PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF RESEARCH PROJECT: Improving **RET**ention and viral load outcomes for people taking **A**ntiretroviral therapy through early **I**dentificatioN of missed doses (RETAIN)

PRINCIPAL INVESTIGATOR: Dr Catherine Orrell

You have agreed to be part of the SUSTAIN study (UCT Ethics reference 568/2021) and have signed the informed consent document explaining that study.

We would like to also explain another study, RETAIN, which is a sub-study of SUSTAIN. You can only take part in RETAIN if you are already taking part in SUSTAIN. RETAIN has an extra visit and some extra blood draws.

We would like to explain the extra visits and study processes this study needs which is why we are giving you this extra form. After we tell you about it, you can decide if you want to take part in the study. The same team of researchers from the Desmond Tutu Health Foundation (DTHF) are conducting this study. The lead researchers are Dr Catherine Orrell (DTHF) and Dr Lauren Jennings – both from the DTHF.

We are happy to answer any questions you might have before you decide whether or not to take part.

This study has been approved by the Human Subjects Research Ethics Committee of the University of Cape Town and by the Ethics Committee of the funder, the European and Developing Countries Clinical Trial Partnership (EDCTP).

Why are we carrying out this study?

Many people find it difficult to stay on treatment and to take their HIV medications every day. The SUSTAIN study team will notice who these people are and invite them to come for extra support to try and help daily tablet taking.

In addition to this, the RETAIN study will look at a number of ways to see if the support offered during SUSTAIN really works to change how people take their tablets on a daily basis from immediately before to just after they receive the support. We will look at the number of tablets taken (based on the Wisepill electronic pill box) and at the ART concentrations in blood and urine both before and just after the adherence support is given.

We hope that the study results will help us select the best methods to measure tablet taking and to support HIV-positive patients in Cape Town.

What happens in this research study?

You may not ever have any procedures as part of the RETAIN study. We are asking everyone who agrees to take part in the SUSTAIN study to think about taking part in the RETAIN study as well, BUT you would only take part in the RETAIN study IF you are noticed to have poor adherence and are asked to attend your clinic adherence support.

There will be two visits as part of RETAIN.

Visit 1: when you are invited back to the clinic to discuss your adherence and be offered extra support (as part of SUSTAIN), we would like to:

- draw blood (±20ml) to measure tenofovir (one of your antiretrovirals) in your blood in two different ways (plasma and dried blood spot); and,
- check your HIV viral load (how much virus there is in your blood at this time); as well as,
- ask you for a urine sample to check if there is tenofovir in your urine;
- ask you some simple questions about how your tablet taking has been going.

We will also look at how many doses of your ART you took over the last 30 days according to the Wisepill device you will be given as an electronic pillbox .

Visit 2: The second visit for RETAIN will happen about 12 weeks after the first visit when you have completed the adherence support offered to you. This is an extra visit (not part of the standard care offered to people on ART in your clinic. The procedures at visit 2 are nearly the same as visit 1. We would like to:

- draw blood (±20ml) to measure tenofovir (one of your antiretrovirals) in your blood in two different ways (plasma and dried blood spot); and,
- check your HIV viral load (how much virus there is in your blood at this time); as well as,
- ask you for a urine sample to check if there is tenofovir in your urine;
- ask you some simple questions about how your tablet taking has been going.

We will also look at how many doses of your ART you took over the last 30 days according to the Wisepill device you will be given as an electronic pillbox.

In addition, we may invite you to take part in a qualitative interview (i.e. to spend an extra hour talking to a counsellor about your adherence; and to tell us if our measures were useful and what you feel the advantages and disadvantages of each might be; if there were any challenges in using them in the clinic; and how you think we should use them in clinical care).

By consenting to participate in this study, you are consenting to allow study staff to access your medical records, including a review of your clinic folder, access to routine blood results (in your folder or online) and pharmacy refill records (in your folder or online), for the purposes of monitoring your medication adherence.

Risks and Discomforts

- Drawing blood from the vein in your arm has some minor risks:
    - You may experience a small amount of pain when the needle goes into your arm and this area may be sore to the touch for a few hours.
    - A small amount of bleeding under the skin may produce a bruise. This will go away in a few days.
    - You may feel dizzy or light-headed for a short period of time.
    - There is a small risk of infection where the needle goes in, but qualified study staff will carefully clean your arm with alcohol before taking your blood and use sterile equipment to reduce the chances of infection.

