ANNEX 4: Consent and Assent Forms

ENGLISH VERSION OF THE PARTICIPANT'S INFORMATION SHEET FOR THE **REACTIVE CASE DETECTION ARM** (≥ 18 YEARS)

Flesch Kincaid Grade Level---- 8.6

Study title: EVALUATION OF THE EFFECT OF TARGETED MASS DRUG ADMINISTRATION AND REACTIVE CASE DETECTION ON MALARIA TRANSMISSION AND ELIMINATION IN EAST HARARGHE ZONE, OROMIA, ETHIOPIA

Principal Investigators: Drs Endalamaw Gadisa (Armauer Hansen Research Institute/AHRI) and Ayele Zewde (Addis Continental Institute of Public Health)

Funder: U.S. President's Malaria Initiative

INTRODUCTION

Hello! My name is _____. I am a member of a malaria research team. This study will be done by Addis Continental Institute of Public Health in collaboration with Armauer Hansen Research Institute, US Centers for Disease Control and Prevention, Tulane University, and The Federal Ministry Health of Ethiopia. We are asking you/your child to join in this study because you live near someone who has malaria, which puts you at risk of getting malaria. Your participation is fully voluntary. Take your time and talk to any person before making your decision. Feel free to ask me any question(s). If your child is between 12 and 18 years of age, we will also ask for their agreement to participate in the study even if you have agreed on her/his participation.

WHAT IS THE PURPOSE OF THE STUDY?

The aim of this study is to learn the best way to get rid of malaria from the community. We want to learn if it is better to test people for malaria before treating them or just treat them without testing. People in your kebele who live near the person who is sick with malaria will be tested first and then treated if positive for malaria. This was decided by chance.

WHY AM I BEING ASKED TO BE A PART OF THIS STUDY?

You live near someone who was sick with malaria. There is a higher chance you/ your child might also have malaria even if you / your child do/does not feel sick.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We are asking all the people that live within 100 meters of the sick person to participate in the study. That will be about 50 people in 10 households.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you agree to participate, we will enroll you/your child into the study. We will ask you some questions about malaria. We will request 5 drops of blood from the tip of your/your child's finger after a needle prick. We will use this blood to test for malaria using a conventional rapid diagnostic test, a highly sensitive rapid diagnostic test, if one becomes available, and to collect blood spots on a filter paper. This will be less than one teaspoon of blood.

We will tell you the conventional rapid diagnostic test result. If the test is positive, we will provide standard malaria treatment as per the national guideline:

- For *Plasmodium falciparum*, artemether-lumefantrine and single dose primaquine is the standard treatment. You/your child will need to visit the health post on Day 3 to make sure that you/your child took the medicine and that you/your child are feeling well.

- For *P. vivax*, chloroquine plus 14 days of primaquine is the standard treatment. For a mixed infection, artemether-lumefantrine plus 14 days of primaquine is the standard treatment. You/ your child will also be requested to visit the health post on Day 3, 7, 13 to make sure that you are feeling well. This is standard practice in Ethiopia.

The blood spots will be sent to a laboratory in Addis Ababa and the United States. There, we will do more tests to learn about malaria. You will not receive these results.

HOW LONG WILL I BE IN THE STUDY?

The duration of your/your child's participation in the study will depend on the conventional rapid diagnostic test result and the type of malaria you/your child have. If you/your child do not have malaria, it will only take about 1 hour. If you/your child has *P. falciparum* malaria, the study will last up to 3 days. If you/your child has *P. vivax* or mixed (*P. falciparum* and *P. vivax*) malaria, the study will last up to 13 days. The study will happen for 24 months in the community. If someone is sick later with malaria near you, we will ask you to participate again.

CAN I STOP BEING IN THE STUDY?

Yes, you can decide to stop at any time for any reason. Your decision to stop will not affect the services that you get from the health facility now and in the future.

WHAT RISK CAN I EXPECT FROM BEING IN THE STUDY?

