Official Title:	A Phase I Study of Subcutaneous Rituximab Hyaluronidase Combined With Local Standard-of-Care Chemotherapy for the Treatment of Burkitt Lymphoma, Diffuse Large B-Cell Lymphoma or as Monotherapy for Kaposi Sarcoma Herpesvirus Associated Multicentric Castleman Disease in Pediatrics and Adults in Uganda
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Fred Hutchinson Cancer Research Center | Uganda Cancer Institute

Study Informed Consent Form

A Phase I Study of Subcutaneous Rituximab Hyaluronidase Combined with Local Standard-of-Care Chemotherapy for the Treatment of Burkitt Lymphoma, Diffuse Large B-Cell Lymphoma or as Monotherapy for Kaposi Sarcoma Herpesvirus Associated Multicentric Castleman Disease in Pediatrics and Adults in Uganda

Diffuse Large B-Cell Lymphoma (DLBCL) Adult English ICF

1.PRINCIPAL INVESTIGATORS

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2. INTRODUCTION

We are asking you to participate in a research study because you have a disease called *diffuse large B-cell lymphoma*, a fast-growing cancer of the immune system.

Receiving treatment in a research study has some differences from standard of care treatment. The purpose of a research study is to answer scientific questions.

This consent form will give you information to help you decide whether joining the study is right for you. Please read this form carefully. We can read it with you if you want. If you do not understand, ask us questions. Also, you can talk to people whom you trust to help you decide about joining the study.

If you agree to join, you will sign your name with your signature/thumbprint on this form. We will offer you a copy of this form to keep.

This study is sponsored by the Fred Hutchinson Cancer Research Center and Roche.

3. PURPOSE OF THE STUDY

Rituximab belongs to a class of drugs called monoclonal antibodies. A monoclonal antibody is a type of protein made in the laboratory that can bind to substances in the body, including cancer cells. Rituximab binds to a protein called CD20, which is found on B-cells, and may kill cancer cells.
This type of treatment has been approved for the treatment of lymphoma in the United States, Europe, among other countries, and it is registered in Uganda by the National Drug Authority (NDA), but it has not yet been evaluated in people in East Africa, therefore, this is an investigational study.
In this study, we want to learn:

- the best way to administer Rituximab.
- how much Rituximab can be administered safely?

There will be two treatment groups. If you are in group 1 you will receive the first cycle of Rituximab through a tube inserted into the vein, and for all other cycles you will receive Rituximab as injections given under the skin. If you are in group 2, you will receive all doses as injections given under the skin. We will watch carefully for any side effects.

The purpose of this study is to evaluate the safety and how well the body can tolerate Rituximab administered under the skin in combination with standard (chemotherapy) in pediatrics, and adults with DLBCL in Uganda, when administered with a site specific supportive care.

4. NUMBER OF PARTICIPANTS

About 40 people will be enrolled into this study.

5. STUDY DURATION

If you join this study, you could be in it for about 15 months.

6.STUDY VISITS

If you join this study, we will ask you to come to the clinic for up to 15 months.

The visits are:

- **Screening visit.** This will take about 2 to 3 hours.
- **Enrollment visit.** This takes about 1-2 hours.
- **Treatment Visits** (Cycle 1 –Cycle 6)**.** This will take 3 to 4 hours.
- **End of treatment visit:** This will take about 1-2hours.
- **Follow-up study visits.** These take about 1 hour.
- **Off study visit:** This will take about 1 hour.

You will come to the Uganda Cancer Institute (UCI) for these visits and we will reimburse you for your travel expenses. We will give you USH 20,000 for transport costs at each visit but if your transport costs exceed USH 20,000, we will pay you the full amount. We will also give you refreshments (a soft drink and a bite) each time you visit the clinic. We will also give you refreshments each time you visit the clinic.

7.STUDY PROCEDURES

Screening visit:

The first visit will be a screening visit to see if you are eligible to join the study. Once you sign the informed consent form for this study, and you are a female of child bearing age, a urine sample will be collected for a pregnancy test.

The other procedures are standard-of-care. We shall collect this data from your UCI medical chart and from evaluations by study doctors and nurses, and from required blood draws:

- Medical history, (information about your health)
- Physical exam, (examination of your body)
- Demographics, (information about your age, sex, where you stay etc.)
- Medications you are currently taking;
- Chest X-Ray results, laboratory results – including HIV testing, examination findings of tissue removed from the body (biopsy), and infectious disease results.

