PARTICIPANT INFORMATION AND INFORMED CONSENT

STUDY TITLE: AntiRetroviral Therapy In Second-line: investigating Tenofovir-lamivudine-dolutegravir (ARTIST) Stage 2: a randomised controlled trial

Participant ID	A	R	T				Participant Initials			

Introduction

You are invited to take part in this study. You should understand the research before you agree to join the study. This form will explain the reason for the research, what you will need to do, and any risks or benefits. Please read this information carefully.

Taking part in this study is your choice. You are free to leave the study at any time. If you decide not to take part, or to leave the study, your rights will not be affected in any way. You will be treated in the same manner as before at this clinic and other health care facilities now and in the future.

About the study

Patients who are infected with HIV (the "Human Immunodeficiency Virus") can be treated and kept healthy by taking medicine called antiretroviral treatment (ARV) every day, which is usually a combination of three different types of ARVs. Each one of these ARVs treats HIV in a slightly different manner to avoid the virus becoming resistant to one of the drugs on its own. Resistance to one or more ARVs may cause the medicine to become ineffective. Different ARVs can be combined into single tablets to decrease the amount of pills a patient must take. In South Africa the first choice (or first-line) of ARVs has been a single daily pill fixed dose combination (FDC) of tenofovir disoproxil fumarate, emtricitabine, and efavirenz; the combination of all three can be abbreviated as "TXE". Some patients have taken a combination of tenofovir disproxil fumarate, emtricitabine or lamivudine, and nevirapine as first line; the combination can be abbreviated as "TXN". HIV can easily become resistant to TXE or TXN if someone takes their ARVs irregularly, and their treatment must then be changed to second-line ARVs. This has until recently included a combination tablet of zidovudine and lamivudine (which is almost exactly the same as emtricitabine) taken twice daily, as well as lopinavir/ritonavir (known as Aluvia). Lopinavir/ritonavir is taken as two tablets twice daily, and often causes unpleasant side-effects like diarrhoea.

A new ARV called dolutegravir has much less chance of causing side-effects than lopinavir/ritonavir, and acts faster to suppress (decrease to almost zero) the level of HIV (viral load) in the blood. Therefore, many patients who need to switch to second line ARVs are now getting a single dolutegravir pill (instead of lopinavir/ritonavir) once daily, along with the twice daily tablet containing zidovudine and

lamivudine (the combination of the three is abbreviated "ALD"). Zidovudine is given as part of second-line treatment because HIV often becomes resistant to tenofovir when a person takes their first line treatment irregularly. Zidovudine may also commonly cause side-effects like nausea and low blood cell counts.

Recent studies have shown, however, that if a person gets dolutegravir as part of their second-line treatment, it might be possible to avoid having to take zidovudine by continuing with tenofovir, even if HIV has become resistant to it. The advantages are fewer side-effects, and the fact that there is a fixed dose combination tablet available containing tenofovir, lamivudine and dolutegravir (abbreviated "TLD"), which only has to be taken once daily.

When patients on first-line with efavirenz are switched to TLD, efavirenz stays in the blood for a few weeks. Efavirenz interacts with dolutegravir, resulting in less dolutegravir in the blood when dolutegravir is started. This could cause the HIV virus to become resistant to dolutegravir and lead to an increased HIV viral load – we do not know if this will happen. The problem of low dolutegravir level in the blood when a patient switched to TLD after efavirenz can be overcome by adding an extra 50 mg to the regular dose of dolutegravir for the first 14 days.

Why is this study being done?

In this study we are wanting to assess whether using TLD as second-line after a patient has failed an efavirenz-containing first-line regimen results in most patients having a good outcomes in terms of their viral load response over a 48 weeks period. We also want to compare the outcomes between people who take TLD alone from the start to those patients who take TLD with an extra 50 mg of dolutegravir taken 12 hours later for the first 14 days. We will look to see how well HIV viral load is decreased, if the HIV virus develops new resistance to the ARVs, and how safe the double dose is. This study will help us get an indication whether it is necessary to add the extra 50 mg dolutegravir for the first 2 weeks or not. It may also inform policymakers in developing guidelines in South Africa and other parts of the world.

Why are you being asked to take part?

You have been invited to take part in this study because you have a HIV viral load (VL) >1000 copies/mL, and a previous VL >1000 copies/mL in the past two years, which means that the HIV in your blood is not responding to first line ARVs and may have become resistant to them. You need to start on second line ARVs, and this study will provide you with the chance to use new medications that was not available previously, for the duration of the study period.