We will use drugs approved to treat malaria in Ethiopia and they are generally safe and well tolerated. However, the drugs in some instances can cause an upset stomach, vomiting, diarrhea, headache, dizziness, mild skin rash, and itching. These are mostly mild. Rarely, more severe side effects like swelling and anemia can occur. If you/ your child have/has any of these severe side effects, stop taking the drugs and return to the health facility immediately. The study will cover the transport and treatment cost if you/ your child needs to go to the hospital.

Finger pricking might cause minor pain, bleeding, and bruising. Very rarely, fainting or infection might occur. To minimize risk, only trained health staff will take samples following proper procedures.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

This study will be of direct benefit to some study participants receiving treatment for malaria that you did not know you had. This study could help the government better understand how to control and eliminate malaria from your community.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There are no financial costs. You/ your child will be asked to follow up at a nearby health post according to the national malaria treatment guidelines.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You/your child will not be paid for taking part in this study.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is entirely your choice. You can decide not to participate in the study now or decide to join the study now and leave at any time during the follow-up period. No matter what decision you make, at any time, there will be no penalty to you/ your child in any way.

HOW WILL MY *SPECIMENS AND* INFORMATION BE USED?

The researchers will use your/your child's blood samples and information collected to help eliminate malaria in the country. When the study finishes, your name and all other variables that identify you/your child will be removed from the sample and the data may be shared with other researchers. The samples and the information without your identification will be kept secured for five years and may be used for other tests and research in the future. We will ask your willingness to keep the sample and information and will keep the sample only if you agree. If you do not agree we will discard the sample and the information at the end of the study.

WILL INFORMATION FROM THE RECORDS BE KEPT PRIVATE?

The information about you/your child will be kept confidential to the extent allowed by law. Your/ your child's name and any information that can identify you/ your child will not be used on labels or in any report. Any information obtained will be kept locked and password protected. The persons responsible for making sure that the research is done properly may look at the study records. Organizations that will examine the data are Addis Continental Institute of Public Health, Armauer Hansen Research Institute, Ministry of Health, US Centers for Disease Control and Prevention, Tulane University, and data safety monitoring board members.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions, please speak with one of the study staff members or the health extension worker in your kebele.

If you have any questions about this study later or feel that you have been harmed by taking part in this study, please contact the principal investigators (Dr Endalamaw Gadisa at 0911868827 or Dr Ayele Zewde at 0911764018). If you wish to ask questions about the study or your rights as a research participant, please call the Armauer Hansen Research Institiute (AHRI)/All African Tuberculosis and Leprosy Rehabilitation and Training Center (ALERT) ethics review office at 0118962183.

Would you like (for your child) to take part in this study?

CONSENT for adults (≥18 years) to participate in the Reactive Case Detection arm

If you agree to participate in this study, we will request you sign below as this is a proof of your agreement.

Participant Consent Signature Form for participation in the Reactive Case Detection Arm

Statement of Consent for participation (signature or thumbprint required)
The above has been read to me, and I agree to take part in the study.

Signature: _____ Date: _____

Thumb print:

Participant's name: _____

For persons who cannot sign
The above consent was read, and the person agreed to take part.

Signature: _____ Date: _____

Witness's name: _____

Statement of consent for storage of samples (signature or thumbprint required):
The above has been read to me, and I agree to let my blood sample be saved for future testing related to malaria.

Signature: _____ Date: _____
Thumb print:

Participant's name: _____

For persons who cannot sign
The above consent was read, and the person agreed to allow her/his blood sample to be saved for future testing related to malaria.

Signature: _____ Date: _____

Witness's name: _____

Study team interviewer
Name: _____ Date: _____
Signature: _____

Parental Consent Form for Children under the age of 18 years for participation in the Reactive Case Detection Arm

Statement of Consent for participation for child:

The above has been read to me.
□ YES, I agree for my child to take part in the study.
□ NO, I do not agree for my child to take part in the study.

Statement of consent for storage of samples:
□ YES, I agree to let my child's blood samples and information be saved for future testing and use.
□ NO, I do NOT agree to let my child's blood samples and information be saved for future testing and use.

