# INFORMATION SHEET

**Project Title:** Siyaphambili

## What is this study about?

This is a research study being conducted by Harry Hausler (TB/HIV Care) and Stefan Baral (Johns Hopkins University) as primary investigators and Deliwe Phetlhu at the University of the Western Cape as a co-investigator. This study is about *how to best use strategies to keep women who are sex workers and living with HIV in care and on their treatment*.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the research staff. You are being asked to take part in this study because you are a female sex worker and tested positive for HIV more than six months ago, and if you are on HIV treatment you have been on treatment for two months or longer. You are also currently not pregnant.

The purpose of this study is to find out which combination of strategies results in the best participation in care and adherence to HIV treatment for female sex workers living with HIV in South Africa. In this study, we are trying to learn how to give sex workers the strategy that work best for them to stay in care and on their HIV treatment. We are also trying to understand how much it would cost to give sex workers these different strategies for HIV care and treatment.

## What will I be asked to do if I agree to participate?

If you agree to participate in this study, the study will last for 18 months. During this time the following will happen:

Today we will ask you to give some blood for testing of your HIV viral load and measure your CD4, or how well your immune system is working. The viral load test measures the level of HIV virus in your body, and we will need to take about 15 mL (equivalent to three teaspoons) of blood. This visit will take about 90 minutes. It will take us about five days to get the result of the test and we will make an appointment with you to come back to collect the result. At this visit, and each study visit you have, you will have the iris in your eye scanned in order to verify your identity with a 12-digit numeric code that will be made by the machine. The images of your iris will not be stored. Iris scanning is a required component for study participation. At this visit we e will also ask you questions about yourself, your work, your sexual history, your HIV care history, and your experiences. At this appointment, you will also be assigned to a strategy to support your HIV care and treatment.

At the second appointment where you will get the result of your CD4 test and viral load. This visit will take about 20 minutes. If the result of your viral load is less than 50 copies/mL, you will continue to receive the “Standard of care” for HIV in South Africa. “Standard of care” means that you will continue with your usual way of receiving your HIV treatment and care.

If your viral load result is more than 50 copies/mL, you will be eligible for one of two strategies. Selection of the strategy that you will receive will be random, a process similar to flipping a coin. The strategies are:

1. Strategy one: Delivery of your HIV care or ARVs (if you are already on HIV treatment) at the TB/HIV Care mobile van, or initiation of ARVs and delivery (if you are not already on HIV treatment), and follow-up with a nurse for your HIV care at the mobile van. The TB/HIV Care mobile van will provide treatment, routine management, and support at or near the location where you do sex work. You will also receive SMS reminders of when you are due to visit the mobile to pick-up treatment or see the nurse. If you are currently receiving care in a Department of Health clinic outside TB/HIV Care, we will assist you in obtaining a referral letter from the clinic.
2. Strategy two: On top of your regular HIV care, a case manager will work with you to provide personal planning support and talking about challenges related to your HIV care and taking treatment. This will involve 1) an initial meeting with the case manager; 2) a follow up meeting within one month with the case manager; 3) if you agree, the case manager will send you follow-up text messages every two weeks; 4) monthly phone calls from case manager; and 5) face-to-face meetings with case manager every three months.

If you are not eligible for the intervention you will continue with the “Standard of Care” strategy, and you will not meet with study staff again, and you will continue to engage in your HIV care as you normally do through TB/HIV Care drop-in centre or through your local clinic.

If you are assigned to the mobile van HIV treatment delivery and care strategy or the case manager strategy, in addition to your treatment pickups or case manager meetings, we will meet with you every six months to ask you questions about your experience with the strategy you have been assigned and to take your blood for viral load testing. These visits should take about 90 minutes each. These visits will be done at the mobile van or at the TB/HIV Care drop-in centre, or at another pre-arranged location, depending on what you would like better.

After six months of being in the study, if you are assigned to the mobile HIV treatment delivery and care strategy or the case manager strategy and your health is good (meaning that your viral load is less than 50 copies/mL), you will be randomly assigned to receive the “Standard of Care” strategy, meaning you will go to the usual procedure of receiving your HIV treatment and care either through the TB/HIV Care drop-in centre or through your local clinic, **or** you will be randomly assigned to continue with the mobile HIV treatment delivery and care or the case manager strategy you have been receiving for an additional 12 months.

If after 6 months of the study your viral load is more than 50 copies/mL you will be randomly assigned (a process similar to flipping a coin) to either:

1. Continue with the strategy you are receiving: mobile treatment delivery and HIV care or support from a case manager. OR

2. Receive a combination of the two strategies. This means you will both collect your HIV treatment and receive HIV care at the mobile, as well as have a case manager to provide you with planning support related to taking your HIV treatment.

