Study Title: A Clinical Trial to Evaluate the Impact of Broadly Neutralizing Antibodies VRC01LS and 10-1074 on Maintenance of HIV Suppression in a Cohort of Early-Treated Children in Botswana

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Consent for Research Study of VRC01LS and 10-1074 to Maintain Viral Suppression version 3.0 dated May 19, 2020

A Clinical Trial to Evaluate the Impact of Broadly Neutralizing Antibodies VRC01LS and 10-1074 on Maintenance of HIV Suppression in a Cohort of Early-Treated Children in Botswana
(Dual bNAb Treatment in Children)

Consent for Research Study of VRC01LS and 10-1074 to Maintain Viral Suppression

1. INTRODUCTION

- Your child is being invited to take part in a research study. This study is sponsored by the National Institutes of Health (NIH) in the United States and is being done together by researchers at the Harvard T.H. Chan School of Public Health and the Botswana Harvard AIDS Institute Partnership (BHP). The investigators in charge of this study are Dr. Roger Shapiro and Dr. Joseph Makhema. The study will see if two experimental antibodies (called VRC01LS and 10-1074) can be given to your child to control the HIV virus without the need for other HIV medications for a limited period of time. VRC01LS has been given to children before; 10-1074 was given to 6 children in the first part of this study but has not yet been studied in other children. To decide whether or not you wish your child to take part in this study, you should understand its risks and benefits to make the best decision for you and your child.

- This consent form gives information about the research study, which the study team will discuss with you. Once you understand the study, and if you agree to allow your child to take part, we will ask you to sign this consent form and will offer you a copy to keep.

- It is important that you understand the following:

  - ✓ Your decision for your child's taking part in the study is completely voluntary.
  - ✓ You may refuse your child to take part in the study or leave it at any time without the loss of other benefits to you or your child.
  - ✓ Your decision to leave the study will not affect your/your child's future medical care or your ability to take part in other studies.

2. WHY IS THIS STUDY BEING DONE?

- Most adults and most children who are HIV infected need to stay on HIV medicines for their whole life, but sometimes those medicines have side effects or are difficult to take every day.
- Your child started HIV medicines very early in life and has responded well to treatment with 3 HIV medicines. This treatment has reduced the virus to very low levels in his/her body.
- This study is being done to see if children with very low levels of virus in their bodies might be able to safely receive the antibodies against HIV once each month instead of their other HIV medicines and remain with very low levels of HIV in their body.
- This study is also being done to learn about the dosing and levels of the antibodies when given to children.

3. OVERVIEW OF THE STUDY

- The study will enroll up to 36 children from the Early Infant Treatment (EIT) Study. All children in the study must have responded well to HIV medicines, with low viral levels in their cells and no recent return of virus or viral rebound while taking HIV medicines. Viral rebound is when the level of HIV in the body is at a low level but then rises to a level where it can be picked up on a blood test.
- Enrolled children will initially continue their usual HIV medicines and will also receive the 2 antibodies (VRC01LS and 10-1074). After 8 weeks of receiving both antibodies, if levels of virus stay low, the other HIV medicines will be stopped and the 2 antibodies will continue to be given each month for 24 weeks.
- Your child will be monitored very closely during the study, especially when receiving the 2 antibodies alone without other HIV medicines. At every study visit, we will test the level of virus in your child's blood, and we will re-start HIV medicines if the virus returns at a level above standard detection. We will monitor your child after re-starting the HIV medicines to be sure that the level goes down again to very low levels (below detection).
- As long as the virus does not return while your child is on antibody treatment alone, the antibody treatment will continue for 24 weeks. After 24 weeks the antibodies will be stopped and your child will re-start his/her usual HIV medicines. If the virus returns sooner, your child will stop the antibodies and re-start their HIV medications at that time.
- Additional study visits will occur through 56 weeks to make sure your child continues to do well and to continue to check the level of virus in his/her body.
- The first 6 children enrolled will have some extra study visits. These first 6 children will be in this part of the study for a longer time (68 weeks to likely no more than 84 weeks). This is to do some extra tests and checks to learn more about the safety and dosing of the antibodies at the beginning of the study.

4. WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

Enrollment / study entry

- If you choose for your child to take part in this study, we will draw blood and your child will start 2 antibodies at the first study visit. Your child's usual HIV medicines will still continue at that time, for 8 weeks.
- Antibodies will be given to your child by an experienced study nurse and physician by an intravenous infusion (also called an IV drip). This means the antibodies will go directly into the vein using a needle and a tube. One antibody will be given at a time. This will take about 30 minutes for each antibody. The IV will be removed at the end of the treatment visit.
- We will ask you to stay at the clinic for 2-4 hours after the first infusion to watch your child for any reaction. The first visit will take about 3-5 hours total.
- Blood will be drawn to measure the amount of HIV in your child's blood, called a viral load; the cells that fight infection, called the CD4; the amount of antibodies, and to perform safety measurements, called "full blood count" (FBC) and chemistry. Some blood also will be stored to perform specialized tests on the virus and to study your child's ability to fight

the virus. Some of these tests may study your child's genes. Genes contain information which is different for each person. This is done as a marker for your child's ability to fight the HIV virus.

- The total amount will be between about 2 and a half teaspoons (up to 12 mL) from your child.
- We may ask you some questions about your child's household, and yourself. You don't have to answer any questions you don't want to answer.
- Your child's records from the EIT study will be available to the study team, and this will make sure that everything known about your child's care in the EIT Study is also available for this research study.
- *Additional procedures for the first 6 children enrolled:* at the first and second infusion visits, blood will be drawn before the infusions, at the end of infusions, one hour later, one day later, and one week afterward. This is to check how the amount of antibodies in your child's blood changes over time.

Study visits

- At every study visit, we will ask questions about your child's health, and while he/she is on HIV medicines, we will always ask whether he/she received every dose of the medicines. We will also weigh your child and adjust the medication doses as needed. We will also perform a physical exam at each visit (except if your child attends an extra visit 1 day after an infusion).
- Study visits when antibodies are given will take about 2 hours, except for the first visit that takes about 3 hours. Other visits will take 30-45 minutes.
- You will receive transportation money and compensation for your time at each visit. If you request it (or if it is necessary for public health reasons during a Covid-19 outbreak), it may be possible to have some study visits at your home, or at a different location than the study clinic, but not when the antibody is given. We will talk to you in advance about any change in location. If necessary, some study visits may also be done by phone, text, or email, whichever you prefer. The study team may check in with you about your child by telephone between visits.

First 8 Weeks from the Start of Dual Antibody Therapy

- Study visits will occur 1 week, 4 weeks, 5 weeks, and 8 weeks after your child starts the study. VRC01LS and 10-1074 antibodies will be given each month. HIV medicines will continue until 8 weeks after both antibodies are started.
- At each visit, some blood will be drawn from your child to see if the antibodies have changed the levels of virus in the body. Tests include FBC and chemistry, CD4, viral load, tests to determine antibody levels, and stored blood for specialized tests to study your child's ability to fight the virus, which may include tests of your child's genes. Between about one-half and 2 and a half teaspoons of blood (2-12 mL) will be drawn at these visits.

- ***Additional procedures for the first 6 children enrolled:***

- There will be additional blood drawn at the first two infusions visits (before the infusion, at the end of the infusions, and one hour later). There will be an extra visit and blood draw the day after the first 2 infusions. At the Week 1 and Week 5 visits a small amount of additional blood will be drawn to check antibody levels.
- There will also be about 4 additional visits (possibly up to 12) while we check the results of the tests done so far. We will check for safety and dosing of the antibodies when given together during this time. These extra 4-12 visits will occur on a regular schedule, every 2 weeks until we have enough information to continue with the next step of the study.
- Your child may receive infusions once a month during this time. If there are delays caused by Covid-19 (for example, if the lab tests cannot be done on time, or if it is necessary to avoid lengthy clinic visits, we may temporarily stop the infusions until we can get back on the regular schedule. If that happens, we will still ask you to come to the clinic at least once every 12 weeks for a physical exam, blood tests, and antiretroviral medication refills. Tests are the same as at other study visits, and include FBC and chemistry, CD4, viral load, tests to determine antibody levels, and stored blood for specialized tests to study your child's ability to fight the virus. Between 1.5 to 2.5 teaspoons of blood (8-12mL) will be drawn at these clinic visits every 12 weeks. The other visits (every two weeks) can be done by phone if necessary. If your child's infusions were temporarily stopped: when we restart giving antibody infusions, your child will be given the antibody infusions two times, 4 weeks apart, before your child can move to or begin the next part of the study.

