Appendix E.

Research Participation Informed Consent
BAYLOR CENTER OF EXCELLENCE CHILDREN- DPART PHARMACOKINETIC STUDY

Protocol Title: DPART STUDY: DIHYDROARTEMISININ-PIPERAQUINE IN THE CONTEXT OF ANTIRETROVIRAL THERAPY

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RESEARCH STUDY SUMMARY

Introduction: We are asking you to join a research study. This research study is being done by Makerere University, Baylor Center of Excellence, University of California-San Francisco, and Yale University, and is sponsored by the U.S National Institute of Child Health and Human Development (NICHD).

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

Purpose of Study: You are being asked to allow your child to participate in this research study because your child is at risk of contracting malaria. The information gained by this study can help us determine if children are receiving the best dose possible for their malaria medication.

We want to know the best dose of malaria medication for all children:

- To reduce the chance for episodes of malaria;
- To lower the risk of negative side effects;
- And to reduce the risk of malaria parasites becoming resistant to the medicine.

Study procedures: While your child is in the study, your child will receive the antimalarial medication, dihydroartemisinin–piperaquine (Duocotexin®) which is one of the first-line malaria medications recommended by the World Health Organization, and is available in Uganda. It is also being studied for its use in preventing malaria infection. Your child will also have a physical exam and medical history taken at the start of the study and blood draws during the course of the study. Up to 11 visits are required for this study over up to 42 days. The amount of time each study visit will take will vary, depending on the type of visit.

Possible Risks:

- **Non-Study Medications and Other Clinical Studies**: There may be a risk of serious side effects when non-study medications are taken with study drugs.
- **Risks of *Duocotexin*®:** Duocotexin® is a first-line malaria medication recommended by the World Health Organization, and is also being studied for its use as a way to prevent malaria in children and in pregnancy. Side effects that can occur in up to 1 out of 10 times include: sleep problems, headache, dizziness, a feeling of a rapid or irregular heartbeat, rash, itching, fever, muscle and joint aches, and fatigue. Rare side effects occurring in less than 1 out of 200 times include changing the pattern of your child's heartbeat.
- **Blood drawing (venipuncture, finger or heel prick) risks**: Drawing blood may cause temporary discomfort from the needle stick, bruising, fainting, and infection. The amount of blood removed will be too small to affect your child's health.

We'll tell you about the other risks later in this consent form.

Possible Benefits: The information we get from this study might help Uganda and other countries to determine dosing and safety of *Duocotexin*® in the context of HIV treatment. In addition, this drug may help prevent malaria infection in your child, and this benefit will depend on how high the risk of malaria is in your area.

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Overview for children who receive a single dose of DP and are followed for 28 Days

Study Day	Study Procedures	Total Blood Volume	Estimated Time in Clinic
Enrollment Day* (Day -1)	1. Consent 2. Physical exam 3. Blood test: blood count, liver function 4. Blood draw via arm prick 5. Blood draw via finger prick 6. HIV screening 7. Malaria screening	Less than 1.5 teaspoons (up to 6.45mL)	1 hour
Day 0	1. Physical exam 2. Receive 1st dose of DP 3. Multiple blood draws (8 total) through tube in arm 4. 2 ECG (1 before DP and 1 after DP)	Less than 1 teaspoon (4.0mL)	8 hours
Day 1	1. Physical exam 2. Blood draw via finger prick	Less than 1/25th of a teaspoon (0.2mL)	Less than 1 hour
Day 2	1. Physical exam 2. Blood draw via finger prick	Less than 1/25th of a teaspoon (0.2mL)	Less than 1 hour
Day 7	1. Physical exam 2. 1 blood draw via finger prick 3. 1 ECG	Less than 1/25th of teaspoon (0.2mL)	Less than 1 hour
Day 14	1. Physical Exam 2. Blood tests: blood count, liver functions, and drug level from arm prick	Less than 1 teaspoon (4.5mL)	Less than 1 hour
Day 21	1. Physical exam 2. 1 Blood draw via finger prick	Less than 1/25th of teaspoon (0.2mL)	Less than 1 hour
Day 28	1. Physical Exam 2. Blood tests: blood count, liver functions, 3. Blood draw via arm prick & finger prick 4. 1 ECG	Less than 1.2 teaspoon (up to 6.7mL)	1 hour