These test results will let the study doctors know if this study is appropriate for you.

Enrollment visit:

If you are a female of childbearing age, we will collect a urine sample for a pregnancy test prior to starting treatment.

We will ask you if you are having any cancer symptoms.

If you provide consent for the correlative studies described below in section #20, we will also evaluate a specimen of stool that will be collected with a small soft brush to look at the types of bacteria living in your gut. Additionally,

- We will collect up to 25.5 mls (5 teaspoons) of blood for Kaposi sarcoma herpesvirus (KSHV)/Epstein Barr virus (EBV) viral load testing.
- And/or 25.5 mls (5 teaspoons) of blood for future studies.

The other procedures are part of standard-of-care. We will collect this data from your UCI medical chart and from evaluation by study doctors and nurses, and from required blood draws:

- CT scan of the head, neck, chest, abdomen and pelvis results;

- Lumbar puncture (a procedure in which a thin needle called a spinal needle is put into the lower part of the spinal column to collect cerebrospinal fluid or to give drugs) results;
- History and physical exam results;
- Clinical disease assessment/staging (the extent of a disease e.g. cancer, in the body);
- And bone marrow results.

In some cases, your doctor may tell you that you need a "lumbar puncture" to see if you have lymphoma affecting your brain.

Treatment Visits

1; Day 1

During this cycle, you will be given Rituximab per dose level together with Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) on day 1 and continue with Prednisone for 4 more days. Cyclophosphamide, Doxorubicin, and Vincristine will be given as a liquid substance injected into your vein. You will take Prednisone orally on days 1-5 of each cycle.

You will be provided with a medical diary to write the dates and times you took Prednisone. You will bring this medical diary to every study visit. The study staff will go over this diary with you.

You will also be given medicines the spinal canal to help prevent cancer from getting into the brain as is done as part of UCI standard of care.

You will be admitted to the inpatient ward during the administration of the first dose of Rituximab to monitor you for any delayed adverse events (AEs) related to Rituximab. For other doses of Rituximab, you may receive Rituximab as outpatients and be discharged home if you have not experienced Adverse Events related to Rituximab.

We will ask you about your medication that you are currently taking and if you have had any AEs.
Up to 10 mls (about 2 teaspoons) of blood will be collected to determine how much of the Rituximab drug is in your body.

The other procedures are standard of care: we will collect this data from your UCI medical chart and from evaluation by study doctors and nurses, and from required blood draws: laboratory results, clinical disease assessment/staging; history and physical exam.

Cycle 1: Day 2

The procedures done at Cycle 1 day 2 are UCI standard of care. We will collect this data (medial information) from your UCI care chart including laboratory results.

Cycle 1; Day 3

The procedures done at cycle 1 day 3 are UCI standard of care. We will collect this data (medical information) from your UCI medical chart: chemistry and laboratory results.

Cycle 2, 3, 4, 5 & 6 day 1

If you are a female you will take a urine pregnancy test prior to starting treatment.

You will be given Rituximab and standard of care CHOP. – (an abbreviation for the four medicines – Cyclophosphamide, Hydroxy doxorubicin, Oncovin (VinCRISTine), Prednisone)

Up to 10 mls (2 teaspoons) of blood will be collected to determine how much Rituximab is in your body.

We will ask you what medication you are currently taking and if you are experiencing any Adverse Events (any illness).

The other procedures are standard of care: We will collect this data from your UCI medical chart and from evaluation by study doctors and nurses, and from required blood draws: your medical and physical exam, and all laboratory results.

End of treatment visit:

We will ask you what medication you are currently taking and ask about any Adverse Events (any illness) you might be experiencing.

If you provide consent for the correlative studies described below in section #20 we will also test a specimen of stool that will be collected with a small soft brush to look at your microbiome (the types of bacteria living in your gut). Additionally, we will collect up to 25.5 mls (5 teaspoons) of blood to test for Kaposi sarcoma herpesvirus (KSHV)/Epstein Barr virus (EBV) viral load testing and/or 25.5 mls (5 teaspoons) of blood for future studies.

The other procedures are. standard of care: We will collect this data (medical information) from your UCI medical chart and from evaluation by study doctors and nurses, and from required blood draws: your medical history and physical exam, demographics, clinical disease assessment/staging, all laboratory results including HIV testing, lumbar puncture results, bone marrow results, and results of your CT of the head, neck, abdomen and pelvis.