Weeks 8-32

- Study visits will occur every week for 4 weeks, then every two weeks for 24 weeks.
- VRC01LS and 10-1074 antibodies will continue to be given each month during weeks 8-32. Antibodies will usually be given by placing an IV in your child's arm, but could be in another place, like the leg, if necessary. This will take about 60 minutes. We will watch your child for any reactions for about 60 minutes after the infusion.
- Your child will stop taking other HIV medicines during this time. At each scheduled visit, some blood will be drawn from your child. These tests may include viral load, CD4, FBC and chemistry, drug and antibody levels, and stored blood for specialized tests to study the virus and your child's ability to fight the virus, which may include tests of your child's genes. About 1-2 teaspoons of blood (4-9 mL) will be drawn at these visits.
- Your child's usual HIV medicines will be re-started at the time of the last antibody treatment at the 32-week visit, or sooner if needed.

Weeks 33-56

- Your child will continue follow-up at the study clinic at 36, 48, and 56 weeks. At these visits, we will provide routine clinical care for your child. We may test viral load, CD4, FBC and chemistry and stored blood for specialized tests to study the virus and your child's ability to fight the virus, which may include tests of your child's genes. About 1.5-2 teaspoons of blood (7-10 mL) will be drawn at these visits.

Checking for return of virus (viral rebound)

- During the first part of the study when your child is taking HIV medicines and receiving the antibodies, we will check for virus in your child's blood once a month. If the level of virus

has risen above 40 copies during this part of the study, your child will stop receiving the antibodies. Your child will have a follow-up visit like the visits scheduled for the first 8 Weeks above, except no antibodies will be given. Then follow-up will occur at a new visit schedule with 3 more visits (one month, 3 months, and 6 months later).

- During follow up from 8-32 weeks, we will check for virus in your child's blood at every study visit by testing for viral load. The result of this test will not take more than a week to return, and in most cases it will be only a day or two. If the virus returns at a level where we think it will continue to rise (greater than or equal to 400 copies), your child will be asked to return so that HIV medicines can be re-started as soon as possible. If the virus returns at a low level (less than 400 copies, but at or above 40 copies), and we are not sure that it will continue to rise, we will have your child re-tested weekly; if this test is still positive at any level, we will re-start the HIV medicines.
- If your child goes back on HIV medicines early, we will see him/her every week until the virus is no longer detectable, and then follow-up will occur at a new visit schedule with 3 more visits (at Week 4, 12, and 24) after the virus is no longer detectable.
- We may test viral load, CD4, FBC and chemistry and stored blood for specialized tests to study the virus and your child's ability to fight the virus. About 1.5-2 teaspoons of blood (8-11 mL) will be drawn at these visits.

Test results

- Results of viral load, CD4, and other laboratory tests that check your child's health will be given to you at scheduled visits as soon as they are available. If a lab test result suggests a health problem we will let you know sooner than your next scheduled visit. Results of other tests that do not affect your child's clinical care will not be provided.

Stored samples and future tests

- If you agree (at the end of this consent form), some of your child's blood taken as part of this study will be stored for up to 10 years after the end of this study, for approved HIV-related research in the future. In most cases, we will use all of the blood drawn for the study tests. However, at some visits a small amount (generally less than half a teaspoon) of blood may be left over after testing occurs, and may be saved for future testing if needed. You can still take part in this study even if you decide to not allow your child's leftover samples to be stored for future approved research. No personal identifiers will be stored with the samples, so your child's identity will be protected in the usual way (see Section 12, Confidentiality of Records). Some of these samples may be shipped outside of Botswana, but only for specialized testing that is not available in Botswana. You may ask that samples be destroyed if you later change your mind and do not want us to keep them. You can request this at any visit, or after the study by calling Dr. Joseph Makhema (Tel: 3902671, Cell 72100846).

5. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

- Up to 36 children will take part in this study.

6. HOW LONG WILL MY CHILD BE IN THIS STUDY?

- Your child will be in this part of the study for up to 56 weeks (up to 84 weeks for the first 6 participants).