Signature: _____ Date: _____

Thumb print:

Participant's name: _____ Parent/Guardian's name: _____

For persons who cannot sign
□ The above consent was read, and the person agreed for their child, to take part in the study.
□ The above consent was read, and the person did NOT agree for their child, to take part in the study.

□ YES, the person agreed for her/his child's blood sample and information to be saved for future testing related to malaria and use.
□ NO, the person did not agree for her/his child's blood sample and information to be saved for future testing related to malaria and use.

Participant's name: _____ Parent/ Guardian's name: _____

Witness's name: _____ Signature: _____

Date: _____

I have explained the purpose of this study to the volunteer. To the best of my knowledge, he/she understands the purpose, procedures, risks and benefits of this study.

Study team interviewer
Name: _____ Signature: _____ Date: _____

ASSENT FORM FOR MATURE MINORS (12–17 YEARS) TO PARTICIPATE IN THE REACTIVE CASE DETECTION ARM

Flesch Kincaid Grade Level----4.2

Study title: EVALUATION OF THE EFFECT OF TARGETED MASS DRUG ADMINISTRATION AND REACTIVE CASE DETECTION ON MALARIA TRANSMISSION AND ELIMINATION IN EAST HARARGHE ZONE, OROMIA, ETHIOPIA

Principal Investigators: Drs Endalamaw Gadisa (Armauer Hansen Research Institute) and Ayele Zewde (Addis Continental Institute of Public Health)

Funder: U.S. President's Malaria Initiative

INTRODUCTION

Hello! My name is _____. I am a part of a study team. We are trying to get rid of malaria in your community. This study will be done by Addis Continental Institute of Public Health with other partners. You are being asked to be in this study because a person living in your household or around you has malaria. You can decide to be in the study or not be in the study. Please take your time to decide. You can discuss with your family or ask any questions. We have asked your parent(s)/guardian(s)' permission because you are under 18 years of age and they said it was ok for you to be in the study.

WHAT IS THE PURPOSE OF THE STUDY?

We are trying to learn the best way to get rid of malaria from the community. We want to learn if it is better to test people for malaria or just treat them without testing them.

WHY AM I BEING ASKED TO BE A PART OF THIS STUDY?

You live near someone who was sick with malaria. You might also have malaria even if you do not feel sick.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

All the people that live near the sick person will be asked to participate in the study. This will be about 50 people.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

We will ask you some questions. About 5 drops of blood will be taken from the tip of your finger using a needle. The blood will be used to learn about malaria. If you have malaria, you will be treated with medicine.

HOW LONG WILL I BE IN THE STUDY?

If you have malaria, you can be in the study for up to 14 days. If you do not have malaria, it will only take about 1 hour.

CAN I STOP BEING IN THE STUDY?

Yes, you can stop at any time for any reason.

WHAT RISK CAN I EXPECT FROM BEING IN THE STUDY?

You will get the medicine used to treat malaria and there may be mild side effects.

The finger prick might hurt and can bleed. We will clean the finger before taking blood. We will use new needles each time. This will be performed by experienced people.

ARE THERE BENEFITS BY TAKING PART IN THE STUDY?

If you have malaria, treating it will make you healthier.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There are no financial costs to you or your family.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

No, you will not be paid for taking part in this study.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

It is your choice. You can stop at any time and nothing bad will happen to you.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions, please ask your parent(s)/guardian(s). They will know whom to ask.

Would you like to take part in this study?

STATEMENT OF ASSENT

If you sign your name below, it means that you agree to take part in this research study.

