you have received your first tablet of tafenoquine. The information obtained in this study will be valuable in determining how good tafenoquine is in protecting people from malaria. We also anticipate that a safe and well tolerated weekly dose of tafenoquine, with improve drug compliance will decrease the development and spread of drug resistant malaria in Africa and other malaria endemic countries.

This PISCF will tell you why this research study is being conducted, the risks associated with your participation, the study design, how you will be selected, the procedures that will be carried out with your support such as safety tests (i.e. blood chemistries), tolerability assessment (i.e. questionnaire response for adverse events with taking the drug), blood collections for monitoring for malaria infections and for measuring your blood tafenoquine concentrations, and how your personal information will be protected.

All this information is designed to help you decide if you want to take part in this study. Please read this PISCF carefully and be comfortable to ask any questions about your participation, so you fully understand the purpose of the study and what is expected of you in this study.

Participation in this study is **voluntary**. If you don’t wish to take part, you don’t have to. If you choose to be in the study and then change your mind, you are free to withdraw from the study at any time, and you do not need to give a reason. If you decide to take part in the study, you will be asked to sign the Consent Form (CF) before any study assessments are carried out on you.

**Why is this research study being conducted?**

Malaria is one of the most severe public health problems worldwide and is responsible for more deaths than other parasitic diseases in the world. In 2019, an estimated 229 million cases of malaria occurred globally with an estimated 409,000 deaths (World Health Organization Malaria Report 2020). Most of the global malaria cases (82%) and deaths (94%) in 2019 were in the African region, followed by South-East Asia regions (cases 10% and deaths 3%). Although, the number of malaria cases has markedly declined over the past two decades with a 50% reduction in malaria deaths, this has now stalled due to the emergence of multi-drug resistant malaria and the decline in the efficacy of current first-line antimalarial treatment drugs. This is of particular concern in tropical African, South-East Asian and South American countries where malaria is endemic.

In an effort to reduce the spread of multi-drug resistant malaria in tropical countries there is an urgent need to have effective and user-friendly prevention drugs against malaria infections that stops the development and spread of drug resistant malaria. The choice of prevention drugs for travelers and special risk groups such as forest workers and military personnel against malaria infections is limited. The major limitations are the requirement to take drugs such as doxycycline or atovaquone-proguanil daily, which can result in poor compliance. Mefloquine, the only other commercially available weekly antimalarial drug can cause adverse events in some individuals such as neurological disturbances (e.g. dizziness, anxiety, and vivid dreams). Ideally, there is an urgent need to develop better, safer and well tolerated antimalarial drugs that can be taken weekly to improve compliance in protecting people against malaria infections.

Recently, in 2018, the U.S. Food and Drug Administration (FDA) and the Australian Therapeutic Administration (TGA) approved the newest prevention (prophylactic) antimalarial drug, tafenoquine (Arakoda™), the only prophylactic drug developed in the past two decades. The approved tafenoquine prophylactic regimen is a loading dose of 200 mg daily for three days before travel, and maintenance dose of 200 mg once weekly to continue until one week after return from travel. Tafenoquine has a lengthy blood elimination half-life of 15 days (i.e. the time is takes for blood concentrations to decline by 50%) and is active against all lifecycle stages of the malaria parasite. These favorable profiles and antimalarial parasite properties of tafenoquine makes the drug an attractive candidate for weekly dosing.

**The risks associated with your participation**

*Adverse events of tafenoquine*

More than 4,000 people have taken tafenoquine and the drug has proven to be safe and generally well tolerated. The most common ill-effects (i.e. undesirable experience) associated with taking tafenoquine (incidence less than 1 in 100 people being affected) were: headache, dizziness, back pain, diarrhea, nausea, vomiting, increased liver protein, motion sickness, insomnia, depression, abnormal dreams, and anxiety. A very small proportion of people experienced depression/depressed mood (incidence less than 3 in 1,000 people being affected). Of these adverse events the most frequently reported was gastrointestinal disturbances (e.g. stomach pain and diarrhea) and these adverse events tended to be rated as mild and not affecting the participant’s daily activities, and transient in nature (i.e. does not persist for more than a few days).