7. WHY WOULD THE STUDY INVESTIGATORS TAKE MY CHILD OFF THIS STUDY EARLY?

The study doctor may need to take your child off the study early without your permission if:

- the study is stopped or modified by the Botswana Ministry of Health, National Institutes of Health (NIH), the Food and Drug Administration (FDA), the United States Office of Human Research Protection (OHRP) and other government agencies, or the study Institutional Review Boards (IRBs). An IRB is a committee that watches over the safety and rights of research participants.
- the Study Monitoring Committee recommends that the study be stopped early. This committee, also known as the SMC, is made up of an outside group of experts who monitor the study.
- you are not able to attend the study visits as required by the study

The study investigators may also need to take your child off of the study without your permission if:

- continuing with the study is considered to be harmful to your child
- your child is not able to follow the procedures of the study

8. CAN MY CHILD LEAVE THE STUDY IF I CHANGE MY MIND?

- You may have your child leave the study at any time for any reason, and your child will still be given medical care at the hospital or government clinic of your choice (we will help arrange this if you want). Your child will be restarted on their HIV medications if they were stopped at the time you wish to leave the study. If you are willing we would like to schedule a final study visit and blood draw before your child leaves the study. If you leave the study, the data collected until that date will remain part of the study database.

9. WHAT ARE THE RISKS OF THE STUDY?

<u>RISKS OF VRC01LS and 10-1074</u>

- VRC01LS and 10-1074 are antibodies. Antibodies are made by the immune system to fight infection. Antibodies can also be made in laboratories. The antibodies used in the study are made in a laboratory. These antibodies are experimental. This means we do not know if they are safe to use in people. We also do not know if they are useful as treatment for HIV. Both have been tested in animals and people, including in HIV-positive people. We have given VRC01LS to 6 children and 10-1074 to 6 children in part of this study that has been completed. VRC01LS has also been used in children in other studies. The studies have had no safety concerns that were considered serious. The 6 children who received 10-1074 in the first part of this study did not have safety concerns that were considered serious, but there have not been other studies of 10-1074 in children yet. Both antibodies are being tested in more research studies to learn more about them, and this study will help us learn about VRC01LS and 10-1074 in children who have HIV.

    - <u>VRC01LS</u>

As of April 2017 VRC01LS had been tested in more than 30 adults. So far, there have been no serious side effects seen in the adults who have received VRC01LS. VRC01LS is being studied in babies now in another study in the United States, South Africa, and Zimbabwe.

VRC01LS is very similar to another experimental antibody called VCR01. As of January 2017, more than 800 HIV-negative and HIV-positive adults have received this very similar antibody in research studies in the United States, Botswana, Malawi, South Africa, Zimbabwe, and other countries. Some people had mild or moderate reactions like itchiness, redness, or swelling where VRC01 was injected. Some people felt tired or had mild body discomfort, muscle or joint pain, headache, chills, or nausea after receiving injections. Some people had hives (rash) while VRC01 was being given or soon after VRC01 was given. In some cases, the hives were severe. One person had chest discomfort and one fainted. Some people had abnormal results on tests of their blood cells, liver, or kidneys. These came back to normal after a few days or weeks.

Also, as of January 2017, at least 33 babies born to mothers who have HIV have received VRC01 in a study being done in the United States, South Africa, and Zimbabwe. Some of these babies had redness, swelling, or a small bruise where VRC01 was injected, which lasted for a short time. No other effects thought to be caused by VRC01 have been seen, and no serious health problems have occurred.

- <u>10-1074</u>

  This study is the first time that 10-1074 is being given to children, but as of August 2017, 10-1074 had been tested in 76 adults at different doses. So far, there have been no serious side effects seen in the research participants who have received 10-1074. Some people had a headache, cold symptoms, or felt tired. A few people had dry eyes, dizziness, abdominal pain, nausea, itchiness, or mildly abnormal results on tests of their liver.

- To watch for any possible reactions, children will be asked to stay in the clinic for at least 2 hours after the first antibody infusion, and at least 1 hour after later infusions. During this time, study staff will check for reactions to the infusion.

