Appendix III: Sample Informed Consent Form for Participation in Cohort 2

IMPAACT 2014
Phase I/II Study of the Pharmacokinetics, Safety and Tolerability of Doravirine (MK-1439) and Doravirine/Lamivudine/Tenofovir Disoproxil Fumarate (MK-1439A) in HIV-1-infected Children and Adolescents

Version 1.0, 7 September 2017

Introduction

[You are/Your child is] being asked to take part in the research study named above.

This form gives information about the study. Please read it, or have it read to you, and ask any questions you may have. We will take as much time as needed for you to fully understand the study. We will ask you questions to see if we have explained the study clearly.

After you understand the study, if you decide that [you/your child] will participate, you will be asked to sign or make your mark on this form. You will be offered a copy to keep.

About the study

The International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) and *[insert site name]* are doing this study to test an anti-HIV medicine (ARV) called doravirine (DOR) for children who have HIV. HIV is the virus that causes AIDS.

The study will include up to 65 children and adolescents 12 years to less than 18 years of age who have HIV. The study will include children and adolescents from the United States, Thailand, and South Africa. There will be two groups of children in this study. Your child will be in a group of up to 45 children. Children and adolescents in this group will be in the study for about 2 years.

The person in charge of this study at this site is *[insert name of Principal Investigator]*. A company called Merck is providing the ARVs, including DOR. The United States National Institutes of Health are sponsoring this study.

1. The study is being done to test DOR as part of a combination medicine in children and adolescents.

Children and adolescents with HIV usually take a combination of three or more ARVs to stay healthy. There are not as many ARVs available for children and adolescents as for adults because many ARVs have not yet been tested in children.

DOR is a new ARV that is being tested in adults in the United States and other countries. The combination of ARVs also includes two other ARVs called lamivudine (3TC) and tenofovir disoproxil fumarate (TDF). *[Sites: insert any locally appropriate names of combination drugs or individual drugs used at your site here and throughout the form.]*

TDF and 3TC are approved in the United States and Europe. Both of these ARVs are commonly used in adults and children. DOR is a newer ARV that is being studied in adults. DOR is not currently approved

in the United States or Europe. *[Sites to modify as needed:* TDF and 3TC are approved in *[site country]].*

This combination of DOR, TDF, and 3TC has been studied closely in 86 healthy adults. DOR, either alone or in combination with other ARVs, has been studied closely in more than 700 adults. DOR has been shown to be safe and effective when compared to the approved ARVs, like efavirenz and darunavir. This is the first study of DOR in combination with TDF and 3TC in children.

The two groups of the study are called Cohort 1 and Cohort 2. Cohort 1 began first. This part will include up to 20 children and adolescents. Cohort 2 will be done after part of Cohort 1 is completed. Cohort 2 will include up to 45 children and adolescents. We will tell you about Cohort 1 first. This is a consent form for Cohort 2.

In Cohort 1, DOR was given one time at one visit to children and adolescents. This group looked at whether DOR causes any bad side effects when given to children and adolescents. This group also looked at the amount of DOR in blood. This is called an intensive pharmacokinetic (PK) evaluation.

Because results from Cohort 1 show that DOR is safe and that the amount of DOR in the blood is correct, Cohort 2 will start. The children and adolescents in this group will either have never received ARVs for treatment or are currently receiving ARVs for treatment and doing well. This group will look at whether this new combination of ARVs is safe or causes any bad side effects when given to children and adolescents. The group will also look at how the combination of ARVs control the virus for children and adolescents. For ARVs to be considered effective, they must be able to control the amount of HIV so that HIV cannot be found in the blood.

Some children and adolescents may join the study who have never taken ARVs before. Some children and adolescents may join the study who are taking ARVs and are doing well on their ARVs. If [you are/your child is] taking ARVs for treatment before the study, we will ask your child to start taking the study ARVs on the same day that your child stops taking the ARVs from before the study (see #8 below).

2. We may have two different ways to take DOR/3TC/TDF.

There are different ways to take ARVs, for example, as tablets that are swallowed or chewed or as liquids. This study may have two different ways for children to take DOR/3TC/TDF. We will tell you if [you/your child] have different options.

