

**Ethics Review Committee
Department of Medical Research
Ministry of Health and Sports
Republic of the Union of Myanmar**

Informed Consent Form

Informed consent form for adult participants (ages 18 and above) invited to participate in the study
“Evaluation of the performance of a highly-sensitive rapid diagnostic test (hsRDT) *versus* conventional RDT (cRDT), compared with polymerase chain reaction (PCR) as the gold standard, in reactive case detection of malaria infections in Rakhine State, Myanmar”

Name of Principal Investigator

Dr. San Kyawt Khine
Vector-borne Disease Control, Rakhine
Department of Public Health
Ministry of Health and Sports (MoHS)

Name of Organizations:

National Malaria Control Program, Department of Public Health, MoHS
Vector-borne Disease Control, Rakhine, Department of Public Health, MoHS
University Research Corporation Myanmar, Yangon, Myanmar
Department of Medical Research, MoHS
Institute for Global Health, University of Maryland Baltimore (UMB), USA
U.S. Centers for Disease Control and Prevention (CDC), USA

Name of Funding Organization:

US President’s Malaria Initiative (PMI)

PART I: Information Sheet**Introduction**

My name is _____, and I am responsible for talking with you about a malaria research study. The title of this study is stated above on this form. This study is led together by the Myanmar Ministry of Health and Sports (MoHS) and University Research Corporation (URC). The URC is a registered iNGO working in Rakhine State, which has been providing malaria services in Myanmar for several years now. The Department of Medical Research under the MoHS and University of Maryland in the USA will provide research and lab support for this study.

I am going to give you some information and invite you to participate in this study. Before you decide, please feel free to discuss this study with anyone, and ask me any questions you have. If I say something you cannot understand, please stop me and ask me to explain more. I will take as much as time as you need to make sure you understand everything about this study clearly. You may also ask the study doctors or other staff in this clinic any questions.

Purpose

The purpose of this study is to see if a new diagnostic test is better than what we are using now for detecting malaria infection. We currently have a rapid diagnostic test (called conventional RDT, or cRDT for short) that can give you a result within a few minutes, but it is not very good when you have only a few malaria parasites. Another way to look for malaria is by using a microscope, but this is too difficult here. Now there is a new test called highly sensitive rapid diagnostic test (hsRDT for short). We want to compare cRDT and hsRDT, using PCR as the gold standard. PCR is very good at finding malaria parasites, able to identify even a very small number if there are any present in your blood. We will use PCR as the standard to decide if the new test is better for detecting malaria infection.

Type of Research Intervention

This research study involves testing your blood just one time. If you test positive for malaria infection we would like to go to where you live (or work, if relevant). We will ask the people who live, or work, with you to participate in this study. If they agree, we will also test their blood and ask them some questions about their work activities and travel. It is also possible that you may be asked to participate in the study since you live or work with someone who has tested positive for malaria.

Participant selection

Age 6 months or older who tested positive for malaria, or who is a member of a household or of a nearby household of someone who tested positive for malaria, or who is a coworker of someone who tested positive for malaria; they may be resident of the village or visitor in the village tract.

The study staff will obtain written informed consent or assent with adult parent/guardian permission, as appropriate.

Voluntary Participation

Your participation in this study is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, all the services you receive at this clinic will continue and nothing will change; there will not be any negative effect on the care you receive. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you receive at the clinic will continue.

Procedures and Protocol

If you agree to participate and sign the consent, we will ask you a few questions and assign you a unique number. Our study doctor, midwife, or nurse will clean the tip of your finger and then prick the tip of your finger to collect 5-7 drops of blood (about a quarter of a teaspoon). Filter paper will be placed on your finger to absorb a couple of the drops of blood. For infants 6 months to one year of age, a heel prick might be more appropriate. Two to three drops of blood will be used to check for malaria infection by cRDT; two to three drops of blood will be used to check for malaria infection by hsRDT; and 3-4 drops of blood will be collected on filter paper for laboratory-based parasite tests, like PCR. These blood samples will be labeled with your unique number only (not your name). We will store the blood on filter paper until we send it to a laboratory in Yangon. Most of the laboratory tests will be completed in Yangon, but we may need to send some of the filter paper blood samples to a laboratory at the University of Maryland in the US for more advanced testing or for quality control. If either the cRDT or hsRDT is positive for malaria infection, we will ensure that you get treatment from your local health care team according to the Myanmar Ministry of Health and Sports guidelines.