Overview for children receiving once a day DP for 3 days and are followed for 42 Days

Study Day	Study Procedures	Total Blood Volume	Estimated Time in Clinic
Enrollment Day* (Day -1)	1.Consent *2.* Physical exam 3. HIV screening 4. Malaria screening	1/20th teaspoons (0.20mL)	1 hour
Day 0	1. Physical exam, 2. Blood tests: blood count, liver function 3. Baseline ECG 4. Receive 1st dose of DP 5. Blood draws via tube in arm 6. 3 blood draws via finger prick	Less than 2 teaspoons (up to 8.1mL)	4 hours
Day 1	1. Physical exam 2. Receive 2nd dose of DP 3. 3 Blood draws via finger pricks	Less than 1/12th of a teaspoon (0.6mL)	4 hours
Day 2	1. Physical exam 2. Receive 3rd dose of DP 3. Multiple blood draws (8 total) via tube in arm 4. 2 ECGs	Less than 1 ½ teaspoon (up to 6.5mL)	8 hours
Day 3	1. Physical exam 2. Blood draws via arm prick	Less than ½ of teaspoon (1.2mL)	Less than 1 hour
Day 4	1. Physical exam 2. 1 Blood draw via finger prick	Less than 1/25th of teaspoon (0.2mL)	Less than 1 hour
Day 7	1. Physical exam 2. 1 blood draw via finger prick 3. 1 ECG	Less than 1/25th of teaspoon (0.2mL)	Less than 1 hour
Day 14	1. Physical Exam 2. Blood tests: blood count, liver functions, & drug level via arm prick	Less than 1 teaspoon (4.5mL)	Less than 1 hour
Day 21	1. Physical exam 2. 1 Blood draw via finger prick	Less than 1/25th of teaspoon (0.2mL)	Less than 1 hour
Day 28	1. Physical Exam 2. Blood tests: blood count, liver functions & drug level via arm prick 3. 1 Blood draw via finger prick	Less than 1 teaspoon (4.7mL)	1 hour
Day 35	1. Physical exam 2. 1 Blood draw via finger prick	Less than 1/25th of teaspoon (0.2mL)	Less than 1 hour
Day 42	1. Physical Exam 2. 1 ECG 3. Blood draw via arm prick 4. 1 Blood draw via finger prick	Less than 1 teaspoon (2.7 mL)	1 hour

***Some Day -1 screening activities may instead be completed on Day 0 at the discretion of the study team.**

DETAILED STUDY INFORMATION

WHY IS THIS STUDY BEING DONE?

Malaria and HIV are common diseases in Uganda. Studies show that the drugs used to treat and prevent malaria, like dihydroartemisinin-piperaquine (DP), also known as *Duocotexin*®, can interact with other medications, such as medications to treat infections like HIV. We need information from children who are infected with HIV, like your child, to help us understand the relationship between antimalarial medications and HIV medications.

The results from the study will help us determine the best *Duocotexin*® dose for children:

- To lower the risk of negative side effects;
- To reduce the chance for episodes of malaria;
- And to reduce the risk of malaria parasites becoming resistant to the medicine.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY AND HOW LONG WILL THE STUDY LAST?

This study will take place at the Mulago Hospital Baylor Center of Excellence. We want to study up to 110 children who are infected with HIV ages 3-17 years, taking one of the following antiretroviral therapies (ART): efavirenz (EFV), lopinavir/ritonavir (LPV/r), or dolutegravir (DTG).

Based on your child's antiretroviral therapy regimen, he or she will be asked to enroll in a group that will receive either 1 or 3 doses of DP. Children will be enrolled as follows:

- If your child is on LPV/r, they may be asked to enroll in a group that will receive either a single dose of DP or 3 doses of DP
- If your child is on EFV or DTG, they will be enrolled in a group that receives 3 doses of DP

WHO CAN PARTICIPATE IN THIS STUDY?

We plan to study HIV-infected children who do **not** have malaria. Your child is being enrolled because he or she has HIV infection. Children must live within 30 km of the study clinic and be available to come to clinic for all follow-up procedures for the duration of study (up to 42 days total).