What happens in this research study?

Patients who agree to participate in our study will be randomly selected to receive either the TLD fixed dose combination daily or TLD with an extra 50 mg dolutegravir 12 hours later daily for the first 14 days. The term "randomly" means that the decision is made similarly to flipping a coin. This is how a randomised controlled trial is done and it is the best scientific way to find out whether a treatment is beneficial or not. Patients and the investigators will not know who is getting the extra dose of dolutegravir, as all patients will get an extra tablet to take 12 hours after the TLD. Half patients will be getting "placebo" (looks the same as the 50 mg dolutegravir tablet but does not contain any

dolutegravir) and the other half will receive 50 mg dolutegravir. Thereafter all patients will continue with a single tablet of TLD daily for 48 weeks. 130 people will be part of this study in total.

How long will the study last?

You will remain enrolled in the study for 48 weeks, after which you will be transferred back to your normal ARV clinic. The type of ARVs that you must continue with will either be the standard second line treatment given to most patients in the country, or another specialised regimen (medication combination), depending on the results of your blood tests during the study.

What will happen if you decide to take part in the study?

If you want to take part in the study, the study doctor/nurse will discuss the reason for the study with you, what will happen during the study, and your risks, rights and study obligations.

If you agree to take part, you will need to sign the consent form at the end of this document. Once you have signed the consent form, the study team will check whether it is safe for you to be on the study (screening). If eligible you will be enrolled and assigned one of the treatment options mentioned above. After that there will be frequent follow-up visits at week 2, 4, then every 4 weeks until week 24, and again at week 36 and 48. At every follow-up visit we will do a brief exam of your body and assess if there are any side-effects from the treatment you are on. There is a small risk of sleeping poorly and changes in mood with dolutegravir. Therefore we will do sleep assessment at every visit, and questionnaires to look for side effects affecting your thoughts and mood from the treatment at the enrolment visit (week 0) and at week 2, 4, 12, 24 and 48. Blood tests will be performed at weeks 2, 4, 8, 12, 16, 20, 24, 36 and 48. See box 1: study schedule for more detail.

Screening: The study doctor will review your medical records, ask you about your medical history and current health, ask you about substances you are using, and examine your body. Your contact details will also be taken in case we need to call you or text you, or do a home visit at a later date.
Your blood (up to 20 ml or 4 teaspoons) will be tested:

- To check how well your liver and kidneys are working
- To test if you are pregnant if the urine test result is not clear (if you are capable of becoming pregnant)
- To measure your CD4 count
- To measure your HIV viral load

Suitability:
In order to take part in the study you need to:

- Be 18 years or older
- Clinically stable
- Have a current HIV VL >1000 copies/mL and a HIV VL >1000 copies/mL in the past 2 years (at least 2 months before the current VL)
- Have a CD4 count >100 cells/µl
- If you are a woman and there is any possibility of you becoming pregnant during the study you must be willing to be on effective family planning (contraception, i.e. “the Pill” or “injection” or implant or intrauterine contraceptive device (IUCD)).

You will not be able to take part:

- If you are pregnant or breastfeeding, or would like to become pregnant in the next 1 year
- If your blood tests are not normal
- If you are allergic or intolerant to any of the study medicines
- If you are on any other medicine that may influence the drug level of dolutegravir
- If you have any mental illness that could affect you taking medication
- If you are using recreational drugs (i.e. Tik, dagga, Mandrax, Unga, cocaine, heroin, etc.) or drinking large amounts of alcohol that could affect you taking medication
- If you are suspected of having, or being treated for active tuberculosis (TB)
- If you are being treated for any serious AIDS related disease
- If you have active cancer
- If you are unable to attend study visits
- If the study doctor thinks that it is best for you not to be on the study

Enrolment: If the screening finds that you are able to take part in the study, we will contact you (by telephone call, sms, whatsapp or home visits) to confirm your participation. We will make an appointment for the first study visit (which should be on the same day that you are switched to your second-line ARV treatment). You will be reminded of things you need to do and the things that you cannot do whilst taking part in the study.

We will also access your routine clinical data, such as laboratory results, medication prescriptions, appointments and clinic encounters and previous diagnoses on electronic databases.