*Blood sampling collections by venipuncture*

To ensure that weekly dosing of tafenoquine is safe for you to take, venous blood collections will be obtained from you for biochemical, hematology, and other tests. With venipunctures or the insert of indwelling catheters there is some risk of pain, local bruising, and infection at the site where blood is drawn for laboratory tests. The PI/Co-PI/Co-Investigator and clinical trial site staff are very skilled in collecting blood from the vein either on top of the hand or elbow. The procedure of venipuncture (i.e. the process of drawing blood from a vein using a needle) is the most common way to collect blood specimens for laboratory testing. In this study covering the screening visit and 25 weekly tafenoquine administrations there will be six time points that venipunctures will be required for safety laboratory tests, with 6 mL of blood collected at each visit when you are in South Sudan.

Venous blood samples (2 mL each time) will be obtained from each participant for measuring blood tafenoquine concentrations for determining drug exposure over the study period and comparing these concentrations against adverse events of tafenoquine. From the same blood sample a malaria rapid diagnostic test and blood film microscopy will be carried out to determine that you are malaria free. The venous blood samples for tafenoquine concentrations will be collected at the same time that you provide blood for your blood chemistries and thus requiring only one venipuncture at each time point to minimize discomfort to you.

The total volume of blood to be collected from you over the entire study of up to 6 months will not exceed 38 mL, which is less than a standard unit of blood provided to the Vietnam Red Blood Cross Service (approximately 250 mL) over any consecutive 30-day period. The maximum blood volume collected in any 30-day period in this study will not exceed 14 mL. The maximum number of venipunctures for blood chemistries and for measuring blood tafenoquine concentrations is six for the entire study.

*Confidentiality*

Loss of confidentiality about your participation in this study is a risk. To protect your confidentiality all study records will be coded and stored in locked areas, locked cabinets, and password protected electronic spreadsheets at the clinical trial site. Your name will not appear in any publications or presentations about this study.

**The study design that involves your participation**

The study design consists of you taking the FDA and TGA approved weekly 200 mg tafenoquine regimen (loading dose of 200 mg daily for 3 days followed by 25 weekly 200 mg doses of tafenoquine). The tafenoquine dose of 200 mg will be administered as two tablets (brand name Arakoda™) each containing 100 mg of tafenoquine.

**How will you be selected to participate in this study?**

You are requested to read this PISCF in full prior to your screening visit. You would have had at least seven days to read these documents before attending the screening visit which will occur from 7 to 21 days prior to you receiving the first loading dose of tafenoquine. A brief description of each visit is provided below:

For the screening visit, you will be asked to come to the clinical trial site at VMMU without the need of an over-night fast. During the screening visit, the PI/Co-PI/Co-Investigator will discuss the details of the clinical trial with you, and you will be asked to read the PISCF and be encouraged to ask questions associated with your potential participation. This will be done in a private room so your discussion with the PI/Co-PI/Co-Investigator including medical information will be kept confidential between yourself and the PI/Co-PI/Co-Investigator. You will be fully informed by the PI/Co-PI/Co-Investigator of the purpose of the study and your role and responsibilities. If you decide to participate in the study, you must sign the ICF before any procedures are carried out between yourself, the PI/Co-PI/Co-Investigator and clinical trial site staff. You will then be given a copy of the signed PISCF for your records.

**Screening visit**

The screening procedures will begin to determine your eligibility to participate in the study. If you satisfy all entry criteria during the screening tests, you be considered eligible to participate in the study. The screening procedures, clinical assessments and laboratory tests involving your participation will be performed by the PI/Co-PI/Co-Investigator and clinical trial site staff and recorded as follows:

* A screening study identification number will be assigned to you.
* Your medical and social histories and current medications will be recorded.
* Your demographic data (date of birth, gender, race, and ethnicity), body height and body weight will be collected.
* You will complete a physical examination.
* You will be given the Beck Depression Inventory questionnaire for assessing your depression level, if any.
* An assessment of your cardiovascular health will be completed, to include vital signs (blood pressure and heart rate) and a 12-lead ECG (electro-cardiogram). The ECG records the electrical activity of your heart by placing electrodes (adhesive tabs attached to wires) on the skin of your chest.
* A blood sample will be collected for biochemical, hematology, and a quantitative glucose-6-phosphate dehydrogenase (G6PD) test and urine will be collected for urinalysis. Note that individuals who are deficient for G6PD are at increased risk for severe hemolytic anemia upon taking tafenoquine and thus are ineligible to be in this study.
* A blood sample will be collected for drug-free measurement of tafenoquine concentrations and for malaria rapid diagnostic test, blood film microscopy and molecular testing to confirm that you are free of malaria infection.
* If you are a female, a pregnancy test (serum beta-human chorionic gonadotropin (β-hCG)) will be performed. Note that pregnant women cannot participate in this study.
* The study clinicians will verify that you meet the inclusion criteria for participation in the study.

