A mixed-method operational research study on the use of tafenoquine and G6PD testing for radical cure of Plasmodium vivax *malaria in passive and active case detection in Vietnam*

Informed Consent Form for patients to participate in the study

This Informed Consent Form is for **PATIENTS** who are treated at ___________________________ [name of facility or community], and who are invited to participate in the above research study on vivax malaria.

Name of Principal Investigator: Associate Prof. Bui Quang Phuc, MD.
Name of Facility/ Community:
Name of Sponsor: PATH
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Reading level: 7.8

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research study with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

1. We are asking you to be in research study.

National Institute of Malariology, Parasitology and Entomology (NIMPE) and PATH are doing a research study on new test and drug for malaria. PATH, the sponsor of this study, is a non-profit organization working to improve health around the world. We are asking you to be in this study because you tested positive for vivax malaria. We will include up to 150 patients in this study.

We are going to give you more information about this study next. We will tell you the risks and benefits of being in the study. Before you decide, you can talk to anyone about the research and show them this information sheet.

Ask questions about anything that is not clear. If you decide to join to join, you will sign or make your thumbprint on this form.

2. Why are we doing this research study?

Malaria is a disease that can make you very sick. It is caused by a tiny parasite that can infect your blood cells and your liver. To treat this type of malaria, patients usually get two medicines. One of these medicines, called primaquine, is the standard treatment in Vietnam but primaquine can be harmful to some people, especially if they do not have enough of a certain enzyme Glucose-6-Phosphate Dehydrogenase (G6PD) in their blood. This research study is trying to find new ways to treat patients with this type of malaria, so that they can get better care and more people can be fully treated.

All people have the G6PD enzyme in their bodies. G6PD helps red blood cells work normally. Some people's bodies do not make enough G6PD. People that do not have enough G6PD can have dangerous side effects if they take primaquine. The biggest risk is severe anemia, due to the drop of the protein carrying the oxygen in the blood.

Because primaquine needs to be taken every day for 7 days or 14 days, a long treatment time, so people do not always finish the treatment. If patients are not given the right medicines or they do not finish the treatment, they will continue to have parasites in the liver.

A new medicine, called tafenoquine, which is the 8-aminoquinoline group, is like primaquine but is a single dose. Tafenoquine was licensed in Vietnam and introduced in the National Malaria Treatment Guideline. Tafenoquine and primaquine can harm patients if they do not have enough G6PD in their blood. Therefore, before you take the drug, we will do a G6PD test for you to make sure that you have enough G6PD values in your blood. The test we use here has been recommended to use for vivax malaria patients in Vietnam.

Before this test and a new treatment of tafenoquine could be widely used in Vietnam. we would like to evaluate how the test and treatment can be used in Vietnam.

The goal of the study is to improve the quality of care and ensure more patients are fully treated for vivax malaria. This will reduce malaria in the community and help eliminate it.

We are interested in information on this test and treatment for treating patients with vivax. We will collect data on how patients are tested and treated. By agreeing to participate in this study, you will help us improve the way health workers may use the G6PD test and tafenoquine in the future.

3. What will happen during this study and what is different from routine care?

3.1 What will be done during my visit?

All vivax patients at this health facility or part of this community will be tested for G6PD. If you agree to be in this study, you will be given either tafenoquine or primaquine based on the test results. If you do not agree to be in the study, you will be given treatment as current routine.

1) All patients will be tested with the G6PD test to determine if they have enough G6PD in their blood. A small amount of venous blood or a few blood drops from a fingerpick, not both, is needed for the G6PD test.
2) If you agree to participate in the study, based on the test result, the health worker will decide what is the best medicine for you: either tafenoquine or primaquine. Women who are pregnant or breast-feeding and those who do not have enough G6PD in their blood cannot take either medicine. Tafenoquine can only be given to patients who are older than 16 years. Primaquine can only be given to patients who are older than 6 months.
3) The health worker will explain to you what side effects can occur with primaquine and tafenoquine and what to do if you have symptoms in the coming days. This discussion will take about 30 minutes.
4) After the first day of treatment (Day 1), you will need to come back to the health facility on Day 2, 3, 4 and 8 for a follow-up visit. This is to check that you are doing well. This visit will take about one hour. We will also call you on Day 15 and 29. This call with take about 30 minutes.