Please note that your child's HIV care will continue through your child's regular medical clinic, which may be the Baylor Center of Excellence. If your child takes the HIV medicine once a day, we ask that your child take their dose in the morning with the exception of EFV, which is taken at night. Additionally, you should record the time when your child is taking the medication in a log book that will be given to you at the time of joining the study. On certain study days, we will ask your child to hold their morning dose and to take it in the clinic. Specific instructions on when to hold doses will be provided by study staff.

WHAT IS DIFFERENT ABOUT THE STUDY INVOLVING CHILDREN ON LPV/R?

LPV/r may cause an increase in the levels of DP in the body, and therefore your child may be at higher risk of having side effects to the medicine. Thus, we will first start by giving a smaller group of 20 children ONLY a single dose of DP and making sure that it is safe over a 4 week period. If it is found to be safe, children in this part of the study may continue and receive 3 doses of DP given once a day for 3 days, and be followed for 6 weeks in the study. Your child does not need to participate in both parts of the study, and may only participate in one of them. The choice to enroll into either group will be dependent on need at the time of enrollment, as determined by the study team, you and your child's preference.

WHAT WILL HAPPEN IF I AGREE TO HAVE MY CHILD PARTICIPATE IN THE STUDY?

Screening and enrollment day (today's visit)

Screening

The study clinic for this study is the Baylor clinic, and your child will be followed by this clinic for the duration of time that he or she is in the study. If your child has symptoms such as a fever, your child will be tested immediately to see if he or she has malaria. If your child does have malaria, we will provide treatment for malaria as per standard of care in Uganda, and continue to follow your child for at least a week to make sure he/she recovers properly.

If your child does NOT have malaria and you are willing to have your child participate in this study, the following procedures will take place:

- We will read this consent form to you to explain the study. If you remain interested in having your child in the study, we will ask that you sign the consent form today to agree to have your child participate in the study. If your child is 8-17 years old, he/she will also need to sign an assent form before being allowed to participate in the study. To help you decide, you may talk to people you know.

If you have agreed and consented to have your child in the study, we will perform the following additional screening procedures to determine if your child is eligible to participate in the study.

- **Physical exam and medical history**: The study doctors will perform a physical examination of your child and ask you about his or her medical history.
- **Finger stick blood draw**: Screening will also entail a drop of blood for testing of your child's hemoglobin, to see if he/she is anemic.
- **Malaria Screening:** Screening will entail a drop of blood to see if your child currently has malaria.
- **ECG Screening**: Screening will involve placing sticky probes on the skin to measure your child's heart activity. This test does not hurt or involve any needle sticks.

Enrollment

If your child meets the criteria to participate in the study, the following will be done on the same initial visit or on the next visit day.

Blood draw: Blood will be collected by a needle stick in one of your child's arm veins and will not be more than 1 or 2 teaspoonfuls. If samples cannot be obtained by vein, a finger prick may be done to collect blood. Tests will be done to determine your child's:

  - blood count and liver function
  - any antimalarial medication in your child's blood from a recent episode of malaria

- If the study doctor confirms your child's participation, your child will receive a study number and study card today. Your child will then be scheduled to begin his or her 1 anti-malarial medicine regimen.

- Your child will receive only brand name *Duocotexin* ® (dihydroartemisinin-piperaquine, DP, made by Holley Pharmaceuticals), so that we can make sure all children participating in this study are receiving the same formulation of the drug.

- If your child does not yet have a long-lasting insecticide treated bed net, the study will provide this as part of a basic care package.

WHICH OF THE TREATMENT GROUPS WILL MY CHILD BE IN FOR THE STUDY?

Depending on the status of study enrollment and your child's ART therapy, your child will be placed into one of three groups.

If your child takes either EFV or DTG as part of their HIV treatment, they will be enrolled in a group that receives 3 doses of DP given once a day for 3 days. Children will be placed into a group that is either 3 to 10 years of age or 11 to 17 years of age

As mentioned above, if your child is taking LPV/r as part of their HIV treatment, they will be placed in a group of 3 to 10 year old children that receives a single dose of DP **or** a group that receives 3 doses of DP given once a day for 3 days. Depending on the status of the study, your child will be placed into one of these groups. If you were placed in the single dose group, you may be asked if you would like to participate in the 3 dose group after completing that study. It is best for our study if we have children participate in both groups, but it will be up to you to decide if you want your child to participate in both regimens. You are free to only join one study group. Once you decide, the boxes on this consent form can be checked to reflect your decision.