Date	Name	Signature or thumb print
_____	_____	_____

Date	Name of Parent/Guardian	Signature or thumb print
_____	_____	_____

Date	Name of Person Obtaining Assent	Signature
_____	_____	_____

PARTICIPANT'S INFORMATION SHEET IN THE TARGETED MASS DRUG ADMINISTRATION ARM (≥18 YEARS)

Flesch Kincaid Grade Level---- 8.2

Study title: EVALUATION OF THE EFFECT OF TARGETED MASS DRUG ADMINISTRATION AND REACTIVE CASE DETECTION ON MALARIA TRANSMISSION AND ELIMINATION IN EAST HARARGHE ZONE, OROMIA, ETHIOPIA

Principal Investigators: Drs Endalamaw Gadisa (Armauer Hansen Research Institute) and Ayele Zewde (Addis Continental Institute of Public Health)

Funder: U.S. President's Malaria Initiative

INTRODUCTION

Hello! My name is _____. I am a member of a malaria research team. This study will be done by Addis Continental Institute of Public Health in collaboration with Armauer Hansen Research Institute, US Centers for Disease Control and Prevention, Tulane University, and The Federal Ministry Health of Ethiopia. We are asking you/your child to join in this study because you live near someone who has malaria, which puts you at risk of getting malaria. Your participation is fully voluntary. Take your time and talk to any person before making your decision. Feel free to ask me any question(s). If your child is between 12 and 18 years of age, we will also ask for their agreement to participate in the study even if you have agreed on her/his participation.

WHAT IS THE AIM OF THE STUDY?

The aim of this study is to learn the best way to get rid of malaria from the community. We want to learn if it is better to test people for malaria before treating them or just treat them without testing. People in your kebele who live near the person who is sick with malaria will be treated for malaria without testing. This was decided by chance.

WHY AM I BEING ASKED TO BE A PART OF THIS STUDY?

You live near someone who was sick with malaria. There is a higher chance you/ your child might also have malaria even if you / your child do not feel sick.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We are asking all the people that live within 100 meters of the sick person to participate in the study. That will be about 50 people in 10 households.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you agree to participate in this study, we will enroll you/ your child into the study. You will be asked some questions about malaria. We will take 1 drop of blood from a finger stick. This blood will be checked for an enzyme to make sure that one of the malaria drugs given for 14 days is safe for you/ your child. If the enzyme level is low, then you/ your child will not get that malaria drug. Pregnant women will also not get this drug. A pregnancy test will be performed on all menstruating women with a last menstrual period over four weeks. If you have normal enzyme levels, you will get two malaria medicines, one for 3 days and the other for 14 days, without testing for malaria. These drugs are nationally recommended treatments for malaria in Ethiopia and can cure all stages of malaria. You/ your child will be observed to swallow the tablets by a treatment supporter, who will be a family member, every day. You/ your child will also be requested to visit the health post on Day 3, 7, 13 to make sure that you are feeling well. This is standard practice in Ethiopia.

HOW LONG WILL I BE IN THE STUDY?

This visit will take about 1 hour. The routine, follow up visits up to day 13 may take about 30 minutes for each visit. The study will happen for 24 months in the community. If someone is sick later with malaria near you, we will ask you to participate again.

CAN I STOP BEING IN THE STUDY?

Yes, you can decide to stop at any time for any reason. Your decision to stop will not affect the services that you get from the health facility now and in the future.

WHAT RISK CAN I EXPECT FROM BEING IN THE STUDY?

We will use drugs approved to treat malaria in Ethiopia and they are generally safe and well tolerated. However, the drugs in some instances can cause an upset stomach, vomiting, diarrhea, headache, dizziness, mild skin rash, and itching. These are mostly mild. Rarely, more severe side effects like swelling and anemia can occur. If you/ your child have/has any of these severe side effects, stop taking the drugs and return to the health facility immediately. The study will cover the transport and treatment cost if you/ your child needs to go to the hospital.

Finger pricking might cause minor pain, bleeding, and bruising. Very rarely, fainting or infection might occur. To avoid this, only trained health staff will take samples following proper procedures.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

For some people, we could be treating malaria that you did not know you had. The study will help the government better understand how to control and eliminate malaria from the country.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There are no financial costs. You/ your child will be asked to follow up at a nearby health post according to the national malaria treatment guidelines.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You /your child will not be paid for taking part in this study.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is entirely your choice. You can decide not to participate in the study now or decide to join the study now and leave at any time during the follow-up period. No matter what decision you make, at any time, there will be no penalty to you /your child in any way.