One way to take DOR/3TC/TDF is as a tablet. The tablet needs to be swallowed whole – it cannot be broken or crushed.

Another way to take DOR/3TC/TDF is as oral granules. Granules are kept in larger capsules or containers *[sites may use any locally understandable term to describe the granules]*. The capsules should not be swallowed whole. The capsules should be opened to sprinkle the granules directly into the mouth or to mix the granules with soft food.

[Sites may adapt the following paragraphs, depending on availability of the granule formulation:
You [and your child] may choose how to take the DOR/3TC/TDF. We will talk to you about the options and ask for your [your child's] decision. We will help [take/give] the DOR/3TF/TDF.

During the study, we would prefer that [you/your child] take the study ARV in the same way. However, [you/your child] may decide to take the study ARV the other way. For example, [you/your child] may start taking the DOR as oral granules and then decide to take the DOR as a tablet. If [you/your child] switch, we will also ask how it felt to take the tablet or granules (for example, how DOR tasted, how easy or difficult it was to swallow the tablet, how easy or difficult it was to mix the granules).*]*

3. It is your decision whether or not [you join/your child joins] the study.

Deciding to join the study is voluntary. You may choose [to allow your child] to join or not join. If you choose [to allow your child] to join, you can change your mind and [stop the study/take your child out of the study] at any time. Your choices will have no effect on your [child's] medical care at this clinic. Access to services and the benefits and rights [you/he or she] normally has will not be affected.

We will tell you about new information from this or other studies that may affect your [child's] health, welfare, or willingness to stay in this study. If you want the results from this study, tell the study staff.

Take your time and consider your decision carefully. If you wish, you can talk to other people about [joining/allowing your child to join] the study. You can bring other people here to learn about the study with you.

No matter what you decide about the study, it is important to receive care and treatment for HIV infection. We will tell you about your options for obtaining care and treatment for your [child's] HIV.

4. Only children who qualify can participate in the study.

If you decide to join the study, we will first do some tests to see if [you qualify/your child qualifies].

Finding out if [you qualify/your child qualifies]

5. We will ask questions and discuss the study requirements with you.

If you decide to [join/let your child join] the study, we will first do some tests to see if [you qualify/your child qualifies]. To find out, we will:

- Review medical records. We may also ask you questions about your [child's] health
- Ask about ARV use
- Talk with you about the study requirements and if [you are/your child is] able to meet these requirements
- Give a physical exam
- Draw blood for tests. We will take up to about 22 mL (less than 5 teaspoons) of blood. These tests will look at your [child's] blood cells and how well the liver and kidneys are working. The tests will also:
  - Confirm that you [your child] has HIV. There are certain HIV tests that are required for this study. If the required tests are not in the medical records, we will do the tests that are needed.
  - Check the amount of HIV in the blood. This is called viral load.
  - If [you have/your child has] never taken any ARVs for treatment, we will check whether [you are/your child is] resistant to certain ARV medications. Resistance means that an ARV may no longer work again HIV.
  - Check if [you have/your child has] Hepatitis B or Hepatitis C. Hepatitis B and Hepatitis C are diseases of the liver.

- Collect urine to check on how your [child's] kidneys are working
- For females, we may also collect urine or blood to check for pregnancy. More information is given in #6 below.

6. For females, we may do a pregnancy test to see if [you/your daughter] qualifies for the study. We may also test for pregnancy during the study. Females who become pregnant will stop the study ARVs.

If [you have/your daughter has] had her period or [you are/your daughter is] sexually active, we will collect urine or blood to test for pregnancy to see if [you/she] qualifies for the study. The pregnancy test must show that [you/she] is not pregnant to qualify for the study. If [you/she] enter the study, [you/she] will be required to use two forms of birth control while in the study. We will talk to [you/your child] about how to prevent pregnancy.

During the study, we will collect blood or urine to test for pregnancy. If [you/your child] becomes pregnant during the study, please let us know right away. If [you/your child] becomes pregnant, [you/your child] will stop taking the study ARVs and leave the study early.