<u>RESISTANCE TO VRC01LS and 10-1074</u>

- It is possible that children who receive VRC01LS and 10-1074 in this study could develop "resistance" to the antibodies. If resistance develops, the antibodies may not be effective in helping to control your child's HIV. It isn't known whether this will have any effect on your child's health. This type of resistance has no impact on the ability of HIV medicines to control the virus.

<u>RISKS OF OTHER ANTIBODIES</u>

- Other antibodies that are different from VRC01LS and 10-1074 have been given to people for other illnesses. With those antibodies, most side effects happen within the first 24 hours including fever, chills, shaking, nausea, vomiting, pain, headache, dizziness, trouble

breathing, high or low blood pressure, itchiness, rash, hives, lip or face swelling, diarrhea, racing heartbeat or chest pain. Rarely, some antibodies have caused serious reactions that may be life-threatening.

- One type of serious reaction may occur soon after getting an antibody. It includes difficulty breathing possibly leading to low blood oxygen, low blood pressure, hives or rash, and swelling in the mouth and face. A second type of serious reaction may occur several days to 3 weeks after getting an antibody. It includes hives or a rash, fever, big lymph nodes, muscle and joint pains, kidney problems, chest discomfort and shortness of breath. Rarely antibodies used to treat other diseases have been linked to a blood disorder that interferes with blood clotting, cancer, damage to the heart muscle, and to the body's immune system attacking healthy cells.
- These rare side effects and reactions have not been seen in other studies of VRC01, VRC01LS, or 10-1074. However, it is possible that children in this study could have these types of reactions. Children could also have other side effects or reactions that we do not yet know about. We will closely check on children in this study for side effects and reactions. Please contact the study staff immediately if any of these problems or any other problems occur.

RISKS OF STOPPING HIV MEDICINES

- We think that some children (up to half) may have return of virus at some point after the HIV medicines are stopped, between week 8 and week 32. If virus does return, there is the risk that your child might become sick with fever, rash, and general weakness. However, we think this is unlikely as long as we re-start the HIV medicines as soon as virus is detectable. It is therefore important for you to bring your child to the clinic for each study visit while your child is off HIV medicines. You should bring your child to the clinic between study visits if he/she has fever, rash, or weakness while off his/her HIV medicines.
- If the virus returns, there is a small chance that the medicines your child was taking will no longer work when they are re-started. This would occur if the virus has become resistant to one or more of the medicines. Because we will re-start the medicines very quickly, we think the risk of resistance is very low. In the unlikely chance that resistance is detected or suspected, we will give your child other medicines approved by the Botswana National program instead.
- There is a small chance that a long period of viral rebound (the virus returning) could increase the amount of virus that is hidden in different parts of your child's body. We don't know if this could have an effect on treatment in the future of not. To prevent a long period of viral rebound, we will check your child's blood frequently.

RISKS OF TAKING BLOOD and IV INFUSION

- Taking blood may cause some discomfort, bleeding, or bruising where the needle pricks your child's skin, and in rare cases, fainting/feeling lightheaded or infection. A clot may form at the site of the needle prick.
- We will follow the guidance of experts to make sure that we do not take too much blood from your child when we are checking the virus and the safety of the medicines and storing blood for research. However, there is a small possibility that drawing blood might make a low blood count even worse, and that this would lead to the need for a blood transfusion for your child.

- VRC01LS and 10-1074 will be given as an infusion in to a vein. An IV infusion can cause stinging, itchiness, discomfort, pain, soreness, redness, bruising, swelling, or a small cut where the needle enters the skin. Rarely, needle sticks can cause infection.

RISK OF STIGMA

- We will try to protect the confidentiality of your/your child's HIV status. We will visit your home only if you have granted permission for this (and you may change your mind about this at any time). In all cases, home visits will be by health workers in plain clothes and in unmarked vehicles or on foot. If your/your child's HIV status were to become known or suspected because of your participation in this study, it is possible that the stigma of HIV could affect your personal relationships. This might cause you or your child stress. We will do everything possible to prevent this from happening, and confidential counseling also will be available to you through this clinic. You may feel uncomfortable answering study questions about yourself, your household, or income. You do not have to answer questions if you don't want to.

10. ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

We are doing this study to learn whether the antibodies being tested will work to keep your child's HIV levels low during the time off HIV medicines. This study will also learn whether and how the antibodies may affect your child's health. It is possible your child will benefit from some of the following things.