WILL INFORMATION FROM THE RECORDS BE KEPT PRIVATE?

The information about you/ your child will be kept confidential to the extent allowed by law. Your/ your child's name and any information that can identify you/ your child will not be used on labels or in any report. Any information obtained will be kept locked and password protected. The persons responsible for making sure that the research is done properly may look at the study records. Organizations that will examine the data are Addis Continental Institute of Public Health, Armauer Hansen Research Institute, US Centers for Disease Control and Prevention, Tulane University, Ministry of Health, and data safety monitoring board members.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions, please speak with one of the study staff members or the health extension worker in your kebele.

If you have any questions about this study later or feel that you have been harmed by taking part in this study, please contact the principal investigators (Dr Endalamaw Gadisa at 0911868827 or Dr Ayele Zewde at 0911764018). If you wish to ask questions about the study or your rights as a research participant, please call the AHRI/ALERT ethics review office at 0118962183.

Would you like (for your child) to take part in this study?

CONSENT for adults (≥18 years) to participate in the targeted Mass Drug Administration arm
If you agree to participate in this study, we will request you sign below as this is a proof of your agreement.

Participant Consent Signature Form for participation in the targeted Mass Drug Administration arm

Statement of Consent for participation (signature or thumbprint required)
The above has been read to me, and I agree to take part in the study.

Signature: _____ Date: _____

Thumb print:

Participant's name: _____

For persons who cannot sign
The above consent was read and the person agreed to take part.

Signature: _____ Date: _____

Witness's name: _____

Study team interviewer
Name: _____ Date: _____
Signature: _____

Parental Consent Form for Children under the age of 18 years for participation in the targeted Mass Drug Administration arm

Statement of Consent for participation for child:
The above has been read to me.
□ YES, I agree for my child to take part in the study.
□ NO, I do not agree for my child to take part in the study.

Signature: _____ Date: _____

Thumb print:

Participant's name: _____ Parent/Guardian's name: _____

For persons who cannot sign

□ The above consent was read and the person agreed for their child, to take part in the study.

□ The above consent was read and the person did NOT agree for their child, to take part in the study.

Participant's name: _____ Parent/ Guardian's name: _____

Witness's name: _____ Signature: _____

Date: _____

I have explained the purpose of this study to the participant. To the best of my knowledge, he/she understands the purpose, procedures, risks and benefits of this study.

Study team interviewer

Name: _____ Signature: _____ Date: _____

ASSENT FORM FOR MATURE MINORS (12–17 YEARS) TO PARTICIPATE IN THE TARGETED MASS DRUG ADMINISTRATION ARM

Flesch Kincaid Grade Level----4.1

Study title: EVALUATION OF THE EFFECT OF TARGETED MASS DRUG ADMINISTRATION AND REACTIVE CASE DETECTION ON MALARIA TRANSMISSION AND ELIMINATION IN EAST HARARGHE ZONE, OROMIA, ETHIOPIA

Principal Investigators: Drs Endalamaw Gadisa (Armauer Hansen Research Institute) and Ayele Zewde (Addis Continental Institute of Public Health)

Funder: U.S. President's Malaria Initiative

INTRODUCTION

Hello! My name is _____. I am a part of a study team. We are trying to get rid of malaria in your community. This study will be done by Addis Continental Institute of Public Health with other partners. You are being asked to be in this study because a person living in your household or around you has malaria. You can decide to be in the study or not be in the study. Please take your time to decide. You can discuss with your family and ask any questions. We have asked your parent(s)/guardian(s)' permission because you are under 18 years of age and they said it was ok for you to be in the study.

WHAT IS THE PURPOSE OF THE STUDY?

We are trying to learn the best way to get rid of malaria from the community. We want to learn if it is better to test people for malaria or just treat them without testing them.

WHY AM I BEING ASKED TO BE A PART OF THIS STUDY?