If you miss an appointment we will call you or send you a text message the next day and if you do not return to the clinic we will call you on the phone. We may also call or send you a text message to remind you about appointments.

The order and timing of the study visits is shown in box 1:

BOX 1: STUDY SCHEDULE		
Time	**Visit type**	**Description**
Appointment before enrolment	Screening	Your contact details and address will be noted. The study team will ask you about your health, other medicines you are taking, and do a physical examination. They will also ask you about your medical history and any previous diagnoses, and will ask you about substances you might be using, including alcohol and other drugs. The study team will also take blood and do a urine test for pregnancy (if you are a woman of child-bearing age). We will check to see if you meet all the conditions to be part of the study and have none of the conditions that would mean that you cannot take part in the study. You will be given a study appointment calendar outlining the dates and times of your scheduled study visits. **Please bring all your regular medicines with you to the next study visit.** **If any of your blood results are out of the normal range, we could**

		ask you to come back to repeat them before the enrolment visit.
Day 0	Enrolment and start of treatment	We will check to see if you meet all the conditions to be part of the study and have none of the conditions that would mean that you cannot take part in the study. The study doctor will do a brief physical exam and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). We will also do sleep assessment and questionnaires. You will receive the fixed dose combination of TLD and either the extra 50 mg of dolutegravir or the placebo tablet (with no active medicine) to take 12 hours later daily for the first 14 days. Thereafter you will take the fixed dose combination of TLD once daily. We will also take a blood sample (6 ml or 1 teaspoon) to do HIV genotyping (testing the genes of the virus for any changes, also called mutations). This test will only be done at the end of the study to test whether the virus was resistant to any of the ARVs before you started ARVs in the study. If your viral load is high during the study, we will take another sample of blood to test the genotype again. This will help doctors to plan for future treatment (see below under "What are the risks of taking part?"). Another blood sample (5 ml or 1 teaspoon) will be taken to check that you are taking your medicines every day*. Your contact details and address will be checked.
Week 2	Follow-up visit	This will be a follow-up visit where the study doctor will do a brief physical exam and take a history about any side-effects of the treatment you are taking. We will do sleep assessment and questionnaires to look for side effects from the treatment. A blood sample (5 ml or 1 teaspoon) will be taken for the level of dolutegravir in your blood and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). Your contact details and address will be checked.
Week 4	Follow-up visit	This will be a follow-up visit where the study doctor will do a brief physical exam and take a history about any side-effects of the treatment you are taking. We will do sleep assessment and questionnaires to look for side effects from the treatment. Blood (10 ml or 2 teaspoons) will be taken for kidney function and HIV viral load and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). Your contact details and address will be checked.
Week 8	Follow-up visit	This will be a follow-up visit where the study doctor will do a brief physical exam and take a history about any side-effects of the treatment you are taking. A sleep assessment will be done. Blood (5 ml or 1 teaspoons) will be taken for HIV viral load, and urine will be taken to test for pregnancy (if you are a woman of child-bearing age).

		Your contact details and address will be checked.
Week 12	Follow-up visit	This will be a follow-up visit where the study doctor will do a brief physical exam and take a history about any side-effects of the treatment you are taking. We will do sleep assessment and questionnaires to look for side effects from the treatment. Blood (15 ml or 3 teaspoons) will be taken for HIV viral load, the level of dolutegravir in your blood, and to check that you are taking your medicines every day*, and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). Your contact details and address will be checked.
Week 16	Follow-up visit	This will be a follow-up visit where the study doctor will do a brief physical exam and take a history about any side-effects of the treatment you are taking. A sleep assessment will be done. Blood (10ml or 2 teaspoons) will be taken for kidney function and HIV viral load and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). Your contact details and address will be checked.
Week 20	Follow-up visit	This will be a follow-up visit where the study doctor will do a brief physical exam and take a history about any side-effects of the treatment you are taking. A sleep assessment will be done. Blood (5 ml or 1 teaspoons) will be taken for HIV viral load and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). Your contact details and address will be checked.
Week 24	Follow-up visit	This will be a follow-up visit where the study doctor will do a brief physical exam and take a history about any side-effects of the treatment you are taking. We will do sleep assessment and questionnaires to look for side effects from the treatment. Blood (20 ml or 4 teaspoons) will be taken for HIV viral load, CD4 count, the level of dolutegravir in your blood, and to check that you are taking your medicines every day*, and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). Your contact details and address will be checked.
Week 36	Follow-up visit	This will be a follow-up visit where the study doctor will do a brief physical exam and take a history about any side-effects of the treatment you are taking. A sleep assessment will be done. Blood (10 ml or 2 teaspoons) will be taken for HIV viral load and to check that you are taking your medicines every day*, and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). Your contact details and address will be checked.
Week 48	Follow-up visit	The study team will ask you about your health and do a physical examination. We will do sleep assessment and questionnaires to look for