Follow up visit After the 6 Cycles:

We will ask you what medication you are currently taking and ask about any adverse events (any illness) you are experiencing.

If you provide consent for the correlative studies described below in section #20 we will also evaluate a specimen of stool that will be collected with a small brush to look at your microbiome (the types of bacteria living in your gut). Additionally, we will collect up to 25.5 mls (5 teaspoons) of blood for Kaposi sarcoma herpesvirus (KSHV)/Epstein Barr virus (EBV) viral load testing and/or 25.5 mls (5 teaspoons) of blood for future studies.

The other procedures are standard of care: We will collect this data (medical information) from your UCI medical chart and from evaluation by study doctors and nurses, and from required blood draws: your medical history and physical exam, clinical disease assessment/staging, and all laboratory results.

Off study visit:

We will ask you what drugs you are currently taking and ask about any adverse events (any illness) you are experiencing.

If you provide consent for the correlative study as described below in section 20, we will also evaluate a specimen of stool that will be collected with a small soft cotton brush to evaluate the types of bacteria living in your gut (microbiome). Additionally, we will collect up to 25.5 mls (5 teaspoons) of blood for Kaposi sarcoma herpesvirus (KSHV)/Epstein Barr virus (EBV) viral load testing and/or 25.5 mls (5 teaspoons) of blood for future studies.

The other procedures are standard of care: We will collect this data (medical Information) from your UCI medical chart and from evaluation by study doctors and nurses, and from required blood draws: your medical history and physical exam, clinical disease assessment/staging, and all laboratory results including HIV testing.

The goal of this study is to treat your lymphoma with up to 6 doses of rituximab combined with chemotherapy. If your lymphoma is not controlled during this study or comes back after completing all the study drug cycles, the study doctors will refer you to the UCI doctors for other possible alternative treatment other than rituximab.

8. INFORMATION ABOUT YOUR BLOOD, CELEBRAL SPINAL FLUID AND TUMOR SAMPLE

We will test your samples collected in this study. We will send your samples without your name to laboratories in Uganda and the United States that are approved by the principal investigators. Researchers at these laboratories will test your samples to learn about cancer, infections, and how your body fights diseases.

9. POSSIBLE RISKS OF STUDY PARTICIPATION

Risks of blood draws:

Blood drawing may cause pain and bruising. It is rare, but sometimes infection can occur on the arm where the blood is taken. Also, people can feel lightheaded or even faint with blood draws. Although we are taking no more than 10 ml (2 teaspoons) of blood while you are receiving therapy to measure Rituximab in your body and no more than 51mls (10.5 teaspoons) of blood from you for research purposes at each of the 4 visits over one year, you could develop temporary anemia (a low blood count). Please tell us if you are in or become involved in another study or have a medical procedure where blood is drawn.

Rituximab risks include:

Common, some may be serious (Occurring in more than 20 out of 100 of participants)

- Pain at the injection site, with or without redness
- Nausea
- Reaction during or following injection of the drug (Reactions may include fever, chills, shivering, headache, vomiting, reddening, difficulty in breathing, pain at the administration/injection site, swelling, running rose, palpations, tiredness. Reactions can be treated and are usually temporary.)
- Infection, especially when one has reduced number of white blood cells.
- Numbness and tingling of the arms and legs
- Tiredness

Occasional, some may be serious (Occurring in 4 - 20 out of 100 of participants)

- Anemia which may require blood transfusions
- Bruising, bleeding
- Abnormal heartbeat
- Heart attack or heart failure which may cause shortness of breath, swelling of ankles, and tiredness
- Sores in eye
- A tear or a hole in the stomach that may require surgery
- Diarrhea, vomiting
- Pain
- Swelling of the body
- Hepatitis (liver disease) which may cause yellow eyes and skin
- Dizziness, headache
- Kidney damage which may require dialysis
- Cough
- Stuffy nose
- Sore throat
- Scarring of the lungs
- Blockage of internal organs which may cause shortness of breath, wheezing, vomiting
- Bowel obstruction, (a functional obstruction of the intestines which prevents the normal movement of the products of digestion)
- Increased sweating
- Itching, rash, blisters on the skin
- Severe skin rash with blisters and peeling which can involve mouth and other parts of the body
- Low or high blood pressure (which may cause feeling faint)