You live near someone who was sick with malaria. You might also have malaria even if you do not feel sick.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

All the people that live near the sick person will be asked to participate in the study. This will be about 50 people.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

We will ask you some questions. One drop of blood will be taken from the tip of your finger using a needle. The blood will be used to test if you can take one of the malaria drugs safely. If it is safe, you will get two medicines to treat malaria. You will also have to visit the health post to make sure you are ok.

HOW LONG WILL I BE IN THE STUDY?

This visit will take about 1 hour. The visits to the health post will happen up to day 13.

CAN I STOP BEING IN THE STUDY?

Yes, you can decide to stop at any time for any reason.

WHAT RISK CAN I EXPECT FROM BEING IN THE STUDY?

You will get the normal medicines used in Ethiopia to treat malaria. Your blood will be checked to make sure that one of the medicines is safe for you. If it is not, then you will not get it.

The finger prick might hurt and can rarely bleed or get infected. We will clean the finger before taking blood. We will use new needles each time. This will be performed by experienced people.

ARE THERE BENEFITS BY TAKING PART IN THE STUDY?

Treating malaria that you did not know you had will make you healthier.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There are no financial costs to you or your family.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

No, you will not be paid for taking part in this study.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

It is your choice. You can stop at any time and nothing bad will happen to you.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions, please ask your parent(s)/guardian(s). They will know whom to ask.

Would you like to take part in this study?

STATEMENT OF ASSENT

If you sign your name below, it means that you agree to take part in this study.

Date	Name	Signature or thumbprint
_____	_____	_____

Date	Name of Parent/Guardian	Signature or thumbprint
_____	_____	_____

Date	Name of Person Obtaining Assent	Signature
_____	_____	_____

ENGLISH VERSION OF THE PARTICIPANT'S INFORMATION SHEET IN THE SURVEY (≥18 YEARS)

Flesch Kincaid Grade Level----8.3

Study title: EVALUATION OF THE EFFECT OF TARGETED MASS DRUG ADMINISTRATION AND REACTIVE CASE DETECTION ON MALARIA TRANSMISSION AND ELIMINATION IN EAST HARARGHE ZONE, OROMIA, ETHIOPIA

Principal Investigators: Drs Endalamaw Gadisa (Armauer Hansen Research Institute) and Ayele Zewde (Addis Continental Institute of Public Health)

Funder: U.S. President's Malaria Initiative

INTRODUCTION

Hello! My name is _____. I am a member of study team conducting a malaria survey. We are doing a study to identify the best method to try to get rid of malaria from Ethiopia. This study will be done by Addis Continental Institute of Public Health in collaboration with Armauer Hansen Research Institute, US Centers for Disease Control and Prevention, Tulane University, and The Federal Ministry Health of Ethiopia. Your kebele was selected to be a part of the study. Thus, I would like to invite you/ your child to participate in this survey. Participation is voluntary. This study is very important to help our government get rid of malaria in the country. Please take your time to make your decision about joining the survey. Feel free to ask me any questions.

WHAT IS THE AIM OF THE STUDY?

The aim of this survey is to see how many people have malaria in your community. This will help us find out if testing and treating or just treating for malaria worked better to get rid of malaria from the community.

WHY AM I BEING ASKED TO BE A PART OF THIS STUDY?

You are living in a malarious area that is targeted for elimination. Your kebele was selected to be part of the study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 2,772 people living in 660 households in your zone will take part in this survey.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree to participate in this study, we will ask some questions about malaria. We will take about 3 drops of blood from the tip of your finger after a needle prick. One drop of blood may be used to check for malaria now. If you have malaria, we will tell you the result and treat you accordingly as per the national treatment guidelines. Additional blood spots on a filter paper will be taken to test for malaria, which cannot be detected by the rapid diagnostic test. These blood spots will be sent to a reference laboratory in Addis Ababa and the United States. There, we will do many tests to learn about malaria. You will not receive the result of these tests.

HOW LONG WILL I BE IN THE STUDY?

It will take approximately 1.5 hours.

CAN I STOP BEING IN THE STUDY?