- Some of the questions we may ask in the qualitative interview may be sensitive and could upset you. You may refuse to answer any questions that cause you discomfort.
- There is a risk that your HIV status may accidentally become known to others due to your participation in this study. We will make every effort to prevent this and maintain your privacy and confidentiality throughout the study.
- There may be some additional risk of contracting COVID-19 if you are required to travel more often (for example, to attend visit 2) due to your study participation. Our staff will ensure that all precautions and protective measures (such as the wearing of face masks, sanitizing and distancing) are adhered to throughout the pandemic.

Benefits

- You may or may not benefit from participating in this study. You will receive the results of the level of tenofovir in your urine and additional viral load results, which might help you improve your adherence.
- Participation could possibly help researchers better understand what helps people who are struggling to take their ARVs every day and this could lead to improved health for people living with HIV.

Study withdrawal

Once you begin study participation, study staff may withdraw you from the study before you complete it. There are several reasons why this could happen:

- You may become so medically or mentally ill that you cannot attend study visits. If this happens, study staff will refer you to appropriate health services.
- The investigator may determine that participating in the study is no longer in your best interest.
- The investigator may judge that you are at sufficient risk of failing to comply with the study procedures so as to cause harm to yourself or seriously interfere with the validity of study results
- Your provider may change your ART medication to one that does not allow you to continue to use the Wisepill device.

Alternatives

Participation in the study is completely voluntary. You are free not to participate or to withdraw at any time during the study. Your treatment will not be affected in any way and you may continue to attend your clinic. It would be helpful for the study team to know why you have decided not to take part, but you do not have to give a reason.

Confidentiality

We will make every effort to protect your confidentially. All study staff are instructed to keep all of your research records private. All study participants will be given a unique participant identification number which will be used to identify all study information. A list matching participant names with study identification numbers will be kept securely in a locked cupboard. Study records will only be accessible by study staff. Reports about the study may be made to government or the funder, but you will not be personally identified in any report about this study. Institutional personnel may access study information as part of

routine audits. Study results will be reported as a group and no individual participant will be identified.

A description of this clinical trial will be available on www.sanctr.samrc.ac.za . This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Costs and reimbursement

You will be reimbursed for you time and transport costs to come to the study visits. You will receive R150 for each of the two study visits and another R150 if you are invited for a qualitative interview.

Participant's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

In case of emergency or if you have any questions, you can contact the study coordinator at the DTHF Gugulethu Research Offices on 021 007 1930 or 021 007 2275.

If you have any concerns about your rights as a research participant that have not been addressed by the study coordinator, you can contact the Human Research Ethics Committee of the Health Sciences Faculty of the University of Cape Town on 021 406 6338.

DECLARATION BY PARTICIPANT FOR PARTICIPATION IN RESEARCH STUDY

By signing or giving my fingerprint below, I agree to take part in this research study.

I declare that:

- I have read or had read to me this information and consent form in a language with which I am fluent and comfortable
- I have had a chance to ask questions and all my questions have been answered.
- I understand that taking part in this study is voluntary and I have not been pressured to take part.
- I may choose to leave the study at any time and will not be penalised in any way.
- I may be asked to leave the study before it has finished if the investigator or my own provider feels it is in my best interests.

_____

Participant Name and Surname

_____ _____

Participant Signature (or right thumbprint) Date

Please indicate your willingness to be contacted for an in-depth interview during your study participation (initial on the line):

_____ I **DO** consent for study staff to contact me to take part in an in-depth interview.

_____ I **DO NOT** consent for study staff to contact me to take part in an in-depth interview.

Please indicate your willingness to be contacted for future research during or after your participation in this study (initial on the line):

_____ I **DO** consent for study staff to contact me for future research.

_____ I **DO NOT** consent for study staff to contact me for future research.

DECLARATION BY STUDY STAFF

I declare that:

- I explained the information in this document to the participant
- I encouraged the participant to ask questions and took adequate time to answer them
- I am satisfied that the participant understands all aspects of the research, as described above

_____

Study Staff Name and Surname

_____ _____

Study Staff Signature Date

WITNESS FOR PARTICIPANT PROVIDING FINGERPRINT

_____

Witness Name and Surname

_____ _____

Witness Signature Date