You will continue with these strategies for an additional 12 months.

For all three strategies, we will also look at your clinical record to determine information about your care, including the results of viral load tests. We will also test if you are pregnant at 6, 12, and 18 month study visits. If you are pregnant, we will support your referral to ANC services and

you may continue with your assigned strategy. If you participate in all study activities, the time from the start of your participation to the end is one and a half years. A summary can be found in Figure 1.

Figure 1. Summary of Study Procedures

***TO SUMMARIZE:***

At the enrolment visit, you will:

- Have your iris scanned and receive a unique study ID.
- You will have 15 mL of blood drawn for viral load and CD4 testing.
- Receive initial baseline questionnaire about your physical and mental health, sexual behaviors, and medications.

You will either continue with Standard of Care or be randomized to receive an intervention. For everyone we will access your health records during the study. We will ensure that the care provided to you will follow the South African Standard of Care. If you are randomized to receive an intervention, you will:

- Have your iris scanned and confirm your unique study ID at all study visits.
- Receive 6-, 12-, and 18-month questionnaire, pregnancy testing, and 15 mL of blood draw for viral load testing.
- Receive either your HIV care and ARVs from the TB/HIV Care mobile **and/or** one-on-one support from a case manager.

If you want more information about the timing of the study, details of activities to be completed each month for the interventions can be found in Annex I. If you would like to learn more I can talk you through it and you are free to ask any questions you may have. Also, a visual aid of the overall study flow can be found in Annex II.

**Would my participation in this study be kept confidential?**

We will do everything possible to protect your confidentiality. In this study, we will use iris scans to generate an individual numeric code for you. We will not save the image of your iris and it will only be used to create this code that will allow us to link your HIV viral load results to your questionnaire. If you decide to participate in this study, we will ask you to sign or put a mark on the consent form. Names and contact information will be collected from women participating in the study, however all contact information will be kept in an encrypted (specially protected) file which will be kept separate from other study related information. To ensure the security and confidentiality of the information you provide us with, all paper forms will be kept in a locked cabinet and only study staff having completed a training in research ethics will have access to it. We will do the questionnaire on a tablet and your responses will be automatically deleted from the device immediately after the interview is over and we have stored the responses on a secure computer server. Your name will not appear on any document or database coming from this study.

**What are the risks of this research?**

The risks of drawing blood may include feeling faint or dizzy when blood is drawn. You may feel sore or have a bruise or swelling at the site where blood is drawn. These are the same risks as when you have your blood taken at the clinic. You may feel some slight discomfort providing a urine sample at your venue, especially outdoor venues, but the study team will work to make sure you are able to do so in the easiest, most accessible way.

You will be asked questions about your experiences with HIV care, opinions about the strategy or strategies to which you are assigned, and sexual behaviour. You might not like the way some of the questions make you feel, and it is okay if you decide not to answer the questions that make you feel worried or bad. If you feel that you would like to speak to someone for counselling, we can refer you to counselling services.

If somebody finds out that you are a part of this study they could find out that you are a sex worker and living with HIV. We will do everything we can to protect this information and stop this from happening. All staff are trained about keeping your information confidential and we have safe, locked spaces where the information is kept. Additionally, a component of the study's interventions included SMS text messages that will be to send to either remind you to pick up your treatment, attend schedule clinic or study visits, generally support your adherence. "Condomize, don't compromise," is an example of a general support SMS text message that would be sent to you if you are assigned to receive support from a case manager. To protect your confidentiality and reduce the risk of potential loss of confidentiality, we will not mention HIV or ARVs or treatment in the text messages. Also, we will use the local study name - Siyaphambili - to refer to the study. If you are assigned to receive your ARVs in the community, an example of a SMS text message reminder to pick up your treatment would be, "Siyaphambili will b in ur area tomorrow. C u soon!"

**What are the benefits of this research?**
Upon enrolment, you will have your CD4 count results provided to you. This will tell you how well your immune system is working. You may not receive any other direct benefits from participating in this study. You may receive SMS text messages, telephone calls, a case manager, or the ability to pick up your HIV treatment and receive HIV care at a mobile clinic. These things may help you with your HIV care and that in turn may help your health. You will also be able to know if you are pregnant at every six-month visit. At the end of the study, the results will help us figure out the best strategy or combination of strategies to use for helping women who are sex workers living with HIV take their treatment and stay in care.

**Will I be compensated?**
You will get a reimbursement of 100 ZAR to cover your round trip transport and time for each study visit to the TB/HIV Care drop-in centre for questionnaires and blood draws, and results and assignment of study strategy. You will not get compensation for visits to meet with your case manager or to pick up your treatment from the mobile.