HOW SHOULD MY CHILD TAKE THE MEDICATION?

- It will be important that all *DP* doses be given on an empty stomach (no less than 2-3 hours before or after meals). Taking this medication on an empty stomach with only water helps minimize any side effects that can occur with *DP*.

- Each dose will be given to your child in the study clinic in the morning. Therefore, it is important that you and your child come to clinic each day to receive the dose and the precise time to come to the clinic for dosing will be explained to you by the study doctor.

- If your child vomits any doses, the clinic will decide if your child should receive another dose.

- If your child is receiving only single dose of DP, the dose should be given in the morning, as instructed by your study doctor

- If your child is receiving three doses of DP, it should be given as in the table below:

Day of study	1st (Study Day 0)	2nd (Study Day 1)	3rd (Study Day 2)
When to give each dose	Morning	Morning	Morning
# Doses per Day	1	1	1

WHAT ELSE WILL HAPPEN WHEN MY CHILD IS IN THE STUDY?

- Your child will be seen in the study clinic several times during each follow-up period for the study. The procedures for evaluating your child for any given day may either be the same or different depending on the study day and study group your child is enrolled in. You will be provided with a study card and a reminder for all visits.

- Your child will be evaluated by a study doctor to see how she or he is doing on up to 10 follow-up days in clinic, depending on what group your child is in. The precise schedule of follow-up will be explained by your doctor or nurse. Blood tests to measure the *impact* of the medication will be drawn by venipuncture on up to 3 of those days, just as this was done at the beginning of the study. In addition, blood tests to measure the *amount* of antimalarial medication in the blood will be drawn on up to 10 of those follow-up days.

- The total amount of blood drawn from your child over the duration of the study will be no more than 6 teaspoons of blood.

- On the day that multiple samples will be taken, a small tube or catheter will be placed in an arm vein of your child so that your child does not have multiple pricks with a needle. This catheter will remain in your child's arm for the duration of blood draws on day. This will allow us to only have to perform a single venipuncture on that day.

- **For those children ages 3 to 17 years and are taking 3 doses of DP:**

  - Day 0 and Day 1 blood samples will be collected at the following times:
    - Before the dose by an arm prick
    - 2 hours after the dose via finger prick
    - 4 hours after the dose via arm prick and finger prick
  - On Day 2, a sample will be collected just before your child receives the last dose of *DP,* and your child will have 7 more small blood samples collected over the next 8 hours by a small tube placed in your child's arm. Each time we collect blood, it will be a very small amount, approximately 1/10th of a teaspoonful.). Thus, the total amount of blood taken on this day will be under one teaspoonful.

- You and your child will remain for this 8-hour period in a special room set up especially for this study that is located within the clinic. The room will be set up so that you and your child will be comfortable. There will be some toys for your child to play with and you and your child will be able to rest if you would like.
- After the 8-hour blood draw, the small tube that is placed in your child's arm will be removed by the study doctor. You and your child will be discharged from the study clinic so that you can return to your home.
- **You and your child will return to the study clinic for up to 10 more times** (study days 1, 2, 3, 4, 7,14, 21, 28, 35 and 42) for more clinical and safety tests and to measure the drug in your child's blood. These samples will again be drawn either by a small needle stick in one of your child's arm veins or by a finger prick blood draw.

- **The following applies only to children who are on LPV/r and are receiving a single dose of DP**

  - The 1st sample will be collected just before your child receives the first dose of DP*,* and your child will have 7 more small blood samples collected over the next 8 hours. Each time we collect blood, it will be a very small amount, approximately 1/10th of a teaspoonful.). Thus, the total amount of blood taken on this day will be under one teaspoonful.
  - You and your child will remain for this 8-hour period in a special room set up especially for this study that is located within the clinic. The room will be set up so that you and your child will be comfortable. There will be some toys for your child to play with and you and your child will be able to rest if you would like.
  - After the 8-hour blood draw, the small tube that is placed in your child's arm will be removed by the study doctor. You and your child will be discharged from the study clinic so that you can return to your home.
  - **You and your child will return to the study clinic up to 6 more times** (study days 1, 2, 7, 14, 21, and 28) for more clinical and safety tests and to measure the drug in your child's blood. These samples will again be drawn either by a small needle stick in one of your child's arm veins or by a finger prick blood draw.