CARE IN THE STUDY

- Your child will see a doctor at every study visit, and he/she will have access to frequent testing and monitoring to help treat his/her HIV infection, and to treat other childhood illnesses. This monitoring includes viral load testing and CD4 testing that will allow us to monitor your child's health very closely, and to make medication adjustments very quickly if these are needed. These extra visits with a doctor, and the extra monitoring, might improve your child's health.

MONTHLY DOSING OF ANTIBODIES

- It may be easier for your child to receive monthly treatment rather than having to take 3 drugs every day. This may also be easier for you and other caregivers. However, this will only happen if your child's HIV levels stay low when the daily HIV medicines are stopped. Your child will need to re-start the HIV medicines and stop the monthly antibodies if his/her virus levels test high.

REDUCED TOXICITIES

- HIV medicines can have long-term toxicities. Long-term toxicities from HIV medicines can include effects on growth, bones, body shape, blood cells, kidney function, heart and blood vessels, and possibly brain development. If your child is able to remain off these medicines for up to 24 weeks, your child may experience fewer toxicities from HIV medicines, but we do not know if that will happen. Although this study cannot measure changes in most of these things, we will monitor your child's growth to see if it improves when off HIV medicines.

IMPROVED IMMUNE RESPONSE TO HIV

- It is possible that the anti-HIV antibodies being tested will help your child's immune system recognize HIV, and it may allow your child to fight HIV better. This might be important if your child stops taking HIV medicines in the future, because the HIV level might not get as high in the body. However, we do not know yet whether this will occur. This study and other studies will help us learn more about the potential for this to occur.

SCIENTIFIC KNOWLEDGE

- Knowledge gained from this study may help other children in the future. If children in this study are able to safely remain off HIV medicines, this may help make that option possible for other children in Botswana in the future.
- A description of this clinical trial will be available on ClinicalTrials.gov. This website will not include information that can identify you/your child. At most, the website will include a summary of the results. You can search this website at any time.

11. WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

Instead of being in this study you may choose not to allow your child take part in the study and your child will be cared for either within the EIT study, or at a government clinic which provides HIV treatment and care. We will refer you to that clinic and make sure your child is seen there.

12. WHAT ABOUT CONFIDENTIALITY?

We will do everything we can to keep your and your child's personal information confidential. We cannot guarantee complete confidentiality. Your or your child's personal information may be disclosed if required by law.

- Your child's medical records at this clinic or at a government clinic or hospital may be reviewed by the Botswana and Harvard T.H. Chan School of Public Health IRBs, the Botswana Ministry of Health, the U.S. National Institutes of Health (NIH); the U.S. Food and Drug Administration (FDA); the U.S. Office for Human Research Protections (OHRP); other local U.S. and international regulatory entities; study staff, and study monitors.
- Your child will be identified by a code number only known to you, the study team, or the health staff responsible for your child's care. All information about your child and the information you give about yourself will be identified by this number. The code will be stored in a secure location. You and your child will not be identified by name in any publication or presentation from this study.
- For purposes of the study, your child`s medical records may be photocopied when there is need. These copies will be kept safe and secure like other study records only accessed by authorized personnel.

13. HOW WILL MY/MY CHILD'S SAFETY BE PROTECTED?

- Your child will be followed throughout the study by the study staff. If any problems are found, VRC01LS and 10-1074 will be stopped if indicated to do so.
- A safety monitoring board will regularly review the safety of this study.
- Counseling services will be available for you if needed throughout the study.

14. WHAT ARE THE COSTS TO ME?

- There is no cost to you or your child for the antibodies, clinic visits or laboratory tests related to this study. All other medical examinations or tests and medicines outside of this study will be given to you either through the study clinic or at a government clinic or hospital.

15. WILL I RECEIVE ANY PAYMENT?

- You will receive no money for your child's participation in the study, but you will be given money for transportation costs to and from the clinic, and to compensate you for your time. Transportation costs will be discussed with you and provided as needed. The compensation for your time will be 150 Pula for each scheduled visit where antibody is given, and 100 Pula for other scheduled visits or for follow-up visits that are requested by the study staff. The amount is more for visits when antibody is given because these visits will take more time.