**Do I have to be in this research and may I stop participating at any time?**
Your participation in this research is completely voluntary. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will still be able to access care and treatment through the TB/HIV Care and/or your local clinic.

**What if I have questions?**
This research study has been approved by the University of Western Cape's Biomedical Research Ethics Committee (BMREC). You may contact the BMREC if you have any worries about the study or you feel that you have been harmed or made to feel bad in any way while

taking part in this study. You may contact the BMREC at the University of Western Cape at 021 959 2948.

If you have worries or questions about the details of the research study itself, you may call the Principal Investigator, Dr. Harry Hausler, at TB/HIV Care. His number is 021 425 0050. You may also leave a message with the person answering the phone and you will be called back as soon as possible. Please leave details of your request and your daytime contact number as this will help with the reply. You may also contact the Principal Investigator, Dr. Stefan Baral, in the United States at 001-410-502-8975.

This research is being conducted by Dr. Harry Hausler (PI) at TB/HIV Care; Dr. Stefan Baral (PI) at Johns Hopkins school of public health and Dr. Deliwe Phetlhu from the school of Nursing (co-researcher) at the University of the Western Cape. If you have any questions about the research study itself, please contact Dr. Harry Hausler at 25th St George's mall, Cape Town, 8001; Tel: 021 425 0050; Email: hhausler@tbhivcare.org

If you have any questions regarding this study and your rights as a research participant or if you want to report any problems you have experienced related to the study, please contact:

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This research has been approved by the University of the Western Cape's Research Ethics Committee. (REFERENCE NUMBER: *to be inserted)*

**Permission to proceed**
Do you wish to participate in the study? If you accept, you agree to the following three important elements: responding to the questionnaires, blood draws, and iris scans for a period of one and a half years.

We would also like to ask for your permission to save your blood sample for future studies. There is no direct advantage to you coming from this. The use of your sample in future studies will be for genetic sequencing, which read the DNA and analyses the characteristics of the virus. In addition, your blood sample could possibly be retested to ensure the quality of study methods. Your name will not appear on your blood sample and the sample will not identify you. Given that the sample will be de-identified, it will not be possible to have access or give you or your doctor the results of any additional testing. We draw blood and conduct testing to better understand how common HIV infection is and how advanced it is among women engaged in sex work in South Africa. The results from these studies will not be added to your medical file or used to treat you. Do you have any questions at this stage?

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**ANNEX I**

**Table 1. Summary of Study Procedures**

| Study Procedure | Screening | Enrolment | Month | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| **All participants receiving either intervention:** | | | | | | | | | | | | | | | | | | | | |
| Consent Process | ✓ | | | | | | | | | | | | | | | | | | | |
| Iris Scan | | ✓ | | | | | | ✓ | | | | | | ✓ | | | | | | ✓ |
| Questionnaire | | ✓ | | | | | | ✓ | | | | | | ✓ | | | | | | ✓ |
| Blood Draw (15mL) | | ✓ | | | | | | ✓ | | | | | | ✓ | | | | | | ✓ |
| CD4 testing | | ✓ | | | | | | | | | | | | | | | | | | |
| Pregnancy testing | ✓ | | | | | | | ✓ | | | | | | ✓ | | | | | | ✓ |
| Intervention assignment | | | ✓ | | | | | ✓ | | | | | | | | | | | | |
| **Participants assigned to receive delivery of ART by Mobile Van:** | | | | | | | | | | | | | | | | | | | | |
| Iris scan | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| ART pick up (monthly) | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| ART pick up (bimonthly if virally suppressed more than 6 months) | | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| **Participants assigned to receive case manager support:** | | | | | | | | | | | | | | | | | | | | |
| Face-to-face Meeting | | | ✓ | | | ✓ | | | ✓ | | | ✓ | | | ✓ | | | ✓ | | |
| Monthly calls | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Biweekly text messages | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| **Participants assigned to receive both delivery of ART by mobile van and case manager support:** | | | | | | | | | | | | | | | | | | | | |
| Iris scan | | | | | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| ART pick up (monthly) | | | | | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| ART pick up (bimonthly if virally suppressed more than 6 months) | | | | | | | | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| Face-to-face Meeting | | | | | | | | | ✓ | | | ✓ | | | ✓ | | | ✓ | | |

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Monthly calls | | | | | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Biweekly text messages | | | | | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