		side effects from the treatment. The study team will also take blood (20 ml or 4 tablespoons) to check your kidney function, your HIV viral load, CD4 count, and to check that you are taking your medicines every day*, and urine will be taken to test for pregnancy (if you are a woman of child-bearing age). Your contact details and address will be checked.

*The level of study medication in your blood will be measured by means of dried blood spots. A few drops of blood are put onto a special filter paper that can be used to test for levels of medicines in the blood.
If your urine pregnancy test is unclear or positive, we will take additional blood for a blood pregnancy test (5 ml or 1 teaspoon).
A follow up visit at week 52 will allow us to check everything is in order before we give you a letter and transfer you back into clinic care.

What are the risks of taking part?

The study medicines: Most people treated with these medicines do not experience bad side-effects. However, the study medicines can cause bad side-effects that you should know about. If you think you might be suffering from a bad side-effect of the medicines at any time during the study, you need to report this to the study doctor (or any other study team member) immediately.

Dolutegravir may cause diarrhoea, nausea, abdominal pain and/or vomiting, as well as dizziness and headaches. It may also cause difficulty with sleep and unusual dreams and can make you feel anxious, unable to concentrate or feel unhappy or depressed. Rarely it can cause severe liver damage and/or skin reactions. In most patients dolutegravir do not cause side effects.

Tenofovir may cause problems with kidney function in a small amount of people. People with kidney problems should not take this ARV. If your first blood results show that your kidney function is normal it should be safe for you to continue with this treatment. We will monitor your kidney function after month 1, 4, and 12, and we will not give it to you if it looks like it is causing any problems with your kidneys and will change it to an alternative ARV. If any problem does occur, this usually improves when the medication is stopped.

Lamivudine may cause low red blood counts in a very small number of patients. We will monitor for this based on symptoms and during physical examinations. If this occurs you may be switched to a different ARV.

Resistance. When HIV is not responding to first line treatment anymore, there is a high likelihood of it being resistant to treatment as a result of various changes in the virus (mutations). It is difficult to say if resistance to tenofovir might make it more likely to get resistance to dolutegravir if it is given with tenofovir. Being on TLD as second line ART might increase the risk of you developing ARV resistance or it might not – that is one of the questions we are planning to answer in this study. There is a small chance that you may develop resistance to the ARV treatment you are given in this study whatever treatment you receive (the ARV medicines will not work as well as they should, because your HIV has

found a way to escape their action). We will test your HIV viral load frequently, and if it is not adequately decreased when it should be, we will perform a special test on the HIV in your stored blood (from before you started the ARV treatment) and the HIV in a current blood sample. This will be to see if the HIV has become resistant to the ARVs you are using and which new ARVs we can prescribe to you that will work effectively.

Risks of taking blood samples. You may have discomfort and mild pain with blood taking (insertion of a needle into your vein). You might have mild bruising. However, as the study staff are experienced, these effects should be minimal. The total amount of blood taken during the study will not exceed a 100 ml of blood. This is less than ½ a cup and far less than the amount of blood drawn at a single blood donation.

Safety monitoring. To monitor the safety of the study treatments we will ask you at each study visit about your health and about any problems that could be caused by the medicines. We will also take regular blood to test your kidney function, and monitor your HIV viral load. If you are worried about a change in your condition, you should contact the study team.

Risk to pregnancy and unborn child. We do not want you to be pregnant before you enter the study or become pregnant during your time enrolled in this study. A recent study has shown that a small percentage of children born to women who became pregnant while using dolutegravir, were found to have neural tube defects. Neural tube defects are birth defects of the brain, spine, or spinal cord. They happen in the first trimester of pregnancy, often before a woman even knows that she is pregnant. This safety signal is not yet confirmed, but we are still concerned about it and want you to be aware of it.