BLOOD DRAW FOR GENETIC RESEARCH:

We will also collect up to 2/5th of a teaspoon of blood from your child's arm to do a genetic test on either Day -1 or Day 0 & the last day of follow up. This will allow us to understand how genetic differences affect the way the malaria and HIV medicines are cleared from the body. We will not put the results of the genetic test in your child's medical record. The research will not change the care your child will receive. Any specimens and information about your child will be kept until it is used up or destroyed. Your child's personal health information cannot be used for additional research without additional approval from either you or a review committee.

WHY ARE STUDIES ON THE HEART BEING DONE?

- Electrocardiograms (also known as ECGs) measure the beating and rhythm of your child's heart. The piperaquine component of DP has been associated with changes in the pattern of heartbeats (measured by ECGs) in less than 1 in 200 individuals. To make sure your child is safe, he/she will have ECGs performed during the study at several times over the course of the study. This will measure the activity of your child's heart. This test will involve placing electrodes on the skin to measure the heart's activity. It will not hurt.

WHAT HAPPENS IF MY CHILD GETS SICK WHILE WE ARE IN THE STUDY?

- If your child becomes sick during the day while in the study, please bring your child to the study clinic. There will be someone at the study clinic every day from 8 am to 5 pm. The clinic is open on weekends and holidays.
- If your child develops malaria during the study, we will provide your child with malaria medicine to treat their infection and follow them for at least 7 days. If your child has severe malaria, they will receive quinine or artesunate at Mulago Hospital. The length of your child's stay in the hospital will be decided by the hospital staff managing your child's illness.
- In the event if your child contract malaria during the study, they will be discontinued from the study and may re-enroll after a 42 days washout period.
- If your child becomes ill after clinic hours (after 5pm), please bring your child to Mulago Hospital for care. Your child will receive care by the hospital staff or be referred to the appropriate clinic for care

HOW LONG WILL MY CHILD BE IN THE STUDY?

We are asking you to let your child participate in this study for up to 42 consecutive days or until you or the study doctors decide your child should stop being in the study. If your child is on LPV/r based ART and is enrolled in the single dose regimen, after 42 days, your child may participate in the 3-day three-dose regimen arm if you choose to. If your child is on EFV or DTG based ART, your child will only be able to participate in 3-day three-dose regimen for 42 consecutive days.

WHY WOULD MY CHILD BE WITHDRAWN FROM THE STUDY EARLY?

You may decide to stop your child from being in the study at any time and for any reason. For your child's safety and health, study doctors might decide he or she should stop being in the study.

Your study doctors may also take your child out of the study. These are the possible reasons:

1. If you are unable to bring your child to the scheduled study visits.
2. If your child misses the correct times for the doses of malaria medication.
3. Any dosing of malaria medications or other medications outside study procedures.
4. Your child develops malaria
5. If the study doctors think the study is no longer good for your child
6. If you withdraw your consent to have your child stay in this study
7. The study is cancelled by the UCSF, Yale University, Uganda National Council of Science and Technology (UNCST), Baylor College of Medicine, National Drug Authority, JCRC-REC, Ugandan Ministry of Health, the U.S. National Institute of Child Health and Human Development (NICHD), or by the U.S. Office for Human Research Protections (OHRP).

If we are unable to locate you during follow-up or you decide to withdraw from the study, follow-up will end. However, in the event that your child stops the study early, they would be eligible to reenroll in the study at a later time after a washout period, if they took any study drugs the

first time. We will also make an effort to follow your child for at least 7 days after beginning the study regimen to obtain a blood sample for safety evaluation.

CAN I DECIDE TO STOP MY CHILD'S PARTICIPATION IN THE STUDY?
Yes. You can decide to stop at any time. Tell the study doctor or nurse if you are thinking about stopping or deciding to stop. He or she will tell you how to stop your child's participation safely. It is important that you tell the study doctor if you are thinking about stopping so that your doctor can evaluate any risks and discuss what alternative follow-up care and testing could be most helpful to your child.