Duration

It will take about 30 minutes to ask the questions and to collect the blood sample.

Risks and discomfort

By participating in this research you have a very small risk of bruising, bleeding, infection, or fainting from the finger-stick. There is also a risk of loss of confidentiality of your information. We will do everything we can to minimize these risks. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also come to this health facility at any time to see the Medical Officer.

Benefits

You may not receive any direct benefit from participating in this study but the study doctors will take care of you when you are sick with any illness. There may not be any other benefit for you but your participation is likely to help us decide whether this new hsRDT is a better test for malaria infection and this will be a benefit to the community and to future generations.

Incentives

You will receive a total of 4000 kyats for the time you spend participating in this research.

Confidentiality

With this study, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the study. The information that we collect from this study will be kept confidential. All the information about you that will be collected from the study will have a number on it instead of your name and it will be secured so that no one but the team members involved in the study will be able to see it. Only the study team members will know what your number is and we will secure the names and numbers under lock and key.

Sharing the Results

The knowledge that we get from this study will be shared with you before it is made widely available to the public. There will be small meetings in the community and these will be announced. Afterwards, we will publish the results in order that other interested people may learn from our study. Confidential information will not be shared.

Right to Refuse or Withdraw

You do not have to take part in this study if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected; your care at the health care center will not be affected.

Who to Contact

If you have any questions you may contact: Dr. San Kyawt Khine, Assistant Director, Vector Borne Disease Control Program, Rakhine State, General Hospital Compound, Sittwe, Rakhine State, Myanmar; Telephone Number 09 450542076. This proposal has been reviewed and approved by Ethics Review Committee, Department of Medical Research, which is a committee whose task it is to make sure that study participants are protected from harm. If you wish to find about more about the ERC, contact The Secretary, Ethics Review Committee, Department of Medical Research, No 5, Ziwaka Road, Yangon 11191, Myanmar; Telephone Number 01 375457 Extension 118.

PART II: Certificate of Consent

I have been invited to participate in the study **“Evaluation of the performance of a highly-sensitive rapid diagnostic test (hsRDT) versus conventional RDT (cRDT), compared with polymerase chain reaction (PCR) as the gold standard, in reactive case detection of malaria infections in Rakhine State, Myanmar.”** I have been informed that the risks are minimal. I am going to involve blood taking procedure from my finger tip for 5-7 drops of blood for one time and an interview for about 30 min. I was informed that my blood sample will be kept confidentially as I consent how long to be kept. I am aware that there may be no benefit to me personally and that I will receive 4000 kyats for compensation of my time spent during this study. I have been provided with the name, phone number and address of the researcher, staff, and Ethic Review Committee if I have questions, concerns, and complaints. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I asked have been answered to my satisfaction. I consent voluntarily to enroll as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my medical care.

Name of Participant _____

Signature of Participant _____

Date _____
(Day/month/year)

If illiterate

A literate **witness must sign** (if possible, this person **should be selected by the participant** and should have **no connection to the research team**). **Participants who are illiterate should include their thumb-print** as well.

Thumb print of participant



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 _____

Signature of witness _____

Date _____
(Day/month/year)

I have accurately read or 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 Researcher _____

Signature of Researcher _____

Date _____ (Day/month/year)

A copy of this Informed Consent Form has been provided to participant ____ (initialed by the researcher/assistant)

**Ethics Review Committee
Department of Medical Research
Ministry of Health and Sports
Republic of the Union of Myanmar**

Informed Consent Form for Parents/Guardians of children (ages 5 to 17 years) involved in the study

Protocol title: “**Evaluation of the performance of a highly-sensitive rapid diagnostic test (hsRDT) versus conventional RDT (cRDT), compared with polymerase chain reaction (PCR) as the gold standard, in reactive case detection of malaria infections in Rakhine State, Myanmar**”

Name of Principal Investigator

Dr. San Kyawt Khine
Vector-borne Disease Control, Rakhine
Department of Public Health
Ministry of Health and Sports (MoHS)

Name of Organizations:

National Malaria Control Program, Department of Public Health, MoHS
Vector-borne Disease Control, Rakhine, Department of Public Health, MoHS
University Research Corporation Myanmar, Yangon, Myanmar
Department of Medical Research, MoHS
Institute for Global Health, University of Maryland Baltimore (UMB), USA
U.S. Centers for Disease Control and Prevention (CDC), USA

Name of Funding Organization:

US President’s Malaria Initiative (PMI)

PART I: Information Sheet

Introduction

My name is _____, and I am responsible for talking with you about a malaria research study. The title of this study is stated above on this form. This study is led together by the Myanmar Ministry of Health and Sports (MoHS) and University Research Corporation (URC). The URC is a registered iNGO working in Rakhine State, which has been providing malaria services in Myanmar for several years now. The Department of Medical Research under the MoHS and University of Maryland in the USA will provide research and lab support for this study.

I am going to give you and your child some information and invite your child to participate in this study. Before you or your child decides, please feel free to discuss this study with anyone, and ask me any questions you have. There may be some words that you or your child do not understand. If I say something that you or your child cannot understand, please stop me and ask me to explain more. I will take as much as time as you need to make sure you understand everything about this study clearly. You may also ask the study doctors or other staff in this clinic any questions.

Purpose

The purpose of this study is to see if a new diagnostic test is better than what we are using now for detecting malaria infection. We currently have a rapid diagnostic test (called conventional RDT, or cRDT for short) that can give you a result within a few minutes, but it is not very good when you have only a few malaria parasites. Another way to look for malaria is by using a microscope, but this is too difficult here. Now there is a new test called highly sensitive rapid diagnostic test (hsRDT for short). We want to compare cRDT and hsRDT, using PCR as the gold standard. PCR is very good at finding malaria parasites, able to identify even a very small number if there are any present in your blood. We will use PCR as the standard to decide if the new test is better for detecting malaria infection.

Type of Research Intervention

This research study involves testing your child's blood just one time. If they test positive for malaria infection we would like to go to where they live (or work, if relevant). We will ask the people who live, or work, with them to participate in this study. If they agree, we will also test their blood and ask them some questions about their work activities and travel.

Participant selection

Age 6 months or older who tested positive for malaria, or who is a member of a household or of a nearby household of someone who tested positive for malaria, or who is a coworker of someone who tested positive for malaria; they may be resident of the village or visitor in the village tract.

The study staff will obtain written informed consent or assent with adult parent/guardian permission, as appropriate.

Voluntary Participation

Your decision to have your child participate in this study is entirely voluntary. It is your child's choice whether to participate or not. If your child chooses not to participate, all the services your child receives at this clinic will continue and nothing will change. Your child may also choose to change his or her mind later and stop participating, even if your child agreed earlier, and the services your child receives at the clinic will continue.

Procedures and Protocol

If your child agrees to participate and you sign this consent, we will ask your child a few questions and assign him or her a unique number. Our study doctor, midwife, or nurse will clean the tip of your child's finger and then prick the tip of your child's finger to collect 5-7 drops of blood (a quarter of tea spoon). Filter paper will be placed on your child's finger to absorb a couple of drops of blood. For infants 6 months to one year of age, a heel prick might be more appropriate. Two to three drops of blood will be used to check for malaria infection by cRDT; two to three drops of blood will be used to check for malaria infection by hsRDT; and 3-4 drops will be collected on filter paper for laboratory-based parasite tests, like PCR. These blood samples will be labeled with your child's unique number only (not his or her name). We will store the blood on filter paper until we send it to a laboratory in Yangon. Most of the laboratory tests will be completed in Yangon, but we may need to send some of the filter paper blood samples to a laboratory at the University of Maryland in the US for more advanced testing or for quality control. If either your child's cRDT or hsRDT is positive for malaria infection, we will ensure that he or she gets treatment from your local health care team according to the Myanmar Ministry of Health and Sports guidelines.

Duration

It will take about 30 minutes to ask the questions and to collect the blood sample.

Risks and discomfort

By participating in this research your child has a very small risk of bruising, bleeding, infection, or fainting from the finger-stick. There is also a risk of loss of confidentiality of your information. We will do everything we can to minimize these risks. We will give you and your child a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also bring your child to this health facility at any time to see the Medical Officer.