3.2 What is done as part of the research study and what changes if you are part of the study?

If you agree to participate in the study, we will use information about your diagnosis, the G6PD test result and your treatment for the research. We will enter this data into specific forms and analyse it with other patient data. We will not collect any name or personal information on the forms. You will also be able to take tafenoquine if you are eligible.

If you do not wish to participate, health staff will collect your data only in the registry and routine forms. Your data will not be shared with the study team. As tafenoquine is not routinely provided by Ministry of Health, you will receive the same test and standard treatment of primaquine. You will not be provided new treatment of tafenoquine.

4. What are the benefits if I decide to participate in the study?

There is no direct benefit to you if you decide to participate in the study. If you participate in the study, you will contribute to improve the quality of care for vivax patients in Vietnam and help to eliminate vivax malaria from your community in the future.

5. What are the risks if I decide to participate in the study?

We keep your personal information secure. However, there is always a small chance that someone who is not allowed could see your personal information by mistake. If this happens, we will tell you. No injuries are expected in this study but if you are injured relating to the study, the study will pay for any care you need. You may feel pain when we take a small amount of blood for testing.

6. Can I say no?

You do not have to be in this study. You can say yes or no to joining. You can leave the study at any time. If you do not join, you will not have any penalties. If you say yes or no, you and your family will receive the same quality of care. You may change your mind later and leave the study. You do not have to give a reason. If this happens, we will only use the data collected before you left the study. If we learn any new information that may affect your decision to participate, we will tell you as soon as possible.

7. Will I be paid for being in the study?

You will not be paid for being in this study. We will compensate your non-working time, travel costs and meals related to follow up visits at study site, you will receive ~21 USD per visit that you attend.

The Ministry of Health provides most of the care for malaria. The study will provide the G6PD test and tafenoquine treatment.

8. What happens to my data?

Your personal data (such as name, age, gender, address, phone number, etc) is collected as part of routine in the health registries. If you agree to be in the study, we will share this with study team members for monitoring the quality of the study.

We will also give you a unique study number. To keep your information confidential, only authorized study staff will have access to the list that connects your name and your study number. Your coded data also may only be shared with authorized persons and organizations as necessary. This data will not be linked to you in any way.

We will store your data in a secure location for a minimum period of 5 years after the study ends.

The results will also be shared with Vietnam Ministry of Health. The results will be shared with the independent committee overseeing the study. The data we collect in this study will be shared with the funders, MMV and Unitaid. It will also be shared with , PATH, those who will analyse the data, and with insurers in case you have study related injuries for claim purpose. It may be made open to the public so that others can learn from it. If data are shared publicly, they will not be linked to you personally."

9. Will the results from the research study be shared with me?

The information we learn from this study will be shared with you through community meetings before it is made widely available to the public.

Your personal data will not be shared. We may write an article or share the study results at meetings or on websites in order that other interested people may learn from our research.

10. Who should I contact if I have questions?

If you have questions about this study, please call Study Coordinator (Dr. Dang Thi Tuyet Mai) at 0393981811 or Dr. Bui Quang Phuc at 0913522874.

If you have questions about your rights in this research study, please contact Dr. Nguyen Quang Thieu, chairman of NIMPE Ethics Review Committee at 0912216817 or email: thieunq@gmail.com. If you have any questions, you may ask now or later, even after the study has started.

This informed consent has been reviewed and approved by NIMPE Ethics Review Committee and Independent Ethics Committee at Ministry of Health which are committees who make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact Dr. Nguyen Quang Thieu at Tel: 0912216817 or email: thieunq@gmail.com. It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO).

You can ask me any more questions about any part of the research study. Do you have any questions?

PART II: Informed Consent Sheet

PATIENTS

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked, have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this research study.

Name of Participant__________________

Signature of Participant ___________________

Date ___________________________

Day/month/year

If illiterate:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____________________ AND Thumb print of participant

Signature of witness ______________________

Date ________________________

Day/month/year

Statement by the health care provider who is taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understood the information.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of health care provider taking the consent________________________

Signature of health care provider taking the consent__________________________

Date ___________________________

Day/month/year