WHAT WILL HAPPEN IF I OR MY CHILD'S STUDY DOCTORS DECIDE TO TAKE MY CHILD OFF STUDY?
If either the study doctors take your child off study or if you decide to stop his or her participation, your child may still get health care at the Mulago Hospital or his or her regular clinic. If your child stops participating in the study for any reason, the study doctors will ask to examine your child and draw a small amount of blood (less than 1 teaspoon) for laboratory tests for the safety of your child. You have the right to not agree to the examination and tests. If your child leaves the study before finishing, if funds are available we will give your child medical care for any problems that began during the study. Your child may be taken out of the study because of a serious health problem. If the study doctors think the health problem is probably related to study treatment, they will arrange for needed follow-up tests.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT MY CHILD TO HAVE FROM BEING IN THE STUDY?

1) **Non-Study Medications and Other Clinical Studies**: There may be a risk of serious side effects when non-study medications are taken with study drugs. You must tell your doctor or study nurse about all other medicines and herbs that your child is taking before your child starts the study. You must tell the study doctor or nurse before taking any non-study therapies while your child is in the study. You must also tell your study nurse and doctor if you join any other research studies.

2) **Risks of *Duocotexin*®:** Duocotexin® is a first-line malaria medication recommended by the World Health Organization, and is also being studied for its use as a way to prevent malaria in children and in pregnancy. A standard treatment course is 3 tablets (one tablet given once a day for 3 days). This regimen is generally well tolerated but may cause rare side effects such as changing the pattern of your child's heartbeat, which can be detected via an ECG. This can result in changes in heart activity and is thought to be from the piperaquine component of this medication. This happens less than 1 out of 200 times the drug is used. Other side effects occur up to 1 out of 10 times the drug is used. Some of these are sleep problems, headache, dizziness, a feeling of a rapid or irregular heartbeat, rash, itching, fever, muscle and joint aches, and fatigue. We will be following your child closely during the course of follow-up for any side effects. If concerning changes are found in the pattern of your child's heartbeat, we will stop additional dosing of the malaria medicine, and follow your child's heartbeat using ECGs and will monitor for other side effects closely.

3) **Blood drawing (venipuncture, finger or heel prick) risks**: Drawing blood may cause temporary discomfort from the needle stick, bruising, fainting, and infection. We will attempt to minimize the number of needle sticks to your child. The amount of blood removed will be too small to affect your child's health.

4) **Genetic information risks**: Genetic information that results from this study does not have medical or treatment importance at this time. We will not be looking at all of your child's genetic information, only the genes involved with removing medications from the body. We will not be looking into any genetic information linked to specific diseases. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record and we will not share this information outside of our research group.

5) **Unknown Risks**: There is always the possibility of side effects that no one knows about yet. The study doctors will let you know if they learn anything that might make you change your mind about your child participating in the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There are some benefits to your child for taking part in this study. Your child will receive close clinical care for up to 42 days and for any other illnesses that may occur during this time.

The information we get from this study might help Uganda and other countries to determine dosing of *DP* in the context of children and HIV that is both safe and effective for the treatment/prevention of malaria.

In addition, this drug may help prevent malaria infection in your child, but this benefit is low since your child lives in a region where the risk of malaria is much lower than other parts of Uganda.

WHAT OTHER CHOICES DO I HAVE IF MY CHILD DOES NOT TAKE PART IN THIS STUDY?
You are free to decide whether or not you want your child in this study. If you decide you do not want your child in the study or decide to stop your child from being in the study at any time and for any reason, this will not affect your child's care at Mulago Hospital or any referral clinics. If you decide not to take part, your child could still get medical care and could still get any of these medicines if your doctor thought they were needed. Currently, *DP* is provided free at government clinics and hospitals.