Benefits

Your child may not receive any direct benefit from participating in this study but the study doctors will take care of your child when sick with any illness. There may not be any other benefit to your child but your child's participation is likely to help us decide whether this new hsRDT is a better test for malaria infection and this will be a benefit to the community and to future generations.

Incentives

Your child will receive a total of 4000 kyats for the time you have spent together participating in this research. However, there will be no additional compensation for the adult guardian/parent who provides this consent.

Confidentiality

With this study, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that your child is participating, they may ask you questions. We will not be sharing the identity of those participating in the study. The information that we collect from this study will be kept confidential. All the information about your child that will be collected from the study will have a number on it instead of your child's name and it will be secured so that no one but the team members involved in the study will be able to see it. Only the study team members will know what your child's number is and we will secure the names and numbers under lock and key.

Sharing the Results

The knowledge that we get from this study will be shared with you and your child before it is made widely available to the public. There will be small meetings in the community and these will be announced. Afterwards, we will publish the results in order that other interested people may learn from our study. Confidential information will not be shared.

Right to Refuse or Withdraw

Your child does not have to take part in this study if you or your child do not wish to do so. Your child may also stop participating in the research study at any time you or your child choose. It is your and your child's choice and all of your rights will still be respected; your child's care at the health care center will not be affected.

Who to Contact

If you or your child have any questions you may contact: Dr. San Kyawt Khine, Assistant Director, Vector Borne Disease Control Program, Rakhine State, General Hospital Compound, Sittwe, Rakhine State, Myanmar; Telephone Number 09 450542076. This proposal has been reviewed and approved by Ethics Review Committee, Department of Medical Research, which is a committee whose task it is to make sure that study participants are protected from harm. If you wish to find about more about the ERC, contact The secretary, Ethics Review Committee, Department of Medical Research, No 5, Ziwaka Road, Yangon 11191, Myanmar; Telephone Number 01 375457 Extension 118.

PART II: Certificate of Consent

My child has been invited to participate in the study “**Evaluation of the performance of a highly-sensitive rapid diagnostic test (hsRDT) versus conventional RDT (cRDT), compared with polymerase chain reaction (PCR) as the gold standard, in reactive case detection of malaria infections in Rakhine State, Myanmar.**” I have been informed that the risks are minimal. My child is going to involve blood taking procedure from his/her finger tip for 5-7 drops of blood for one time and an interview for about 30 min. I was informed that my child’s blood sample will be kept confidentially as I consent how long to be kept. I am aware that there may be no benefit either to myself personally or to my child and that I will not receive any compensation for my time in providing consent for the participation of the child minor for this study. I have been provided with the name of an investigator who can be easily contacted using the number I was given for that person.

I have read the foregoing 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 have my child enroll as a participant in this study and understand that my child and I have the right to withdraw from the study at any time without in any way affecting our medical care.

Name of Guardian _____ Name of Child _____

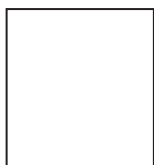
Signature of Guardian _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

Thumb print of participant



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

Name of witness _____

Signature of witness _____

Date _____
Day/month/year

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

Name of Researcher _____

Signature of Researcher _____

Date _____
Day/month/year

A copy of this Informed Consent Form has been provided to the guardian of the participant ____ (initialed by the researcher/assistant)

**Ethics Review Committee
Department of Medical Research
Ministry of Health and Sports
Republic of the Union of Myanmar
RESEARCH ASSENT FORM
Verbal assent for children between 8-9 years of age
Written assent for children between 10-17 years of age**

Research Study Title: “Evaluation of the performance of a highly-sensitive rapid diagnostic test (hsRDT) versus conventional RDT (cRDT), compared with polymerase chain reaction (PCR) as the gold standard, in reactive case detection of malaria infections in Rakhine State, Myanmar”

Name of Principal Investigator

Dr. San Kyawt Khine
Vector-borne Disease Control, Rakhine
Department of Public Health
Ministry of Health and Sports (MoHS)

Name of Organizations:

National Malaria Control Program, Department of Public Health, MoHS
Vector-borne Disease Control, Rakhine, Department of Public Health, MoHS
University Research Corporation Myanmar, Yangon, Myanmar
Department of Medical Research, MoHS
Institute for Global Health, University of Maryland Baltimore (UMB), USA
U.S. Centers for Disease Control and Prevention (CDC), USA

Name of Funding Organization:

US President’s Malaria Initiative (PMI)

Please read carefully/ read the information to the child

Why are we doing this study

We want to tell you about a malaria research study we are doing. A research study is a way to learn information about something. We would like to find out more about how well a new malaria test can find malaria parasites in the blood, compared with the usual test and also compared with the ability to detect malaria parasites found in the blood using a special laboratory method called ultra-sensitive PCR (usPCR).