## ANNEX II

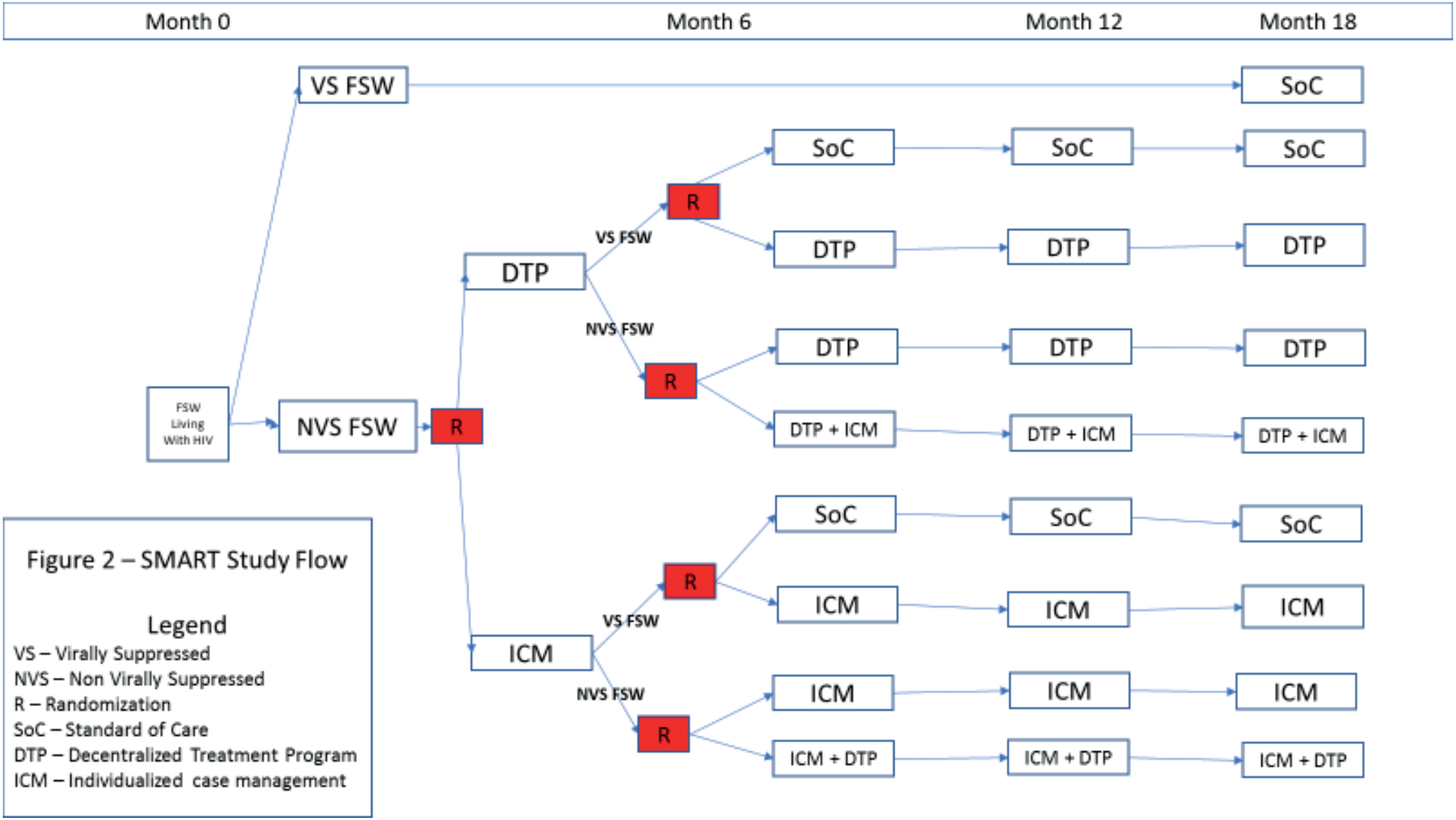


Figure 2 – SMART Study Flow

Legend

VS – Virally Suppressed
NVS – Non Virally Suppressed
R – Randomization
SoC – Standard of Care
DTP – Decentralized Treatment Program
ICM – Individualized case management

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## CONSENT FORM

**Project title:** Siyaphambili

The study has been described to me in language that I understand. My questions about the study have been answered. I understand what my participation will involve and I agree to participate of my own choice and free will. I understand that my identity will not be disclosed to anyone. I understand that I may withdraw from the study at any time without giving a reason and without fear of negative consequences or loss of benefits.

Do you consent to the questionnaire?
**Yes** ☐ **No** ☐

Do you consent to the blood draws, viral load tests, and baseline CD4 tests?
**Yes** ☐ **No** ☐

Do you consent to the iris scan?
**Yes** ☐ **No** ☐

Do you consent to pregnancy testing ?
**Yes** ☐ **No** ☐

Permission to save blood samples for future studies (**optional**): Do you consent to the conservation of your blood sample for future studies that could be conducted after this study?
**Yes** ☐ **No** ☐

***Signature or mark of the participant:*** _____ **Date:** _____
***Signature of study staff conducting informed consent:*** _____ **Date:** _____