[Sites may modify the following paragraph to include locally appropriate language regarding disclosure of pregnancy results to parents or legal guardians: We will talk over the test result as soon as it is available with [you/your child] in private without parents/guardians present. [You/Your child] must give us permission before we can share these results with parents/guardians. If [you are/your child is] pregnant, we will take [you/your child] off the study early. This means that even if we did not tell your parent or guardian, they might find out you were pregnant. If the test shows that [you are/she is] pregnant, we will give [you/your child] information on where medical care and other services can be received.*]*

We will contact [you/your child] after [your/your child's] last study visit to find out the outcome of the pregnancy. We will also ask about any ARVs [you/your child] took during the pregnancy.

7. We will tell you if [you/your child] qualifies.

We will give you the results of all procedures and explain the results to you.

If these procedures show that [you do/your child does] <u>not</u> qualify for the study, we will tell you this and [you/your child] <u>will not</u> be entered into the study. We will give you information on where medical care and other needed services can be received.

If these procedures show that [you <u>do</u>/your child <u>does</u>] qualify for the study, [you/your child] <u>will</u> be entered into the study.

Being in the study

8. If [you qualify/your child qualifies], [you/he or she] will enter the study. Participants will have about 12 scheduled visits over 2 years.

Visits will be more frequent in the first year. During this time, visits will be at entry, 2, 4, 8, 12, 16, 24, 36, and 48 weeks. After the first year, there will be at least three more visits, each four months apart.

Some children and adolescents may need to stop the study early. More information about this is given in #14 below.

Each visit will take about 2 to 3 hours. At these visits, we will:

- Review medical records
- Ask about ARVs
- Do a physical exam. At the first visit, this exam will include examination of your [child's] genitals to see the stage of development.
- Draw blood for tests. We will take between 10 mL and 19 mL of blood at each visit (about 2 and less than 4 teaspoons). At some visits, we will only do some of the tests. At other visits, we will do all of the tests. These tests may check:
  - Blood cells and the amount of fat in the blood
  - How well the liver and kidneys are working
  - How much HIV is in the blood
  - How many CD4 cells are in the blood. CD4 cells are cells that fight infections
  - How much of the study ARVs are in the blood (see #9 below)
  - If [you have/your child has] never taken any ARVs for treatment, we will save some blood for later resistance testing
  - We will also save any extra blood for future testing after the study is over. We will not tell you the results of any future tests. We will ask you about saving these extra samples in a separate form.
- Collect urine to check on how the kidneys are working.
- We may also do a test to check if [you are/your child is] pregnant (see #6 above).

[You/Your child] will also receive study ARVs at the entry, or first, visit. We will show you [and your child] how to take the ARVs. It is very important that [you/your child] takes the ARVs as instructed. We will take as much time as needed for you [and your child] to understand the instructions and identify strategies that will help to take the ARVs are instructed. After [you/your] child has been taking the study ARVs for two weeks, we will also ask how it felt to take the tablet or oral granules (for example, how DOR tasted, how easy or difficult it was to swallow the tablet, how easy or difficult it was to mix the granules).

If [you were/your child was] taking ARVs for treatment before the study, we will ask [you/your child] to stop taking the ARVs from before the study and start taking the study ARVs on the same day.

9. At some visits, we will look to see how much of the study ARVs are in your [child's] blood.

[You/Your child] will also have blood drawn to measure the amount of study ARVs in the blood. This is called a pharmacokinetic evaluation, or PK evaluation.

At 6 visits, we will take about 3.5 – 7 mL of blood drawn (less than 2 teaspoons). This blood will be drawn in the same way that other blood for the study is drawn.

At 4, 24, and 48 weeks after [you start/your child starts] the study, we may ask [you/your child] to take the study ARVs while at the study clinic so we can note the time [you/your child] took the study ARVs. On the day of this visit, we may ask [you/your child] to **not** take the study ARVs at home. We will help you remember this before each visit.

At 24 weeks and 48 weeks after [you start/your child starts] the study, we will draw blood two times at least 30 minutes apart.

10. For the first 10 participants in this part of the study: there will be an extra visit about one week after [you start/your child starts] the study where we will look very closely at the amount of study ARVs in the blood.

About one week after [you start/your child starts] the study, [you/your child] will have blood drawn to very closely measure the amount of study ARVs in the blood and how long it stays. This is called an intensive pharmacokinetic (PK) evaluation.