WILL MY CHILD'S MEDICAL INFORMATION BE KEPT PRIVATE?
Other people may learn that your child is part of this study because you will get medical care at the study clinic. These study staff will not be allowed to discuss your child's medical information outside of the study clinic. Only study staff, the local Joint Clinical Research Centre Research Ethics Committee (JCRC-REC) and Uganda National Council for Science and Technology (UNCST) may have access to private information that will be able to link your child's medical records and personal study number. The universities and research organizations running this study or making sure that the research is done properly are not allowed to let others know the identity of the people in the study. These organizations include the National Institutes of Health (NIH), University of California San Francisco Human Research Protection Program (UCSF HRPP), Yale Human Investigations Committee (Yale HIC), Baylor College of Medicine IRB, Joint Clinical Research Centre Research Ethics Committee (JCRC-REC), the National Drug Authority in Uganda (NDA) and the Uganda National Council for Science and Technology (UNCST). The medical records for the study will be kept in a locked office and will only be able to be seen by study staff. Your name or your child's name will not be written in any reports based on this research.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost for you or your child to take part in this study. We will pay for the cost of all tests or drugs prescribed by our doctors that you may have to purchase outside the clinic. Payment for visits outside the study clinic or Mulago Hospital will only be possible if we have enough funds.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?
You or your child will not be paid for participation in the study. We will be giving you money as a reimbursement for time and transport to and from your home to the study clinic for all study visits and visits needed if your child is sick. This amount will be up to an average of 30,000 Ugandan schillings, but variable depending on travel distance. On certain days, participants will have to be in the clinic for several hours. On those days, we will provide food and drink to participants (breakfast, dinner, and/or snacks) to ensure their well-being. You will also be provided the amount of 50,000 Ugandan Shillings in compensation for your time on those days. If you agree for your child to be in this study, your child will be given a long-lasting insecticide-treated bed net.

WHAT HAPPENS IF MY CHILD IS INJURED BECAUSE HE OR SHE TOOK PART IN THIS STUDY?
If your child is injured or becomes ill, please contact the doctors at the study clinic. If you have questions about injuries as a result of being in the study, contact the doctors at the study clinic. You can get health care services at Mulago Hospital in case of such injuries. In the event there is a study related injury, the study investigators will ensure that your child receives the best care available until complete cure or stabilization of a research related injury. You will not have to pay for care for study-related injuries.

WHAT ARE MY CHILD'S RIGHTS IF HE OR SHE TAKES PART IN THIS STUDY?
You are free to decide whether or not you want your child in this study. You have the right to stop your child's participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled. We will tell you about new information or changes in the study that may affect your child's health or your willingness to have your child continue in the study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
Drs. Mwebaza, Aweeka, and Parikh, and their staff can answer questions you have about the study. You may call Dr. Norah Mwebaza at 0782589889, Dr. Richard Kajubi at 077621159, Dr Grace Kisitu 0772749154 at the study clinic. You can also contact Dr. Aweeka at 014154760339, and Dr. Parikh at 012037377906. If your child has been injured or becomes ill, please contact the doctors.

FOR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH PARTICIPANT
You may also contact the Chairperson.at the Joint Clinical Research Centre Research and Ethics Committee (JCRC-REC) (+256 414201148) which approved this study for questions about participants' rights and research-related harm.

DISSEMINATION OF RESULTS:
You will get feedback on findings and progress of the study. Any new information that affects the study or data that has clinical relevance to research participants will be made available to you, your health care provider, Ministry of Health and publications.

CONSENT: WHAT YOUR SIGNATURE OR THUMBPRINT MEANS

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to allow your child to participate or to withdraw your child at any point in this study without penalty or loss of benefits to which your child is otherwise entitled. A copy of this consent form will be given to you. Please check the box(es) corresponding to the duration of regimen you want to participate in. A check in the box will indicate the regimen duration your child will receive. Depending on the need, you may check both boxes if you would like for your child to consent to both study arm. If so, your child may first participate in the 1-Day, single dose regimen, followed by a 42 days washout period, before participating in the 3-Day, three-dose regimen. Your signature or thumbprint below means that you have had this study explained to you. Your signature or thumbprint below means you have had the opportunity to ask questions and get answers. If you wish your child to participate in this study, you should select the check box(es) and, sign or place your thumbprint below.

☐ 1-Day, single dose regimen (**LPV/r-based ART only**)

☐ 3-Day, three-dose regimen

Name of Participant (printed)

Name of Parent or Guardian (printed)

Signature or Thumbprint * of 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 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 parent or guardian, and after he or she has orally consented to his or her child's 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 parent or guardian, and that consent was freely given.

Name of Person Witnessing Consent (printed)

Signature of Person Witnessing Consent | Date/Time