Occasional, some may be serious (Occurring in 4 - 20 out of 100 of participants)

Rare, but serious (< 3 out of 100 of participants)
• A rare and usually fatal viral disease characterized by progressive damage or inflammation of the white matter of the brain at multiple locations (progressive multifocal leukoencephalopathy) • Heart stops beating

CHOP risks include:

Likely: (Occurring in more than 20 out of 100 of participants)	
• Lowered white blood cell count that may lead to infection. • Lowered platelets (tiny, disc-shaped piece of cell that is found in blood) which may lead to an increase in bruising or bleeding. • Lowered red blood cells which may cause anemia, tiredness, or shortness of breath. • Should low counts occur, they can be treated with blood products (transfusions), antibiotics, and there may be a reduction in the amount of drug given to you. • Constipation.	• Fatigue or tiredness. Tingling of fingers and/or toes. • Hair loss. • Fever and/or chills. • Urine colored red for a day or two after the doxorubicin infusion. • Fingernail and toenail changes. • Tearing or dry eyes. • Runny nose. • Bony pain.

Less Likely: (Occurring in 4 - 20 out of 100 of participants)	
• Nausea and/or vomiting. • Loss of appetite, change in taste and weight loss. • Headaches. • Muscle aches and muscle weakness. • Hoarseness or pain in the jaw. • Elevated blood sugar levels. • Elevated or decreased blood pressure. • Confusion. • Mouth & throat sores. Temporary irritation to the mouth may lead to mouth ulcers (similar to canker sores). Medications to numb the mouth may ease the mouth discomfort.	• Stomach ulcers. • Skin rashes and/or dry skin. • Loss of control of muscles or reflexes. • Abnormalities in blood results such as elevated liver enzymes, low blood protein and low blood calcium. • Mood changes such as agitation or depression. • Trouble sleeping.

Rare, but serious: (in less than 3 out of 100 of participants)	
• Severe constipation may result in abdominal pain and cramping. • A tear in the large or small bowel • Bladder irritation with painful and bloody urine. • Damage to the heart muscle. • Skin rash that may be serious and life-threatening.	• Allergic reaction that may be severe or life-threatening. Symptoms may include difficulty breathing, low blood pressure, fast heart rate, and sweating. • Severe neutropenia (*a condition in which there is a lower-than-normal number of neutrophils (a type of white blood cell) in the blood*) and associated infections have previously resulted in death in R-CHOP regimens.

Reproductive risks

Receiving the chemotherapy, CHOP, creates risk for an unborn baby or nursing infant. Taking Rituximab may involve unknown risks to an unborn baby or nursing infant. Therefore, you cannot join this study if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding.

If you join this study, you would have to use an effective method of family planning from the time this form is signed until at least 12 months after the last dose of Rituximab. If you are already using a method of family planning, you would have to check with the study doctor or a member of the study staff to make sure it is acceptable.

If you became pregnant after joining this study, you would have to notify the study doctor immediately. You will be stopped by the study doctor from taking part in this study.

The effects of fathering a child are also unknown. Men who join this study must also agree to use one or more forms of effective and acceptable family planning methods from the time this form is signed until at least 6 months after the last dose of Rituximab.

Risks of being asked questions:

You may feel uncomfortable answering some of the questions we ask. You can refuse to answer any question.

Risks of waiting for and receiving test results:

It can be stressful to be tested for HIV. You may have stress or anxiety to find out that you have HIV. By having HIV, you could face discrimination and other problems from people outside of the study. If you have HIV, we will encourage you to tell your sexual partner(s). Sometimes partners get angry when they learn that their partner is HIV-positive. We will give you counseling to help you with this situation.

Risks of body examination

You may feel embarrassed during the physical exam. You may request that the physical exam be done by a medical doctor of the same gender.

Risks of disclosure of your personal information:

We will do our best to protect your personal information. Although the risk is very low, it is possible that personal information about you could be given to someone who should not have it. If that happened, you could face discrimination, stress, and embarrassment. We will tell you about how we will protect your personal information below.