Yes, you can decide to stop at any time for any reason. Your decision to stop will not affect you in any way.

WHAT RISK CAN I EXPECT FROM BEING IN THE STUDY?

Finger pricking might cause minor pain, bleeding, and bruising. Very rarely, fainting or infection might occur. To avoid this, only trained health staff will take samples following proper procedures.
If you have malaria, you will be given the normal drugs recommended to treat malaria in Ethiopia. The drugs can cause an upset stomach, vomiting, diarrhea, headache, dizziness, mild skin rash, and itching in few individuals taking the drugs. But these are mostly mild and soon go away.

ARE THERE BENEFITS TO TAKING PART IN THE SURVEY?

There will be no direct benefit to you/ your child. The possible benefits of taking part in this study include being treated if you have malaria. This study will help the government to better understand how to control and eliminate malaria from the country.

WHAT ARE THE COSTS OF TAKING PART IN THIS SURVEY?

There are no financial costs to you.

WILL I BE PAID FOR TAKING PART IN THIS SURVEY?

No, you will not be paid for taking part in this survey.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS SURVEY?

Taking part in this survey is your choice. If you decide to take part in the survey, you may stop at any time. No matter what decision you make, there will be no penalty to you.

HOW WILL MY *SPECIMENS AND* INFORMATION BE USED?

The researchers will use your/your child's blood samples and information collected to help eliminate malaria in the country. When the study finishes, your name and all other variables that identify you/your child will be removed from the sample and the data and may be shared with other researchers. The samples and the information without your/ your child's identification will be kept secured for five years and may be used for other tests and research in the future. We will ask your willingness to keep the sample and information and will keep the sample only if you agree. If you don't agree we will discard the sample and the information at the end of the study.

WILL INFORMATION FROM THE RECORDS BE KEPT PRIVATE?

The information about your identity will be kept confidential to the extent allowed by law. Your/ your child's name and any information that can identify you/ your child will not be used on labels or in any report. Any information obtained will be kept locked and password protected. The persons responsible for making sure that this research is done properly may look at the survey records. Organizations that will examine the data are Addis Continental Institute of Public Health, Armauer Hansen Research Institute, US Centers for Disease Control and Prevention, Tulane University, Ministry of Health, and data safety monitoring board members.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions, please speak with one of the study staff members or the health extension worker in your kebele.

If you have any questions about this survey later or feel that you have been harmed by taking part in this survey, please contact the principal investigators (Dr Endalamaw Gadisa at 0911868827 or Dr Ayele Zewde at 0911764018). If you wish to ask questions about the survey or your rights as a research participant, please call the AHRI/ALERT ethics review office at 0118962183.

Would you like (for your child) to take part in this survey?

CONSENT for adults (≥18 years) to participate in the Survey

If you agree to participate in this study, we will request you sign below as this is a proof of your agreement.

Participant Consent Signature Form for participation in the Survey

Statement of Consent for participation (signature or thumbprint required)
The above has been read to me, and I agree to take part in the survey.

Signature: _____ Date: _____

Thumb print:

Participant's name: _____

For persons who cannot sign:
The above consent was read, and the person agreed to take part.

Signature: _____ Date: _____

Witness's name: _____

Statement of consent for storage of samples (signature or thumbprint required):
The above has been read to me, and I agree to let my blood sample be saved for future testing related to malaria.

Signature: _____ Date: _____
Thumb print:

Participant's name: _____

For persons who cannot sign
The above consent was read, and the person agreed to allow her/his blood sample to be saved for future testing related to malaria.

Signature: _____ Date: _____

Witness's name: _____

Study team interviewer
Name: _____ Date: _____
Signature: _____

Parental Consent Form for Children under the age of 18 years for participation in the Survey

Statement of Consent for participation for child:
The above has been read to me.

□ YES, I agree for my child to take part in the survey.
□ NO, I do not agree for my child to take part in the survey.

Statement of consent for storage of samples:
□ YES, I agree to let my child's blood samples and information be saved for future testing and use.
□ NO, I do NOT agree to let my child's blood samples and information be saved for future testing and use.