Some of the benefits of taking dolutegravir are that it has fewer side effects and you only have to take it once a day. The risk of these neural tube defects when taking dolutegravir is low: less than 1% of pregnancies. The risk on dolutegravir that was found was 0.3% of pregnancies, compared to 0.1% without dolutegravir. It is your decision to balance these risks against the potential benefits of taking dolutegravir as your treatment.

However, for this reason, if you are a woman who is capable of becoming pregnant and would like to take part in this study, we do emphasise that you must be using an effective method of contraception to avoid becoming pregnant for the duration of the study. We will talk with you about contraception options and help you choose the best method for you at each visit. Your birth control method must be one that is considered effective: a hormonal injection, oral contraceptive, implant or an intrauterine contraceptive device. This can be provided by your usual clinic. We will check at each visit that you are consistently using an effective birth control method and in this way the chance of you becoming pregnant during the study is reduced.

It is important that you inform the study doctor or study team whenever you change your pregnancy intentions. If you have decided to fall pregnant or become pregnant during the study, the study medication including dolutegravir will be stopped and you will be changed to alternative ARV medication. We will monitor your progress and follow up on the outcome of your pregnancy.

What are the possible benefits of taking part?

Aside from receiving a treatment regimen (combination of treatments) that is only one pill a day and might prove to have fewer side-effects than the standard treatments, you will not benefit directly from taking part in the study. The results of the study may benefit future patients with HIV who need to be switched to second line ARVs, and may be able to take a single pill containing TLD instead of a multi-pill regimen of ALD or other medication. We will inform your clinic doctor of the results of the tests performed at the screening and last study visits. This information will help your doctor to adjust your management appropriately when you resume your normal appointments at your ARV clinic.

How will the information and samples collected in the study be handled and stored?

Information will be recorded by the study staff on case report forms, which will be captured and uploaded into a study database. The data will be stored on a password protected hard drive, kept at the University of Cape Town. These records will be kept for ten years after the end of the trial.

Blood samples will be taken and sent to the National Health Laboratory Service for the tests explained above. A small amount of blood will be stored for tests of dolutegravir levels at a later date in the study. Blood samples will be kept for ten years after the end of the trial.

If in future, you decide that you do not wish for your samples to be stored anymore, you can contact the researchers or the UCT ethics committees and inform them of your decision. Your samples will then be destroyed and no further tests will be done on them.

Use of the information for other studies

Other researchers may apply to University of Cape Town Human Research Ethics Committee for permission to use the information we gather or the samples we store for other studies. Further tests on these samples and further analysis of the information will only be performed if the ethics committee agrees and grants this permission. The information and samples will not be linked to your name so any further research will not have access to your identity.

When you sign the consent below, your permission to store your samples and use them for future testing will be asked as a separate question for you to agree to. You are free to decline the request to store your samples for future testing and still participate in this study.

Will your privacy be protected?

All patient interactions will maintain strict confidentiality. To protect your identity, all information and all samples collected will be labelled with a study code. This code (and not your name) will be used for all study data and samples. Your medical records and the information collected for the study will be looked at by authorised persons from the study team. Your records may be reviewed by the research ethics committee overseeing the study, the South African Health Products Regulatory Authority, the funders who have authority to check that the study is being carried out correctly, or by an independent committee of doctors who will be making sure that the study is safe. All persons will treat any information about you as a research participant confidentially, and nothing that could reveal your identity will be disclosed outside the research site.

What if ‘Something Goes Wrong’?

This research study is covered by an insurance policy taken out by the University of Cape Town if you suffer a bodily injury because you are taking part in the study. The insurer will pay for all reasonable medical costs required to treat your bodily injury, according to the SA Good Clinical Practice Guidelines 2006, which are based on the Association of the British Pharmaceutical Industry Guidelines.

The insurer will pay without you having to prove that the research was responsible for your bodily injury. You may ask the study doctor for a copy of these guidelines. The insurer will not pay for harm if, during the study, you:

- Use medicines or other substances that are not allowed
- Do not follow the study doctor's instructions
- Do not tell the study doctor that you have a bad side effect from the study medicine
- Do not take reasonable care of yourself and your study medicine.

If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court.

You must notify the study doctor immediately of any side effects and/or injuries during the study, whether they are research-related or not.

Will you be compensated for your travel costs, time and inconvenience?

You will be compensated for your time, inconvenience and transport expenses for each scheduled visit (R300 per visit). Unscheduled visits will not be compensated unless the study team requests you to return for an appointment.