Why have you been selected?

You are being asked to join the study because you either tested positive for malaria infection or are a member of a household in which at least one individual has tested positive for malaria infection or you live nearby to someone else who has tested positive for malaria infection.

What you will do in this study

If you agree to join this study and sign this assent, we will ask you a few questions and assign you a unique number. Our study doctor, midwife, or nurse will clean the tip of your finger and then prick the tip of your finger to collect 5-7 drops of blood (about a quarter of a teaspoon). Filter paper will be placed on your finger to absorb a couple of the drops of blood. Two to three drops of blood will be used to check for malaria infection by cRDT; two to three drops of blood will be used to check for

malaria infection by hsRDT; and 3-4 drops of blood will be collected on filter paper for laboratory-based parasite tests, like PCR. These blood samples will be labeled with your unique number only (not your name). We will store the blood on filter paper until we send it to a laboratory in Yangon. Most of the laboratory tests will be completed in Yangon, but we may need to send some of the filter paper blood samples to a laboratory at the University of Maryland in the US for more advanced testing or for quality control. If either the cRDT or hsRDT is positive for malaria infection, we will ensure that you get treatment from your local health care team according to the Myanmar Ministry of Health and Sports guidelines.

Risks for you

By participating in this research you have a very small risk of bruising, bleeding, infection, or fainting from the finger-stick. There is also a risk of loss of confidentiality of your information. We will do everything we can to minimize these risks. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also come to this health facility at any time to see the Medical Officer.

Benefits for you and the community

We do not know if you will be helped by being in this study. We may learn something that will help other children with malaria someday.

Confidentiality

Anything we learn about you from this study will be kept as secret as possible.

Who to Contact

If you have any questions you may contact: Dr. San Kyawt Khine, Assistant Director, Vector Borne Disease Control Program, Rakhine State, General Hospital Compound, Sittwe, Rakhine State, Myanmar; Telephone Number 09 450542076. This proposal has been reviewed and approved by Ethics Review Committee, Department of Medical Research, which is a committee whose task it is to make sure that study participants are protected from harm. If you wish to find about more about the ERC, contact The Secretary, Ethics Review Committee, Department of Medical Research, No 5, Ziwaka Road, Yangon 11191, Myanmar; Telephone Number 01 375457 Extension 118.

Agreement to Participate

I have been invited to participate in the study “**Evaluation of the performance of a highly-sensitive rapid diagnostic test (hsRDT) versus conventional RDT (cRDT), compared with polymerase chain reaction (PCR) as the gold standard, in reactive case detection of malaria infections in Rakhine State, Myanmar.**” I have been informed that the risks are minimal. I am going to involve blood taking procedure from my finger tip for 5-7 drops of blood for one time and an interview for about 30 min. I was informed that my blood sample will be kept confidentially as I consent how long to be kept. I am aware that there may be no benefit to me personally and that I will receive 4000 kyats for compensation of my time spent during this study. I have been provided with the name, phone number and address of the researcher, staff, and Ethic Review Committee if I have questions, concerns, and complaints. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I asked have been answered to my satisfaction. I consent voluntarily to enroll as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my medical care.

I agree to take part in the above study.

Name of study child

Signature or left thumb impression

Date

Name of the PI or his/her representative

Signature of the PI or his/her represent

Date

**Ethics Review Committee
Department of Medical Research
Ministry of Health and Sports
Republic of the Union of Myanmar**

Research project on “Evaluation of the performance of a highly-sensitive rapid diagnostic test (hsRDT) versus conventional RDT (cRDT), compared with polymerase chain reaction (PCR) as the gold standard, in reactive case detection of malaria infections in Rakhine State, Myanmar”

The following information should be provided to the subjects before collecting biological material from them.