At this visit, we will ask you [and your child] when she or he took the study ARVs in the past three days. For three days before this visit, you must be sure that the child takes the study ARVs on time. **This is very important.** We will help you remember this before the visit.

On the day of this visit, **do not [take/give]** the medicine [to your child] at home. [You/Your child] will take the study ARVs while at the study clinic so that we know the time [you/your child] took the study ARVs.

[You/Your child] will then stay at the clinic or hospital for up to 24 hours. *[sites: modify language as appropriate to indicate procedures for overnight stays* – If the study clinic is able, you and your child may be allowed to stay at the clinic the night before and during your first PK visit.*]*

[Sites: modify language as appropriate to indicate procedures for the intensive PK collection. A small plastic tube (like a "drip") will be placed in your [child's] arm to draw blood samples. This tube is attached to a plastic needle so that we can draw blood several times. We will not need to stick your child with a needle each time. The plastic tube may stay in place until all the blood samples are drawn.*]*

We will draw about 2.0 mL (less than 1 teaspoon) of blood at six different time points during the first day for the PK test and at one time point during the second day of the PK test (a total of about 21.5 mL or less than 5 teaspoons). We will look at the amount of ARVs in your [child's] blood at each of these times.

11. Children and adolescents will have an extra visit if their HIV is not controlled.

Participants will have viral load tests at all visits. If the study ARVs are your [child's] first anti-HIV medicine, your [child's] viral load should be very low after about six months. If tests show that the viral load is higher than expected after six months, [you/your child] will have an extra visit. If [you were/your child was] on other ARVs before starting the study, your [child's] viral load should stay very low during the study. If tests show that the viral load is higher than expected at any time during the study, [you/your child] will have an extra visit. If your [child's] viral load is high at the last study visit, we will ask you to come back to the clinic after that to have an extra visit.

These extra visits will take about one hour. At these visits we will:

- Review medical records
- Ask about your [child's] health, ARVs, and other medicines
- Do a physical exam
- Draw blood (up to 13 mL or less than 3 teaspoons) for tests. The tests will check the HIV viral load. We will save some blood for later resistance testing.
- Give you additional supplies of ARVs as needed

If the repeat test also shows the high numbers of HIV in your [child's] blood, we will talk with you about whether [you/your child] should stay on the study ARVs.

12. The tests for the amount of ARVs in your [child's] blood will be done at different laboratories.

We will do most of the blood tests here at our laboratory. Some of the blood tests will be done in the U.S. or other countries. We will give you the results of most of these tests at the next scheduled visit, or sooner, if necessary. We will explain the results and give you counseling and referrals as needed.

We will also draw blood to check the amount of ARVs in your [child's] blood here in the clinic. The test will be done at laboratories in the U.S. or other countries.

Some tests may be done while the study is ongoing; others after the study is done. We will not give you the results of the pharmacokinetic tests during the study.

13. We may stop your [child's] study ARVs or take [you/your child] off the study early.

We may take your child off the study ARVs if:

- [You are/Your child is] not able to come to the study visits or we determine that [you/your child] cannot meet the study requirements.
- [You are/Your child is] not able to take the study ARVs.
- The study ARVs are not controlling the HIV in your [child's] blood.
- [You/Your child] becomes pregnant (see #6 above).
- Continuing the study ARVs may be harmful to [you/your child].
- You request to stop the study ARVs [for your child].

If [you stop/your child stops] the study ARVs, [you/your child] will stop the study early. We will ask you to come back to the clinic [with your child] about four weeks after [you stop/your child stops] the study ARVs. [You/Your child] will not have any other visits after this.

We may also take [you/your child] off the study early if the study is stopped for any reason.

The study cannot provide other types of ARVs, but we will give information, counseling, and referrals to where children can get care and treatment they need. We will help make sure [you/your child] can get ARVs from outside of the study. If the study stops early, every effort would be made to make certain that there is no interruption in your [child's] therapy.

14. Please tell us if you want [your child] to leave the study.

[You are/Your child is] free to leave the study at any time for any reason. The care that [you receive/your child receives] at this clinic will not be affected, but it is important for us to know about your decision. We will ask you to [come/bring your child] to the clinic for one last visit. At this visit, we will do the same types of procedures listed in #8 (see above). We will answer any questions you may have and give you information on how to contact us in the future, if you wish.