10. POSSIBLE BENEFITS OF STUDY PARTICIPATION

Rituximab has been shown to benefit patients with Diffuse Large B Cell Lymphoma (DLBCL) when used in the United States and Europe. However, its use in East Africa has not been tested, and the doses used in this study have minor differences from those used in the United States. One possible benefit is that the combination of Rituximab and standard of care CHOP might result in improved disease control and survival. However, it is possible that you may not directly benefit from being in this study but the information we learn in this study may help others in sub-Saharan Africa and other countries in future with Diffuse Large B Cell Lymphoma (DLBCL)

11. ALTERNATIVES TO TAKING PART IN THIS RESEARCH STUDY

You do not have to join this study if you do not want; you will continue to receive treatment under UCI outside of this study. You have other choices. These choices have risks and benefits.

- You could join a different study.
- Alternative treatment, (discuss with your UCI doctor)

The study doctor or your own doctor can give you more information about these choices.

12.CONFIDENTIALITY

We will do our best to protect your privacy. We will label all your samples and your study records with a code number, your name will not be used or other personal information. However, we may have to release personal information if the law requires us to do so. If we give your personal information to others, we will tell you through your contacts – e.g. telephone.

Some people can look at your study records. These include:

- Staff from the Fred Hutchinson Cancer Research Center (FHCRC) Institutional Review Board (IRB), Uganda Cancer Institute Research Ethic Committee (UCIREC), National Drug Authority (NDA) and the Uganda National Council for Science and Technology (UNCST).
- Study staff and Roche (The pharmaceutical company providing us with Rituximab) and
- Staff from the United States Office for Human Research Protections

People who may look at your study records will keep them private.

We will publish the study results but we will not include any personal information about you in the publications.

13. VOLUNTARY PARTICIPATION

Study participation is voluntary. You can say yes or no. If you say no, nothing bad will happen. You will still get treatment from the UCI. You can join and then change your mind to leave the study You will still get good medical care at the UCI.. Please tell us when you decide to leave the study.

14. REASONS FOR REMOVING YOU FROM THE STUDY WITHOUT YOUR CONSENT

We may take you off the study early without your permission. We would do this if:

- The study is cancelled by the study sponsor or by FHCRC, UCIREC, NDA, or UNCST.
- You are not able to attend the study visits.
- You do not follow study instructions.
- If your standard of care doctor feels it is not in your best interest to stay on the study
- If for some reason you cannot adhere to the study procedures.

15. NEW FINDINGS

If we learn something that may change how you feel about staying in the study, we will tell you. When the study ends, we will tell you how you can learn about the results. Some study results may not be available for several years.

16. OTHER RESEARCH USING YOUR SAMPLES AND LIMITED INFORMATION

We will review with you a separate consent form that will explain the possibility of other research using your samples and limited information. You can decide not to allow us to use your samples and limited information for other studies and still be in this study.

17. COST TO YOU

There is no cost to you for taking part in this study. You do not have to pay for the study visits, examinations, or laboratory tests that are part of the study. However, all other medical costs outside of this study will be paid by you or your health insurance (if you have insurance).

18. RESEARCH-RELATED INJURY

While we believe you will not be injured by joining this study, if you get sick or injured during the study, contact us immediately. We will tell you about the care that we can give here. For the care that we cannot provide, we will explain how you can get care elsewhere.

There is a process to decide if your sickness or injury is related to study procedures. If it is, we call it a study-related injury. Some injuries are not physical. For example, you might be harmed emotionally by being in this study. Or you might lose wages because you cannot go to work.

If your physical injury is severe and directly related to your taking part in this study, we have secured insurance that will be able to treat and/or compensate you.

The study will not be able to treat you or compensate you for non-physical injuries or injuries that are deemed not study related. If the injury is not study-related, then you will be responsible for treatment costs. You will not be giving up any of your legal rights by signing this consent form.

You can call Dr. Ddungu the lead study PI at 0772 426 806 or Dr. Kambugu the Co- investigator at 0790 501 117 if you have any questions or concerns.

19. RELEASE OF YOUR MEDICAL RECORDS TO STUDY STAFF

We will need to see and make a copy of your medical records to get information about your medical history, physical exam, demographics and medications you are currently taking, chest x-ray results, laboratory results, biopsy results, and infectious disease results.

20. CORRELATIVE STUDIES

A correlative study is a type of study that tests for a relationship between a condition and a potential causal factor of the condition.

The collection of all the microorganisms and viruses that live in the gut is referred to as the **gut microbiome**. People have different bacteria in the gut, and this can be related to your health. We will also evaluate the bacteria in your gut (*stool microbiome*). The type of bacteria in your stool may be related to disease status.

