INFORMED CONSENT:

Study Title: A randomized experiment of malaria diagnostic **te**sting and conditional **s**ubsidies to **t**arget **A**CTs in the **r**e**t**ail sector: the TESTsmART trial AIM 2 - **Quality Assurance Exit Testing (QAET)**

Investigators: [redacted]

CONCISE SUMMARY

Moi University, in collaboration with Duke University, is conducting a research study about purchasing medicines for fevers such as malaria and how malaria diagnostic tests could be used by people buying medicine in a pharmacy or drug store. You have been selected for this survey because you have visited the drug shop to purchase medicine for an illness today and have consented to participate in the exit interview. The purpose of this part of the study is to determine whether you have malaria parasites in your blood. The test done by our study team will be compared to the results from the outlet if you were already tested or will give new information about your illness by confirming whether or not you have parasites in your blood.

WHAT IS INVOLVED IN THIS STUDY

As part of this study, you will be provided with an opportunity to retest for malaria for free and the retest shall be provided by our research team who have been trained in performing malaria Rapid Diagnosis Testing (mRDT). The results of the test will tell you whether you have malaria parasites in your blood or not.

If you were already tested, by comparing your test results to those provided by the outlet, we can confirm that outlets are providing accurate diagnosis. If you were not yet tested, the results will show us how many people fail to get the right malaria medicine if they don't get a test.

In case the test result shows that you HAVE MALARIA and you did not get artemether lumefantrine (AL), the antimalarial recommended by the Government of Kenya, then the study will provide an AL to you free of charge.

In case the test result shows that you DON'T HAVE malaria, you will be advised to adhere to the advice you have received at the outlet.

We anticipate that this whole procedure may take up to 15 to 20 minutes. In order to avoid waiting for the result, airtime worth 200/= Kenya shillings will be provided to allow you to call the study team to learn about your results. If your result will indicate that you have malaria but you did not get AL at the outlet, then the study team will provide AL to you free of charge at the nearest study participating outlets.

IS THERE A RISK OF PARTICIPATION IN THIS STUDY?

There is a small risk of discomfort at the site of the finger prick. There is a very small risk of infection at the site. Our research assistants have been trained in blood safety and a new needle and test is used for every person so the test is very safe. There is a small risk

of breach of confidentiality. Your malaria result may become known to others unintentionally. However, we will do everything possible to protect this information and I will not discuss your malaria result with anyone else.

ARE THERE BENEFITS OF PARTICIPATION IN THIS STUDY?
You may benefit from knowing whether or not you have malaria if you choose to have a malaria diagnostic test. If the test shows you have malaria, you may benefit from a free antimalarial medicine in case you did not get one. If you do not have malaria, the test may help you make a different choice about the right medicine for your illness.

WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THIS STUDY?
Taking part in this research study is voluntary. You may choose not to take part in this study and this will not affect your relationship with the study team or the care provided at this outlet.

WHAT ABOUT MY RIGHTS OR MY CHILD'S TO DECLINE OR WITHDRAW FROM THE STUDY
You are free to decline or stop at any time if you change your mind about participating. If you wish to decline or stop no penalty will be associated with your decision and you will continue to receive appropriate advice from the study team.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS
If you have any questions, you may contact the study at any time. Contact: [redacted]

STATEMENT OF CONSENT
The purpose of this study, the procedure to be followed, and the risk and benefits have been explained to me. I have been allowed to ask questions and the questions have been answered to my satisfaction. I have been told whom to contact if I have questions. I have read I freely volunteer to take part in this study.

Printed name of the participant: _____

Signature of the participant: _____ Date: _____ Time: __ : __

I have fully explained the research study described in this form. I have answered the participants questions and will answer any future questions to the best of my ability.

Printed name and signature of the researcher obtaining consent

Name: _____ Signature/Initials: _____Date: _____