After the study

15. Receiving the study ARVs after the study is over.

As [you come/your child comes] to the end of the study, we will work with you to plan for your [child's] care and treatment outside the study. It is important that we plan for this in advance, so that there is no gap in your [child's] taking ARVs as [you finish/he or she finishes] the study. Taking ARVs without interruption is the best-known way for [you/your child] to stay healthy.

We will tell you where [you/your child] can go to receive needed care and treatment after [you finish/he or she finishes] the study. If [you are/your child is] gaining benefit from the ARVs given in the study, the company that is providing these ARVs (Merck) will try to provide these ARVs to your child. They will be provided until they are otherwise available locally, until [you are/your child is] no longer gaining benefit, or if the company decides to stop studying the ARVs. However, there is no guarantee this will be possible. If this is <u>not</u> possible, [you/your child] will need to switch to other ARVs that are available locally. We will explain the options to you and help ensure your [child's] access to ARVs outside the study. We will also contact you again within the first four weeks after [you finish/your child finishes] the study to confirm that [you are/he or she is] receiving ARVs.

Risks of the study

16. There is little risk from the study procedures.

Most procedures done in this study are routine medical procedures, with little risk to [you/your child]. Drawing blood can cause pain, swelling, bruising, or bleeding where the needle is inserted. Rarely, drawing blood can cause fainting or infection.

17. There are some risks from the study ARVs.

All ARVs can cause side effects, whether taken along or when taken in combination. This includes any ARVs that you would receive outside the study. The study ARVs, doravirine, lamivudine, and tenofovir disoproxil fumarate, may have side effects. Some of the most common or most serious effects are listed below. There may also be unknown side effects because this is the first time DOR will be studied in children. The lists do not include all the possible side effects. If you have questions about side effects not included in these lists, you can ask us.

Each of the study ARVs can cause side effects, when taken alone or when taken in combination. Some side effects are minor; others can be severe. Some are common and some are rare. Some people who take the study ARVs have some of these effects. Some people have different side effects. We do not expect to see different side effects if the ARVs are combined or if they are given separately.

If [you join/your child joins] the study, we will tell you about the side effects of the study ARVs that [you/your child] will take. We will also check for any side effects during the visits and tell you what to do if [you have/your child has] any side effects.

18. We will tell you about the most severe side effects first.

First, you should know about the possible severe side effects. These effects are rare, but they can cause serious health problems and can result in death:

- Liver problems. The liver is an organ near the stomach. If there are liver problems, [you/your child] might have yellowing of the skin or whites of the eyes; dark or tea-colored urine; pale colored stools; upset stomach or vomiting; loss of appetite; pain, aching or tenderness of the right side below the ribs; or itchy skin. This can be caused by DOR, 3TC, and TDF.

- Build-up of acid in blood, called lactic acidosis, very enlarged liver, fatty liver, or death have been reported. If [you have/your child has] these problems, [you/your child] might have unexplained weight loss, stomach discomfort, nausea, vomiting, fatigue, cramps, muscle pain, weakness, dizziness, and shortness of breath. This can be caused by 3TC and TDF.

- Pancreas problems. The pancreas is an organ near the stomach. If your [child's] pancreas becomes inflamed, [you/your child] may have stomach pain, upset stomach or vomiting, or more fats in the blood. This can be caused by 3TC.

- Kidney problems. The kidneys are organs near the middle of the back (one on each side). Doctors usually find out about kidney problems from tests of the blood. These effects can be caused by TDF.

19. There are also more common and not severe side effects from the study ARVs.

You should also know about the more common side effects. These side effects are not severe. There are many possible mild and moderate side effects. The most common ones are listed below:

<table>
<tr>
<td rowspan="2">Overall Body Effects
• Changes in the placement of body fat (increasing around the stomach, neck, or breast or decreasing in the arms, legs, or cheeks)
• Overall weakness
• Headache
• Back pain
• Allergic reaction
• Numbing, tingling, or pain in the hands and feet
• Fever</td>
<td>Effects on Blood
• Decrease in the blood cells that fight infection
• Other changes in the blood tests that may show problems with the liver or pancreas. The blood tests may show how well these organs are working, or they may look for substances made by the organs, or they may look for fats in the blood.</td>
</tr>
<tr>
<td>Effects on Skin
• Rash
Effects on the Chest
• Shortness of breath</td>
</tr>
<tr>
<td>Effects on Muscle and Bones
• Aches and pains
• Loss of muscle
• Bone thinning or softening (which could increase the chance of breaking a bone)</td>
<td rowspan="2">Effects on Activity
• Drowsiness and tiredness
• Trouble sleeping
• Dizziness
• Abnormal dreams, hallucinations and nightmares
• Clumsiness or lack of coordination
• Feeling of deep sadness or unworthiness (depression)</td>
</tr>
<tr>
<td>Effects on Stomach
• Pain or upset stomach
• Loose or watery stools
• Vomiting
• Gas
• Dry mouth
• Change in your sense of taste</td>
</tr>
</table>

20. There may be other possible risks from the study ARVs.

Possible effects on pregnancy or unborn babies

HIV and ARVs may lead to some pregnancy complications, like early delivery or low weight of the baby at birth. We do not know if some ARVs are more likely to cause these effects than others. We do not yet know if this combination of ARVs with DOR is safe in pregnancy. There were no pregnancy complications seen when DOR was given in animals.

If [you/your child] becomes pregnant during the study, please let us know right away.

Immune reconstitution syndrome

In some people with advanced HIV infection, signs and symptoms from other infections or certain diseases may occur soon after starting combination ARVs but can also occur later. Some of these symptoms may be life threatening. If [you start/your child starts] having new symptoms, or if you notice that any existing symptoms are getting worse after starting the ARVs, tell your doctor immediately.

Hepatitis B

Some ARVs are active against hepatitis B. For children who have hepatitis B, and take ARVs that are active against hepatitis B, stopping the ARVs could cause the hepatitis B to worsen. If this happens, most children get better quickly without treatment, but in rare cases this has resulted in death.

Risk of resistance

All ARVs can cause some resistance. Resistance means that the ARVs may not work against HIV if it is taken again in the future. To stop resistance, it is important that [you take/give your child] the ARVs as instructed, and do not miss any doses.

Risk related to stopping study ARVs

If the study is unexpectedly stopped early or if you reach the end of the study and it is not possible to continue the study ARVs and you therefore need to change to different anti-HIV medicines, there is a risk that the new ARVs would not work as well as the study ARVs.

[Sites should include for participants who are ART-experienced: Risk of switching ARVs

If [you are/your child is] switching to study ARVs from different anti-HIV medicines, there is a possibility that the study ARVs will not work as well as your [child's] current anti-HIV medicines. We will test the viral load during the study to check (see #8 above).*]*

21. There could be risks of disclosure of your [child's] information.

We will make every effort to keep your [child's] information private and confidential. Study records and specimens will be kept in secure locations. All specimens and most records will be labeled only with a code number. However, your [and your child's] names will be written on some records.

Despite our best efforts to keep your [child's] information private, it is possible that the information could be obtained by someone who should not have it. If this were to happen, [you/your child] could be treated badly or unfairly. You could feel stress or embarrassment.

[To be included at US sites:] To help us protect your [child's] privacy, we have obtained a Certificate of Confidentiality that protects us from being forced to release information that may identify [you/your child], such as by the courts or police. The certificate cannot be used in all situations, but it can be used to resist demands for information that would identify [you/your child]. The certificate does not protect against requests for information from the US federal government or from the US Food and Drug Administration. Regardless of the certificate, you can release information about your [child's] participation in the study to others, if you wish.

Benefits of the study

22. There may be no benefit to [you/your child from being in the study.

By joining the study, [you/your child] will be part of the search for ARVs that may be better for children. We do not know if being in the study will benefit [you/your child] in any way. There may be a direct benefit to [you/your child] by taking part in this study, but no guarantee can be made. For example, the study drugs may lower the amount of HIV in the blood. There may also be benefit if the results from this study lead to a safe and effective dose of the study drugs for children. It is also possible that [you/your child] may receive no direct benefit from this study. Information learned from this study may help other children who have HIV.

