CONSENT FORM

Project title: PRELIMINARY EVALUATION OF DYNAMICS OF SUBCLINIICAL MALARIA

Principal investigators:	Myaing M. Nyunt MD MPH PhD, Tel +1-202746-2444; +959-420110613; Christopher V. Plowe M.D. M.P.H. Tel 1-410-917-2523
Site Principal investigators:	Kay Thwe Han MBBS MMedSc Tin Maung Hlaing MBBS PhD Xiao-Nong Zhou PhD Wasif A. Khan MBBS, MPH
Ethical oversight:	Institutional Review Board (IRB), Duke University Health System Myanmar Department of Medical Research Ethics Review Committee IRB of Defense Services Medical Research Center (DSMRC) IRB icddr,b, Bangladesh IRB National Institute of Parasitic Diseases (NIPD), China
Sponsor:	U.S. National Institute of Allergy and Infectious Diseases, NIH
Site:	Myanmar, Bangladesh and China

Participant Enrollment Number: __ __ __

Introduction: My name is _____, and I am responsible for enrolling research volunteers for a research study of malaria, approved by our government and sponsored by a research agency of the U.S. government. I invite you to participate in the long-term malaria study because you are eligible for study participation. If you agree, I will give you some information. Please ask me or any other doctors or staff, any questions you have, and take as much time as you need. You must understand everything about what will be done, before you consent.

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 from the village 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.

Purpose: We are planning to conduct a preliminary short longitudinal research study to understand malaria infection without feeling sick. Standard malaria test RDT may be negative in many, but not all, people with this type of infection. But we can find them by a special lab test called PCR. PCR can find tiny pieces of malaria that RDT cannot find. The purpose of this study is to assess how stable your PCR status is. If you are PCR-positive today, we want to know if you remain positive on repeated testing for about 1.5-3 months, and if you are negative PCR today, we want to know if you are still negative in about 2-4 weeks.

Participant selection: We invite everyone who is at least 6 months old and who is well and willing and able to strictly follow study procedures for up to 1.5-3 months, and to provide written informed consent to participate in our study.

Procedure: If you agree and sign this consent, we will enroll you in the study and give you a unique identification number. We will ask you several questions about you, your demographic and travel data, about your malaria history. Then we will take 1 drop of finger prick blood to test malaria using standard rapid test for malaria called RDT.

If you are RDT-positive, we will collect 5 mL of blood from your forearm to test parasite gene. That means that we will try to understand where they came from, how they are related to other malaria parasites, and how they may spread from one place to the other, which may help us do better job of malaria control.

If you are RDT-negative, we will take 7 drops of finger prick blood onto two types of filter paper, air-dry, and store them. We will send these dried blood spots on filter paper to the lab for PCR test. You must come back to us in about 2-4 weeks. We will have a result of PCR testing.

If you are PCR-negative, we will take 4 drops of your finger prick blood on one type of filter paper, and your study participation is finished.

If you are PCR-positive, we will take 4 drops of your finger prick blood on one type of filter paper on that day of 2-4-weeks follow up visit. Then you must come back here 4 more times two weeks apart (At week 6, 8, 10 and 12, or at weeks 2, 3, 4, 5 and 6). We will make you a calendar for when to come back here, and call to remind you a day before. Please try not to miss any follow up visit in the 6-12 weeks of our study. If you miss two consecutive visits (meaning if you don't show up for a month), we will have to end your study participation.

During the study, every time you are unwell, you should come to us. We will test you with standard RDT for malaria. If you are RDT-positive, we will take 5 mL of blood from your forearm. We will refer you to a care provider and make sure that you receive proper treatment with malaria drugs. We will process your blood and send it to the central lab where we will further study malaria genes.

Duration: It will take about 30 minutes to ask the questions and to collect the blood samples at each visit.