If you fulfill all the selection criteria requirements with normal clinical and laboratory assessments indicating that you are in good health, and you are G6PD normal you will then be allocated a unique study participation identification number. A flow chart of activities for the screening and tafenoquine loading visits in Hanoi and visits in South Sudan is shown on page 12 of this PISCF.

To ensure that you have good blood tafenoquine concentrations to protect you from malaria infections in South Sudan, a loading dose of 200 mg tafenoquine daily for three consecutive days will be administered to you in Hanoi starting on Day 0 at the clinical trial site at VMMU. The 200 mg tafenoquine doses will be administered at about 24 hour intervals between each dose. The following procedures to be carried out by the PI/Co-PI/Co-Investigator will occur during the loading doses:

**Tafenoquine 3-day Loading Dose in Hanoi**

* You will be fed a normal Vietnamese breakfast 30-60 minutes prior to each 200 mg tafenoquine administration to improve drug absorption and minimize gastrointestinal disturbances from the drug.
* Your taking of the 200 mg tafenoquine will be observed and recorded (i.e., date and time).
* Record your use of other medications and any medical condition they you may be experiencing at the time of dosing.
* Record any adverse events that you may have before (0-1 hour) the administration of tafenoquine and after (1-4 hours) taking the drug. You will be observed for a minimum of 60 minutes after tafenoquine administration to evaluate for any immediate adverse events from the drug.

### Safety and Tolerability of Tafenoquine after the Loading Dose

At about 22 hours after the last (3rd) loading dose of 200 mg tafenoquine the following activities will be performed on you by the PI/Co-PI/Co-Investigator:

* A physical examination.
* Record vital signs (supine and standing blood pressure and heart rate).
* Record the use of concomitant medications and any other medical condition.
* Collect urine for urinalysis.
* Collect blood samples for biochemical and hematology testing as well as for the measurement of your maximum blood tafenoquine concentration and for malaria rapid diagnostic test, blood film microscopy and molecular testing to confirm that you are free of malaria infection.
* Record any adverse events that you may have had since taking your last tafenoquine tablet the day before.

### Tafenoquine Weekly (200 mg) at Weeks 4, 8, 16 and 26 (end of study)

Just before weeks 4, 8, 16 and 26 of the weekly (200 mg) tafenoquine maintenance dose the following activities will be performed on you by the PI/Co-PI/Co-Investigator:

* A physical examination.
* Record vital signs (supine and standing blood pressure and heart rate).
* Record the use of concomitant medications and any other medical condition.
* Collect urine for urinalysis.
* Collect blood samples for biochemical and hematology testing, as well as for the measurement of your minimum blood tafenoquine concentration and for malaria rapid diagnostic test, blood film microscopy and molecular testing to confirm that you are free of malaria infection.
* Record any adverse events that you may have before (0-1 hour) the administration of tafenoquine and after (1-4 hours) taking the drug.
* Complete an acceptability questionnaire of the weekly 200 mg tafenoquine at weeks 4 and 26 only.

### Participant Self Reporting of Drug Administration and Adverse Events

So we can monitor your wellbeing throughout the entire study you will be provided with a diary to enter the dates and timing of tafenoquine administration for each week from weeks 1 to 25. The diary will also have a list of common adverse events such as abdominal pain that some people experience when taking weekly tafenoquine for malaria protection. At weeks 2, 6, 10, 12, 14, 18, 20, 22, and 24 the PI/Co-PI/Co-Investigator will review your drug administration, adverse event responses, and general wellbeing.

### Participant Experiences a Malaria Infection during the Study

If you are diagnosed with a malaria infection during the 26 weeks study, based on a positive rapid diagnostic test with a confirmed blood film microscopy finding, the following activities will be carried out by the PI/Co-PI/Co-Investigator on you:

* A physical examination.
* Record vital signs (supine and standing blood pressure and heart rate).
* Record the use of concomitant medications and any other medical condition.
* Collect urine for urinalysis.
* Collect blood samples for biochemical and hematology testing as well as for the measurement of tafenoquine concentrations at the time of malaria diagnosis. Molecular analysis of your blood sample will be used confirm the *Plasmodium* species that has infected you and the drug-resistant profile of the parasite.
* Record any adverse events that you may have experienced after your last weekly tafenoquine dose.