Signature: _____ Date: _____

Thumb print:

Participant's name: _____ Parent/Guardian's name: _____

For persons who cannot sign
□ The above consent was read, and the person agreed for their child, to take part in the study.
□ The above consent was read, and the person did NOT agree for their child, to take part in the study.

□ YES, the person agreed for her/his child's blood sample and information to be saved for future testing related to malaria and use.
□ NO, the person did not agree for her/his child's blood sample and information to be saved for future testing related to malaria and use.

Participant's name: _____ Parent/ Guardian's name: _____

Witness's name: _____ Signature: _____

Date: _____

I have explained the purpose of this study to the participant. To the best of my knowledge, he/she understands the purpose, procedures, risks and benefits of this survey.

Study team interviewer
Name: _____ Signature: _____ Date: _____

ASSENT FORM FOR MATURE MINORS (12–17 YEARS) TO PARTICIPATE IN THE SURVEY

Flesch Kincaid Grade Level----5.0

Study title: EVALUATION OF THE EFFECT OF TARGETED MASS DRUG ADMINISTRATION AND REACTIVE CASE DETECTION ON MALARIA TRANSMISSION AND ELIMINATION IN EAST HARARGHE ZONE, OROMIA, ETHIOPIA

Principal Investigators: Drs Endalamaw Gadisa (Armauer Hansen Research Institute) and Ayele Zewde (Addis Continental Institute of Public Health)

Funder: U.S. President's Malaria Initiative

INTRODUCTION

Hello! My name is _____. I am a member of study team conducting a malaria survey. We are doing a study to find the best way to get rid of malaria. Addis Continental Institute of Public Health and other partners are doing the study. I would like to invite you to participate in this survey. Your participation is voluntary. This study is very important to help our government get rid of malaria in the country. Please take your time to make your decision about joining the survey. Feel free to ask me any clarification/questions. The purpose of the study is to find new ways to get rid of malaria. We have asked your parent(s)/guardian(s)' permission because you are under 18 years of age and they said it was ok for you to be in the survey.

WHY AM I BEING ASKED TO BE A PART OF THIS SURVEY?

You are living in an area where we want to get rid of malaria.

HOW MANY PEOPLE WILL TAKE PART IN THIS SURVEY?

About 2,772 people living in 660 homes in your zone will take part in this survey.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH SURVEY?

If you agree and your parent(s)/guardian give permission, we will ask you some questions. You will give about 3 drops of blood from a finger stick. One drop of blood may be used to check for malaria now. The other drops will be saved on paper to learn more about malaria later at a laboratory.

HOW LONG WILL I BE IN THE SURVEY?

This will take about 1.5 hours.

CAN I STOP BEING IN THE SURVEY?

Yes, you can decide to stop at any time for any reason.

WHAT RISK CAN I EXPECT FROM BEING IN THE SURVEY?

The finger prick might hurt and can bleed or get infected. We will clean the finger before taking blood. We will use new needles each time and experienced people.

If you have malaria, you will be given the usual drugs to treat malaria, which are safe with minor side effects.

ARE THERE BENEFITS TO TAKING PART IN THE SURVEY?

If you have malaria you will be treated. The information that you give will help us to get rid of malaria from the country.

WHAT ARE THE COSTS OF TAKING PART IN THIS SURVEY?

There are no financial costs to you.

WILL I BE PAID FOR TAKING PART IN THIS SURVEY?

No, you will not be paid for taking part in this survey.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS SURVEY?

Taking part in this survey is entirely your choice. If you decide to take part in the survey, and you want to leave later, you can stop at any time. No matter what decision you make, nothing bad will happen to you.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions, please ask your parent(s)/guardian(s). They will know whom to ask.

Would you like to take part in this survey?

STATEMENT OF ASSENT

If you sign your name below, it means that you agree to be part of this survey.

Date	Name	Signature or thumb print
_____	_____	_____
Date	Name of Parent/Guardian	Signature or thumb print
_____	_____	_____