Type of sample, how it will be obtained, how long it will be kept and disposed

1. Detailed procedure in sequential order

If you agree to participate and sign the consent, we will ask you a few questions and assign you a unique number. Our trained research assistants will clean the tip of your finger and then prick the tip of your finger to collect 5-7 drops of blood (about a quarter of a teaspoon). Filter paper will be placed on your finger to absorb a couple of the drops of blood. For infants 6 months to one year of age, a heel prick might be more appropriate. Two to three drops of blood will be used to check for malaria infection by cRDT; two to three drops of blood will be used to check for malaria infection by hsRDT; and 3-4 drops of blood will be collected on filter paper for laboratory-based parasite tests, like PCR. These blood samples will be labeled with your unique number only (not your name). We will store the blood on filter paper until we send it to a laboratory in Yangon. Most of the laboratory tests will be completed in Yangon, but we may need to send some of the filter paper blood samples to a laboratory at the University of Maryland in the US for more advanced testing or for quality control. If either the cRDT or hsRDT is positive for malaria infection, we will ensure that you get treatment from your local health care team according to the Myanmar Ministry of Health and Sports guidelines.

2. Degree of invasiveness

By participating in this research, you have a risk of bruising, bleeding, infection, or fainting from the finger-stick.

3. How long the samples will be kept?

We will be keeping the filter paper sample at room temperature for a short time, and in refrigerator for a long-term storage, up to ten years.

4. Arrangements for final disposal of the samples at the end of the research study.

We will destroy any remaining samples after 20 years, following the Institutional Guideline for biological waste disposal.

Type of consent to be obtained (Explain briefly)

The samples will be stored longer than the end of the research study. We aim to analyze the sample only for this study (fully restricted consent). If a permission is given to use left-over

samples in future research related to this study (partially restricted consent) or any new research (unrestricted consent), then we will seek appropriate administrative and ethical approval from relevant ethic review committees if and when we plan to use the left-over samples.

Whether identity will be retained or not? (Explain briefly)

The study code will be used and linked to identifier in a separate document. Your personal information linked to the samples will be destroyed one year after the research is completed, to protect your confidentiality and your sample will become anonymous if you consent to continue your left-over specimen for other study.

How will confidentiality be ensured?

1. How confidentiality and privacy of personal information will be protected?

We will not be sharing the identity of those participating in the study. The information that we collect from this study will be kept confidential. All the information about you that will be collected from the study will have a number on it instead of your name and it will be secured so that no one except the team members involved in the study will be able to see it. Only the study team members will know what your number is and we will secure the names and numbers under lock and key.

2. Where samples and clinical information will be kept?

Samples will be stored in refrigerator for a long-term storage. Documents including clinical information will be kept under lock and key.

3. Who will have access to samples and research results?

Only the study team members will have access to samples and research results.

4. Whether the results of research will be relayed back to the research subject?

The knowledge that we get from this study will not be shared individually, but we will share the findings as aggregate data in your community before it is made widely available to the public.

**Ethics Review Committee
Department of Medical Research
Ministry of Health and Sports
Republic of the Union of Myanmar**

Consent for use of human blood, body fluids or tissues given for research study

(This form should be used if the tissues/blood samples or any other human biological material will be stored for duration longer than the research study, or is likely to be used for a purpose other than mentioned in the research study.)

I consent the use of my specimen of blood for the research study entitled “**Evaluation of the performance of a highly-sensitive rapid diagnostic test (hsRDT) versus conventional RDT (cRDT), compared with polymerase chain reaction (PCR) as the gold standard, in reactive case detection of malaria infections in Rakhine State, Myanmar**”.

1. I give permission for the left-over specimen to be kept for future research that is related to this study, understanding that

my identity has been removed from the specimen



or

my identity is kept with the specimen



OR

2. I give permission for the left-over specimen to be kept for future research of any type on the understanding that

my identity has been removed from the specimen



or

my identity is kept with the specimen



3. I do not give permission for any remaining specimen to be kept for future research

I do not give permission to use my remaining specimen in the future



Name

SignatureDate.....

◆ The research subject should initial or thumb print the boxes of their choice.