16. WHAT HAPPENS IF MY CHILD IS INJURED?

- Immediate, necessary care will be given to your child free of charge if he/she becomes injured due to taking part in this study. Our clinic has insurance to cover medical treatment in the case of a study-related injury. In rare cases the insurance funds may not be enough. The study sponsor (NIH) does not have a program to provide compensation for research related injury.

- If you are injured because of this study, you should contact:
  - ✓ Dr. Joseph Makhema: Tel: 3902671 Cell: 72100846

17. WHAT ARE MY CHILD`S RIGHTS AS A RESEARCH PARTICIPANT?

- Taking part in this study is completely voluntary. You may choose not to allow your child take part in this study or leave this study at any time. No matter what you decide, we will help your child receive the best possible HIV treatment available at a government clinic or at another clinic if this is possible.
- We will tell you about new information from this or other studies that may affect your child's health, well-being, or willingness to stay in this study. When the study ends, the results will be available from the study staff or clinic.

18. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

- If you have any questions about this study or your child`s rights as a participant, either while participating or after you have completed the study, you should contact:

  - ✓ Dr. Joseph Makhema (for study-related questions): Tel: 3902671 Cell: 72100846
  - ✓ The Chief Research Officer at Botswana Ministry of Health (for rights as a participant): Tel: 3632775

Overall Study Participation

The purpose of the study, procedures to be followed, and risks and benefits have been explained to me. By signing or placing my fingerprint below, I am agreeing for my child to participate in this study. I also understand that study staff may ask me some questions about my child's household and about myself. I also give consent for Botswana Harvard Partnership study staff to access and use the information in my child's medical records if needed for the purposes of the study, and all records from the EIT study. I understand that this may involve photocopying any of my child's medical records relevant to this study. I understand that I may withdraw my child's participation at any time without affecting my rights or those of my child to receive medical care.

Parent/guardian's name (first-last):_____

Parent/guardian's Omang / Passport number: ☐☐☐☐☐☐☐☐☐

OR Parent/guardian's Omang receipt number: ☐☐☐☐☐☐☐☐☐

Signature or thumbprint of the Parent/guardian: _____

Date of Parent/guardian's signature:____/____/____ (dd/mm/yy)

Time of Parent/guardian's signature: ___ ___ : ___ ___ hours

Consent for Storage and Use of Blood Specimens

The purpose of storing and potentially using blood samples from my child has been explained to me. I understand that remaining leftover samples of my child's blood obtained in the course of this study may be stored for up to 10 years after the end of the study in the laboratories where the samples for the study were tested (in the Botswana Harvard Partnership laboratory whenever possible, or in Boston when specialized testing for the study was required). These samples may be used for HIV-related research in the future if such research is permitted by Botswana and Harvard ethical review boards. I understand that these specimens will contain no personal identifiers. I also understand that I may ask for my child's stored samples to be destroyed, if I later change my mind, by notifying a staff member during any study visit or, if I change my mind after the end of the study, by contacting Dr. Joseph Makhema (Tel: 3902671, Cell 72100846). I understand that my child can still take part in this research even if I do not agree to store my child's leftover samples for future approved research. By signing below, I agree to store samples for future approved health research (note: if this is not signed, it indicates that permission was not given to store samples for this purpose).

Signature or fingerprint of the Parent/guardian:_____

Date of Parent/guardian's signature:____/____/____ (dd/mm/yy)

Time of Parent/guardian's signature: ___ ___ : ___ ___ hours

Witness (*for use if a* **Parent/guardian** *is illiterate, in addition to the* **Parent/guardian's** *thumbprint)*
The purpose of this study and the procedures, risks and benefits to her child have been explained to the parent/guardian. To the best of my knowledge she/he understands the purpose, procedure, risks and benefits to her/his child.

Witness's signature_____

Witness's name (first - last) _____

Date of signature ____/____/____ (dd/mm/yy)

Time of signature: ___ ___ : ___ ___ hours

I have explained the purpose of the study to the participant's parent/guardian. To the best of my knowledge, she/he understands the purpose, procedures, risks and benefits to her/his child.

Study Staff name: _____

Study Staff signature: _____

Date of signature ____/____/____ (dd/mm/yy)

Time of signature: ___ ___ : ___ ___ hours