Risks and discomfort: There is a risk of bruising, bleeding, infection, or fainting from the finger-stick or blood drawing, and a risk of losing your confidentiality. 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. Your participation makes this study happen and results will help us decide whether having tiny pieces of malaria in your blood without symptoms of illness makes you more likely to become ill from malaria later or to transmit malaria to mosquitoes, so that we can know whether it is important to treat people with these pieces of malaria in their blood.

Cost and Compensation: All blood testing will be provided without cost to you. Care will be provided by a care provider as appropriate, according to the local standard of care. You will receive a compensation for the time, in a local currency that is equivalent to US$4, or in a culturally acceptable material worth US$4, determined by the ethics committee of your country, for each visit.

Confidentiality: It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not share your identity or private information. All study information will be kept confidential, to the extent allowed by law. All study documents and samples will have a number instead of the name. Your data will be saved on a computer with limited access only by study team members. We will secure all the study documents under lock and key.

Sharing the Results: The knowledge from this study will be shared with your community, and published in a scientific journal. Your identity and confidential information will not be shared with anyone.

Alternative to participation and 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 your rights which will be respected; your care at the health care center will not be affected.

Who to Contact: If you have any questions about participating in this study, any questions/concerns later or if you feel that you have been injured by taking part, you may contact the following individual or institution:

Site	Lead Institution	PI or co-PI	Address/Phone
Myanmar	DMR	Kay Thwe Han	#5 Ziwaka Road, Lanmadaw, Yangon, Myanmar Tel. +959-516-9228 (Cell)
Myanmar	DSMRC	Tin Maung Hlaing	Directorate of medical services, Nay Pyi Taw, Myanmar Tel. +959-860-1604 (Cell)
Bangladesh	Icddr,b	Wasif Khan	68, Shaheed Tajuddin Ahmed Sarani, Mohakhali Dhaka 1200, Bangladesh Tel: +880-2-9827057; +88-01730093257 (Cell)

China	NIPD	Xiao-Nong Zhou; Huang Fang	207 Rui Jin Er Road, Shanghai 200025, China (Zhou) Tel. +86-21-64738058; +86-13916230620 (Cell) (Huang) Tel. +86-21-54653514; +86-13817268947 (Cell)
USA	Duke Global Health Institute	Chris Plowe Myaing M. Nyunt	Trent Hall, Durham, NC, USA (Plowe) Tel. +1-410-917-2523 (Cell) (Nyunt) Tel. +1-202-746-2444l +959-420110613 (Cell)

If you agree to participate in this study, please sign or put your thumbprint below.

Participant name: _____
First Middle Last

_____ Date: _____/_____/_____
Participant's signature or thumbprint *dd mm yy*

_____ Date: _____/_____/_____
Investigator's Signature *dd mm yy*

_____
Investigator's name

Complete if participant or adult guardian is illiterate:

Witness to Consent Interview: On the date given next to my signature, I witnessed the consent and assent procedure for screening tests and one-time enrollment, as part of the Research Study named above in this document. I attest that the information in this screening consent form and the written summary was explained to the participant and his/her adult guardian, and concerns were adequately addressed.

Name of Witness _____

Signature of Witness _____ Date: _____/_____/_____
dd mm yy

Use of blood specimens that are left-over after the completion of research study entitled "Preliminary evaluation of dynamics of subclinical malaria"

[The research participant must read and understand the statements 1, 2 and 3 below, and provide the initials of his or her name or thumb print in the box next to the statement/s they agreed to]

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 is not recorded on the specimen and the link between my specimen and identifiers has been removed. ☐

   OR

   I give permission for the left-over specimen to be kept for future research that is related to this study, understanding that my identity is not recorded on the specimen and the link between my specimen and identifiers is kept. ☐

2. I give permission for the left-over specimen to be kept for future research of any type, understanding that my identity is not recorded on the specimen and the link between my specimen and identifiers has been removed. ☐

   OR

   I give permission for the left-over specimen to be kept for future research of any type, understanding that my identity is not recorded on the specimen and the link between my specimen and identifiers is kept. ☐

3. I do not give permission to use my left-over blood specimen in the future ☐

Name of participant ……..

Signature of participant ……Date…….