**Early Termination Visit**

If you decide to withdraw from the study at any time, you will be asked to complete a termination study evaluation, with the following activities to be carried out by the PI/Co-PI/Co-Investigator on you:

* A physical examination.
* Record vital signs (supine and standing blood pressure and heart rate).
* Record the use of concomitant medications and any other medical condition.
* Collect urine for urinalysis.
* Collect blood samples for biochemical and hematology testing, as well as for the measurement of your blood tafenoquine concentration and a molecular test (i.e. confirmation that you are malaria parasite free).
* Record any adverse events that you may have experienced since your last weekly tafenoquine dose.
* Complete an acceptability questionnaire of the weekly tafenoquine dosing.

**What will happen if I withdraw from this study?**

Although you do not have to give a reason for withdrawing from the study, the Principal Investigator and Sponsor would be keen to know as it may impact on people’s acceptability to take tafenoquine. If you withdraw during the study, any data collected up to the point you withdraw will still be used in the analyses for this study.

**If new information on tafenoquine arises during this study is the Sponsor required to inform you?**

Yes. The Sponsor must provide you with any new information on tafenoquine that becomes available during the study, which identifies any additional risks that you may be exposed to or that may affect your willingness to participate further in this study. Based on the new information you may have to sign an amended PISCF outlining any additional risks that you are willing to accept to continue your participation in the study.

**What will happen to your blood and urine samples?**

Your blood and urine samples collected during the study at VMMU and L2FH will not identify you by name, but only by your study number. These samples will be stored according to the laboratories’ testing requirements, for the duration required to complete the tests, and then they will be destroyed as per the laboratories’ procedures. Your blood samples for the measurement of tafenoquine concentrations will be sent to the Australian Defence Force Malaria and Infectious Disease Institute (Brisbane, Australia) for analysis where they will be stored for 15 years following completion of this study. We will seek your approval to store your unused blood samples to be used for future studies of tafenoquine to improve our knowledge of the drug. Note that future research studies of your blood samples will not involve whole genome sequencing and will only be used for researching tafenoquine metabolism and its role in drug resistance. At the end of 15 years these blood samples will be destroyed by incineration. Your decision about the use of your samples for future research will not affect your participation in this study.

**What will happen with your personal information and your study data?**

Any personal information that we collect from you is freely available for you to see at your request. Your name and assigned study identification number will be entered in a separate spreadsheet only accessible by the PI/Co-PI as a locked document and to be only accessed for reporting and follow up purposes such as a serious adverse event.

Please be aware that this study will be conducted under the regulatory guidelines of the Drug Administration of Vietnam. All your hard copy study records will be kept for a minimum of 20 years at VMMU in a lockable cabinet or archive room as well as electronic forms of your records secured on a password protected computer. After 20 years the Director of VMMU, with written agreement from the Sponsor, may destroy the hard copies of your study documentation by incineration and by erasing scanned copies of your study documentation. All your study documentation and research data, including personal information, and clinical and laboratory assessments covering your health before, during and at the end of the study, will be kept confidential by the PI/Co-PI/Co-Investigator and clinical trial site staff with restricted accessed to your stored study documentation.

This research study will be registered in the public clinical trial registry of http://www.anzctr.org.au which outlines a description of the study (e.g. study objectives and design, targeted population, selection criteria, summary of results, etc.) that will be readily available to you at the website. For privacy protection the website selected will not include any information that can identify you. The clinical report of the study will be submitted to the Sponsor, partners, the ethical agencies that approved the study as well as the Drug Administration of Vietnam. The clinical findings of this study will be published in a peer-reviewed international scientific journal and at national and international conferences. Only your study identification number (and in some cases your initials, gender, and age) will be included in reports, publications and at conferences.

**Will you receive any benefits from their participation in the study?**

As a participant you will be receiving an antimalarial drug that should protect you from malaria infections in South Sudan. Also, the level of monitoring in this study will provide a good insight into your general health status and wellbeing during the deployment. By participating in this study, important safety and tolerability data on weekly tafenoquine will be obtained. From the user drug regimen acceptability questionnaire, your response and acceptance rating of the weekly tafenoquine regimen will provide valuable information about weekly tafenoquine in enhancing drug compliance.

