APPENDIX I.

Research Participation Assent form
CHILDREN 8 to 18 years- EXALT PHARMACOKINETIC STUDY

Protocol Title:	EXALT trial: Extended duration artemether-lumefantrine treatment for malaria in children
Funding Source:	National Institute of Child Health and Human Development (NICHD)
UCSF-CHR Number:	17-22578
SOMREC Number:	2017-117
UNCST Number:	HS 2323
Yale HIC Number:	2000021248
Clinicaltrials.gov number:	NCT03453840
Sites of Research:	Tororo District Hospital, Tororo, Uganda; Masafu General Hospital, Busia, Uganda
Principal Investigators:	Francesca Aweeka, Pharm.D. Sunil Parikh, M.D., M.P.H. Norah Mwebaza, MBChB, DPPM, PhD.
Version Date:	2.0, 18 July 2018

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something. Dr. Mwebaza and some other doctors are doing a study to learn more about children with malaria. After we tell you about it, we will ask if you'd like to be in this study or not.

Why are we doing this study?

We want to find out how well your malaria treatment is working. So, we are getting information from lots of boys and girls like you.

In the whole study, there will be children, who are 6 months to 10 years old, and have malaria, and some who have malaria and other infections.

What will happen to you if you are in this study?

Only if you agree, three things will happen:

1. If the doctors do not know if you have malaria or if you have other infections a small amount of your blood will be drawn. That means it will be taken by a needle prick in your arm. This test is to see if you do have malaria and other infections.

2. If you have malaria, before you start the study, the doctors will do a physical exam and additional blood tests, if needed, to check how sick you are and what type of malaria parasite you are infected with. The doctors will then give you a drug called Coartem. You may have already taken this drug to treat malaria in the past.

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3. You will be in the study for 42 days and visit the study clinic several times. On some of these days, but not all of the days, you will have blood drawn either by a needle in your arm or a finger stick. On one of the days, you will have a catheter or tube placed in your arm for 8 hours. We will collect small amounts of blood at certain times during those 8 hours. By using this tube, we will not have to use a needle many times over the course of the day.

4. The total amount of blood we take from you over the course of the study will not be over 5 to 6 teaspoons.

Will this study hurt?

The stick from the needle to draw your blood will hurt, but the hurt will go away after a while. It will not hurt for the doctors to do a physical exam.

Will you get better if you are in this study?

This study may make you feel better or you may stay healthier for a longer time but we don't know if that will happen. The doctors might also find out something that will help other children like you later.

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in this study?

No, you don't. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. Or if you do want to be in the study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you/ You will be treated for your malaria whether you are in the study or not. You can choose to not have all the study procedures done. You just need to tell the study staff if you do not want to do something or have something done to you

If you don't want to be in this study, just tell us.

If you want to be in this study, just tell us.
The doctor will give you a copy of this form to keep.

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SIGNATURES OF CHILD ASSENTING TO STUDY PARTICIPATION

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The purpose and procedures of the study have been explained to me in language I can understand, and I have agreed to be in the study.

_____ _____
Signature of Child Assenting to the study Date

_____ _____
_____
Name of the child Assenting (*print*)

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION

I have explained the study to _____(*print name of child here*) in language he/she can understand, and the child has agreed to be in the study.

_____ _____
Signature of Person Conducting Assent Discussion Date

_____
Name of Person Conducting Assent Discussion (*print*)

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Appendix J.

Future Use of Biological Specimens Informed Consent

Protocol Title:	EXALT trial: Extended duration artemether-lumefantrine treatment for malaria in children
Funding Source:	National Institute of Child Health and Human Development (NICHD)
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Principal Investigators:	Francesca Aweeka, Pharm.D. Sunil Parikh, M.D., M.P.H. Norah Mwebaza, MBChB, DPPM, PhD.
Version/Date:	1.0, 9 November 2017

INTRODUCTION AND WHAT SAMPLES WILL BE USED FOR

We would like to keep some of these samples that are left over for future research. If you agree, these samples will be kept and may be used in research to learn more about malaria. Future research must be approved by the appropriate ethics committee or Institutional Review Board. These samples will be stored for a long time at one of the universities or research organizations which are running this study including Makerere University, University of California, San Francisco, and Yale University. Samples may be shared with researchers at other institutions.

HOW WILL MY BLOOD SAMPLES BE USED AFTER THE STUDY IS COMPLETED?

Your child's samples may be helpful for research, and is not designed specifically to help your child. It might help people who have malaria in the future.
Reports about research done with your child's samples will not be given to you and will not be put in your health record. The research will not influence your child's care.

Your child's samples will be used only for research and will not be sold. The research done with your samples may help to develop new or improved treatments for malaria in the future.

LEVEL OF IDENTIFICATION IN RESEARCH RESULTS/MEDICAL RECORDS

We will code you or your child's samples using study identification numbers. The link between the study identification number and information collected on you or your child during the course of this study will be maintained after the study is over. However, the link will only be to data records and will not include personal information such as names and addresses. Researchers who study you or your child's samples in the future may need to know more about you or your child. Such information could include age, gender, and race. We may give information to a researcher if it is available from you or your child's study participation. We will not give your or your child's name or anything that might identify you or your child personally. We will not ask you to sign another consent form.

RISKS

There are few risks to your child from future use of your or your child's samples. A potential risk might be the release of information from your child's health or study records. We will not put reports about research done with your child's samples into his or her health record. We will keep these reports with the study records. We will keep the study records as private and safe as possible.

BENEFITS

You or your child will be not benefit directly from this future research on stored blood. From studying you or your child's samples, we may learn more about malaria and/or HIV or other diseases. We may learn how to prevent them, how to treat them, how to cure them.

QUESTIONS

You may call Dr Norah Mwebaza at 0782589889 or Dr. Richard Kajubi at 0776211591 if you decide you would no longer like to have your child's samples stored for future usage. You may also contact Dr. Ponsiano Ocama (+256-414-530555/0772421190) at the Makerere University School of Medicine - Research and Ethics Committee which approved this study.

FREEDOM TO REFUSE

The choice to let us keep the left-over samples for future research is up to you. No matter what you decide to do, it will not affect your child's care. If you decide now that your child's samples can be kept for research, you can change your mind at any time. Just contact Dr. Norah Mwebaza (telephone 0782 589889) or Dr. Richard Kajubi (0776211591) and let us know that you do not want us to use your samples. Then any samples that remains will no longer be used for research.

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MAKING YOUR CHOICE

Please read each sentence below and think about your choice. After reading each sentence, put your initials in the appropriate box. If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number. No matter what you decide to do, it will not affect your care.

☐ I give my permission for my child's to be used for future research on Malaria
☐I do not give my permission for my child's to be used for future research on Malaria

Name of Participant (printed)

Name of Parent or Guardian (printed)

Signature or Thumbprint * Parent or Guardian Date/Time

Name of Study Staff Administering Consent (printed) Position/Title

Signature of Study Staff Administering Consent Date/Time

Name of Translator (if necessary)

Signature of Translator Date/Time

*If the participant, parent, or guardian is unable to read and/or write, an impartial witness must be present during the consent discussion. After the written informed consent form is read and explained to the participant, parent, or guardian, and after they have orally consented to participation in this study, and has either signed the consent form or provided his or her fingerprint, the witness must sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant, parent, or guardian and that consent was freely given.

Name of Person Witnessing Consent (printed)

Signature of Person Witnessing Consent Date/Time

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