[You/Your child] will have regular visits here and frequent checks on your [child's] health, including tests for amount of HIV in your [child's] blood, called viral load, and for the amount of cells that fight HIV, called CD4. It is possible that the study ARVs will slow your [child's] HIV infection. Information learned from this study may help other children with HIV.

Other information about the study

23. There are no costs to you from [you/your child] being in the study.

There are no costs to you for study visits, study ARVs, or procedures.

[Insert information about compensation/reimbursement here, e.g., You will be reimbursed for the cost of transport to study visits. For each visit, you will be given (specify amount).*]*

24. Study records may be reviewed by study staff and groups that oversee the study.

Groups that oversee the study include:

- *[insert name of site IRB/EC]*
- *[insert name of site drug regulatory authority]*
- *[insert name of other site regulatory entities]*
- The United States National Institutes of Health and its study monitors
- The United States Food and Drug Administration
- The United States Office for Human Research Protections
- The IMPAACT Network that is coordinating the study
- Merck Ltd. (the company that makes the study ARVs)
- Other United States, local, and international regulatory entities

The study staff and these groups are required to keep study records private and confidential.

The results of the study may be presented publicly or published. However, no presentation or publication will not use your [child's] name or identify [you/your child] personally.

A description of this study will be available on ClinicalTrials.gov. This website will not include information that can identify you or your child. At most, the website will include a summary of the results. You can search this website at any time.

Your [child's] study information may be disclosed to other authorities if required by law.

25. If [you take/your child takes] any new medication or uses alcohol or recreational drugs, please inform your study doctor.

Some medications, including herbal medications, may make the ARVs not work as well or be less safe. Please let the study doctor know if [you start/your child starts] any new medicines. Use of alcohol or intravenous drugs may increase the risk of side effects from the ARVs. [Please discuss with the study doctor if [you are/your child is] using intravenous drugs or drinking alcohol].

26. If [you get/your child gets] sick or injured, contact us immediately.

Your [child's] health is important to us. We will make every effort to protect your [child's] well-being and minimize risks to [you/your child]. It is possible, however, that [you/your child] could have an illness or injury that is study-related. This means that the illness or injury occurred as a direct result of the study procedures.

[Sites may modify this paragraph to reflect local institutional policies; information regarding coverage available through clinical trial insurance obtained by the site should be included if applicable; the statement regarding no program for compensation through the NIH may not be removed.] If a study-related illness or injury occurs, we will treat [you/your child] or tell you were you can get the treatment your child needs. The cost for this treatment may be charged to you or your insurance company. There is no program for compensation either through *[site name or]* the National Institutes of Health.

Whom to contact

27. If you have questions, concerns, or problems at any time, use these contacts.

- If you have questions about the study:
  [insert name and telephone number of investigator or other study staff]

- If you have questions about your [child's] rights as research participants or concerns about how [you are/your child is] being treated in the study:
  [insert name and telephone number of IRB/EC contact person or other appropriate person/organization]

- If [you have/your child has] any health or other problems that may be related to study participation:
  [insert name and telephone number of investigator or other study staff]

- If you want [your child] to leave the study:
  [insert name and telephone number of investigator or other study staff]

Signatures

If you agree to [let your child] participate in this study, please sign or make your mark below.

Before deciding whether to [let your child] participate in this study, make sure you have read this form, or had it read to you, and that all your questions have been answered. You should feel that you understand the study, its risks and benefits, and what is expected of you [and your child] if you decide [allow your child] to join.

If you decide to [allow your child to] join, we will tell you any new information from this study or other studies that may affect your willingness [for your child] to stay in the study. You are welcome to ask questions or request more information at any time.

You do not give up any rights by signing this form.

[Insert signature blocks as required by site IRB/EC policies.]

Signature blocks for participants <u>below</u> legal age to provide independent informed consent

Participant Assent

_____	_____
Participant's Name (print)	Participant's Signature and Date

Parent/Guardian Consent

_____	_____
Parent/Guardian Name (print)	Parent/Guardian Signature and Date
_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature and Date
_____	_____
Witness's Name (print) (As appropriate)	Witness's Signature and Date

Signature page for participants of legal age to provide independent informed consent

_____	_____
Participant's Name (print)	Participant's Signature and Date
_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature and Date
_____	_____
Witness's Name (print) (As appropriate)	Witness's Signature and Date