**Will you be compensated as a participant in the study?**

Yes. If you decide to participate in the study and fulfil the selection criteria you will be compensated for the discomfort and inconvenience of providing blood samples, physical examination and answering adverse event questionnaires during the screening visit and the other visits (total 6 visits) during the 26 week study period. You will be paid compensation after each visit. Overall, you will be compensated $USD140 for each visit (i.e. screening visit, day 3 visit after starting tafenoquine dosing and at weeks 4, 8, 16 and 26 of the study (total of $USD840). The compensation will not be made for risks that may be associated with your participation in the study nor will it be to compensate for loss of any earnings as a result of your participation. If you are administered tafenoquine and then decide not to continue, or you are withdrawn from the study by the PI/Co-PI/Co-Investigator you will receive a pro rata compensation.

**What support will you receive if you become ill during the study?**

As this study has a primary focus on the safety and tolerability of tafenoquine in Vietnamese military personnel on peacekeeping duties in South Sudan, your wellbeing and health are of primary concern to the Sponsor and the clinical trial site staff. If you suffer a research-related injury or complications as a result of your participation in this study, please contact the PI/Co-PI/Co-Investigator at the clinical trial site as soon as possible, so the PI/Co-PI/Co-Investigator can arrange appropriate medical care free of charge to you. Depending on the nature of your injury, the PI/Co-PI/Co-Investigator may refer you to a medical specialist as appropriate. Participants will not receive additional compensation for injury beyond medical care.

**Malaria prophylaxis after completing the tafenoquine study**

After you have completed your participation in the 26 weekly tafenoquine study, you will need to continue to take an antimalarial drug such as doxycycline or mefloquine for at least another 6 months as you are deployed to a highly malarious country.

**CONSENT FORM**

|  |  |
| --- | --- |
| **Title** | Evaluation of the safety, tolerability and effectiveness of weekly tafenoquine in protecting Vietnam People’s Army personnel in South Sudan against malaria infections |
| **Short title** | Evaluation of weekly tafenoquine antimalarial prophylaxis in Vietnam People’s Army personnel in South Sudan |
| **Protocol number** |  |

I, ................................................................………………... give my consent to participate in the project named above on the following basis:

I have had explained to me the aims of this research project, how it will be conducted and my role in it.

I understand:

* the risks involved as described in the Participant Information Sheet
* there is no obligation to take part in this study
* if I choose not to participate there will be no detriment to my career
* I am free to withdraw at any time with no detriment to my career. The data obtained from me up to the date of withdrawal can still be used by the Investigators at their discretion
* I am deemed to be on duty whilst participating in this research

I am cooperating in this project on condition that:

* the information I provide will be kept confidential
* the information will be used only for this project
* the research results will be made available to me at my request and any published reports of this study will preserve my anonymity
* I have been given a copy of the ‘Departments of Defence and Veterans’ Affairs Human Research Ethics Committee (DDVA HREC) Guidelines for Volunteers’.

I have been given a copy of the participant information sheet and consent form, signed by myself and by the Principal Investigator (Prof. Dr. Do Quyet) or the Co- Principal Investigator (Dr. Vu Minh Duong) to keep.

**Storage and re-use of blood samples**

I GIVE permission for the researchers to store a portion of my blood samples for a period of 15 years at ADFMIDI for use in future studies of tafenoquine to improve our knowledge of the metabolism of tafenoquine and its role in drug resistance.

 **[ ]**  Yes **[ ]**  No Signature of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I understand that, as I am participating in a clinical trial, my name and military service details will be retained for this study and may be provided to the VMMU and DDVA HREC in case I need to be traced at some time in the future. These records will not be used to consider you medical employment standard or for compensation purposes. This information will be kept secure and your contact information will not be passed onto a third party without your permission.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name in full

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Principal Investigator/ Co- Principal Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name in full

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date

**If you have any questions or complaints, who can you contact?**

If you require any further information about the study or your participation such as any medical concerns or you wish to raise any complaints about any aspect of the study, you can contact the following doctors who are directly responsible for your health and wellbeing as listed below:

* Principal Investigator is Prof. Dr. Do Quyet on +84 983301839
* Co-Principal Investigator is Dr. Vu Minh Duong on +84 912134655
* Co-Investigator is Dr. Vu The Anh on +84 348970705
* Independent Medical Monitor is Dr. Huynh Hong Quang on +84 905103496
* Vietnam MoH IRBNBR via the Secretariat on +84 243-384-6688
* DDVA HREC on +61 2 6192 7821 or via ddva.hrec@defence.gov.au

## **Flow chart for tafenoquine loading and weekly tafenoquine prophylaxis in**

## **Vietnam People’s Army personnel on peacekeeping duties in South Sudan**