Who is managing this study?

This study is sponsored by the University of Cape Town, who are responsible for maintaining the quality of the trial and ensuring that the trial is conducted in compliance with the protocol, good clinical practice and regulatory requirements. The trial is funded by a grant from the Wellcome Trust and by Médecins Sans Frontières (MSF). There are no potential conflicts of interest for any of the researchers or organisations sponsoring, funding, supporting or involved with the study in any way

What will happen with the results of the research?

The results of the study will be published so that they are available to the medical profession throughout the world. No patients will be identified individually.

Withdrawal from the study

You have the right to stop taking part in the study at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible. The investigator may decide to stop your participation without your permission because he/she may decide that staying in the study will be bad for you. If one of the study medicines causes you harm, you will be withdrawn from the study and your treatment changed to an alternative. If you withdraw early, the study team will encourage you to continue to be followed up by the study team, but it is your

right to decide. You will be referred back to your local primary health clinic to continue your treatment if you choose not to be followed up by the study team.

What if you have complaints about the study?

The ethical oversight of this study is performed by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee. If you want any information regarding your rights as a research participant, or have complaints regarding this research, you may contact: your doctor or the Ethics committee, by contacting:
Prof. Marc Blockman, the Chairperson of the Research Ethics Committee at the University of Cape Town
The Human Research Ethics Committee
Floor E53, Room 46
Old Main Building
Groote Schuur Hospital
Observatory, 7925

After you have consulted your doctor or the Ethics Committee, and if they have not provided you with answers to your satisfaction, you should write to the South African Health Products Regulatory Authority (SAHPRA) at:
The Chief Executive Officer
South African Health Products Regulatory Authority (SAHPRA)
Department of Health
Private Bag X828
Pretoria
0001

Contacting the study team

If you experience any worrying effects on the study treatment, please contact the study team as soon as possible. If you or your health care provider have important questions or concerns, please contact the study team.

You can contact the study nurse or doctor (073 815 9538) You can also send a please call me and we will call you back.

If you have general questions about the study you can also contact the Principal Investigator: Prof Graeme Meintjes (telephone: 021 406 6075).

Statements of agreement and signatures

1.	I have read the information pages about the study, or they have been read to me. I understand the advantages and disadvantages, as well as the benefits and risks, of taking part in the study. The details of the study have been explained to me and my questions have been addressed. I will receive a copy of this signed consent form.

2.	I understand that participation in the study will involve: • Tests including physical examination and questionnaires, and collection of blood samples • Taking doses of the ARV medicines, fixed dose combination TLD with an extra dose of dolutegravir or placebo for the first 14 days • There might be or might not be an increased risk of developing ARV resistance if TLD is taken as second line ARV treatment. This might be different depending on whether I receive the extra dolutegravir or the placebo – this is the main question the research is asking. • Attending the study visits and taking of blood samples for safety tests and measurements of the blood ARV levels • If I am a woman capable of becoming pregnant that I will be on effective contraception throughout the study, and if I wish to become pregnant I will inform the study doctor before doing so. • The study team and the clinic staff may contact me by telephone, text messages, WhatsApp or home visits.

3.	I understand that I can withdraw permission to take part and leave the study at any time, without having to give a reason, and without affecting my normal care and treatment.

4.	I understand that the information will be reviewed by authorised individuals and that the individuals are obliged to treat the information as confidential.

5.	I agree to take part in the study.

PLEASE INITIAL/MARK THE BOX IF YOU AGREE

6.	I agree to have blood samples stored. These will be used to test to see what ARVs the virus is resistant to and to test levels of ARVs in my blood. This could help doctors to plan for future treatment if the current ARVs are no longer working.	

7.	I agree to have blood samples stored after the study has been completed. Other tests related to HIV may be performed on these samples in the future if the UCT Human Research Ethics Committee agrees to this.	

Participant's signature	Given (first & middle) names – please print									
	Surname (last/family) name – please print									
	Date:	D	D	M	O	N	2	0	Y	Y

Witness signature (if applicable)	Name – please print	Date								
		D	D	M	O	N	2	0	Y	Y

Responsible study team member's signature	Name – please print	Date								
		D	D	M	O	N	2	0	Y	Y

1st Review _____ _____/_____/20

initials date

2nd Review _____ _____/_____/20

initials date

Spot Check _____ _____/_____/20

initials date