We will evaluate the relationship between the bacteria in your gut and your lymphoma. We will look at differences in gut microbiome between HIV+ and HIV negative participants. When microbiome studies are completed, we will put the information from the studies into a protected database so that other researchers can access it. The other researchers may use the information to learn about other diseases.

You or your child will collect anal swabs using a small wad of cotton on the end of a short rod, figure 1) to collect a sample from the anus at baseline, at 6 month and 12 months follow ups.

Figure 1: Laboratory cotton swab

I agree to participate in this gut microbiome correlative study.

☐ Yes *Initials: _____ ☐ No *Initials: _____

*For participants unable to read or write, place your right thumbprint besides your decision unless otherwise indicated.

We would like to collect up to 25.5 mls (about 5 teaspoons) of blood to test for Epstein Barr Virus (EBV) and Kaposi sarcoma herpesvirus (KSHV) viral load kinetics after rituximab-based therapy at each time point listed below. EBV and KSHV are herpes viruses. We are looking at possible cancer-causing viruses before and after treatment. Blood will be collected at baseline, end of therapy, and at six months and 12 months follow up visits. We will look at changes from baseline Rituximab treatment to 1 year after starting treatment regimen.

I agree to participate in this EBV/KSHV correlative study.

☐ Yes *Initials: _____ ☐ No *Initials: _____

*For participants unable to read or write, place your right thumbprint besides your decision unless otherwise indicated.

I agree to allow my blood to be stored for future studies related to my lymphoma.

☐ Yes *Initials: _____ ☐ No *Initials: _____

*For participants unable to read or write, place your right thumbprint besides your decision unless otherwise indicated.

21. CONTACTING YOU DURING THE STUDY

If you miss a study visit, we will try to contact you by phone or by visiting your home. If we visit your home, we will come in an unmarked vehicle to protect your privacy. You may choose not to have someone from our research team visit your home. Please indicate your decision below to tell us what you would like.

I agree that study staff can come to my home if I miss a study visit.

☐ Yes *Initials: _____ ☐ No *Initials: _____

*For participants unable to read or write, place your right thumbprint besides your decision unless otherwise indicated.

If the participants checks "No" they will be reached on phone.

22. FUTURE CONTACT

We may want to contact you in the future. We may find new information about DLBCL. Also, we may want to tell you about other research studies you may want to join. Please indicate your decision below to tell us what you would like.

I agree you can contact me in the future.

☐ Yes *Initials: _____ ☐ No *Initials: _____

* For participants unable to read or write, place your right thumbprint besides your decision unless otherwise indicated.

23. QUESTIONS

If you have any other questions, please ask us. In the future, if you have any questions about this study, contact:

- Dr. Ddungu at 0772 426 806 or Dr. Kambugu at 0790501117.
- For questions about your rights as a research subject or if you feel you have been harmed by the research, contact:

  UCI IRB's Committee Chair, Dr. David Kyaddondo,

  - Tel: +256-772-410-806,
  - Mail: Uganda Cancer Institute, Upper Mulago Road, P.O Box 3935, Kampala - Uganda, or,
    Email: kyaddondo@hotmail.com or kyaddondo@chdc.mak.ac.ug
- FHCRC's Institutional Review Office Director, Karen Hansen, Tel: 000-1-206-667-4867.

We will also give you a card with a 24-hour study phone number to call in case of any inquiries/emergencies.

24.ETHICAL APPROVAL

This document has been approved and stamped by Uganda Cancer Institute Research and Ethics Committee. (UCIREC)

25. PARTICIPANT'S STATEMENT & SIGNATURE OR THUMBPRINT

The study described above has been explained to me. I agree to join the study. I have had a chance to ask questions. Study staff has told me that if I have future questions about the research, I can ask one of the contacts listed above. By signing this form, I do not give up any rights that I have as a research participant.

If you have read this consent form or had it explained to you and you understand it, please print your name and signature/thumbprint below.

Participant's Printed Name	Participant's Signature/Thumbprint	Date (dd-MMM-yyyy)

For participants unable to read or write, study staff should write their name and date of consent on the appropriate lines in the box below:

Participant's name (printed by study staff)		**Date** (dd-MMM-yyyy)
Witness's name (print)	**Witness's signature**	**Date** (dd-MMM-yyyy)

26. STUDY STAFF SIGNATURE

Study staff conducting consent discussion (print)	**Study staff signature**	**Date** (dd-MMM-yyyy)