INFORMED CONSENT FORM FOR YOUNG WOMEN AGED 18 to 20 YEARS

*Each participant must receive, read and understand this document **before** any study-related procedure is conducted*

SHEET 1:	Screening and Enrolment
STUDY TITLE:	A Pilot Randomized Controlled Trial to Assess a Model of Decentralised STI-Self Testing and Risk Self-Assessment Among Adolescent Girls and Young Women in South Africa to Trigger PrEP Re-start
SHORT TITLE:	**PALESA**: **P**rEP restart for Ado**le**scent girls and young women using **S**TI Self Testing and **A**ssessment of risk
FUNDER:	US National Institute of Mental Health
PARTNERS:	University of Alabama, Birmingham, Alabama, USA University of California, San Francisco, California, USA
PRINCIPAL INVESTIGATORS:	Prof Thesla Palanee-Phillips and Ms. Krishnaveni Reddy
INSTITUTION:	Wits Reproductive Health and HIV Institute (Wits RHI), a Division of Wits Health Consortium (Pty) Ltd, a wholly owned company of the University of the Witwatersrand
DAY TIME CONTACT NO.:	011 358 5424
AFTER HOURS CONTACT NO.:	083 783 3574

To the potential participant: *This consent (permission) form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home **an unsigned copy of this consent** form to think about or discuss with family or friends **before making your decision.***

DATE AND START TIME OF INFORMED CONSENT DISCUSSION:

				:
DD	**MMM**	**YYYY**		**Time** *(24hr clock)*

INTRODUCTION

Hello my name is _____ and I work at the Wits Reproductive Health and HIV Institute, a Division of Wits Health Consortium (Pty) Ltd, (Wits RHI) as a _____. Wits RHI does research in reproductive health, including HIV and has projects in many areas including Esselen Street in Hillbrow (Esselen Street Clinic and Research Centre). Wits RHI is a part of the University of Witwatersrand, Johannesburg. Wits RHI would like to invite you to take part in a study called PALESA.

PURPOSE OF THE STUDY

This study is being done to see if adolescent girls and young women (AGYW) checking their own risk of getting HIV using a set of questions (HIV risk self-assessment) **and** self-testing themselves for sexually transmitted infection (STI) helps them to restart pre-exposure prophylaxis (PrEP) compared to just self-assessing their HIV risk using a set of questions only. We also want to see if AGYW find STI self-testing and self- assessment of HIV risk acceptable and find out about their experiences. The persons in charge of the study at this site are Prof. Thesla Palanee-Phillips and Ms. Krishnaveni Reddy. This study has been reviewed and approved by the University of the Witwatersrand (Wits) Human Research Ethics Committee (HREC) in Johannesburg, South Africa.

Before you decide if you want to join PALESA, we want you to know more about it. This form gives you information about this study. I will talk to you about the study and answer your questions. If you would like to speak with a medical doctor or if you have medical questions, please let me know so that this can be arranged. You may choose to stop being in the study at any time. Once you read this form (or have it read to you), discuss the information and understand the study, we will ask you to sign or mark this form to indicate your agreement to take part. We will offer you a copy of this form to keep. If you have a personal doctor, you are welcome to discuss with or inform him/her of your possible participation in this study. If you wish, I can also tell your personal doctor about this study.

YOUR PARTICIPATION IS VOLUNTARY

Taking part in this study is voluntary. This means you should join of your own free will and you and you can decide not to take part. If you decide not to take part in the study, you can still get the care you need from your local/public clinic. You may also still have chances to join other studies in the future, if one is available and you qualify. However, you cannot join the PALESA Study if you are already taking part in another research study involving drugs, medical devices, or vaccines for STI prevention or treatment. You are asked to tell the study staff if you are taking part in or thinking of taking part in any other studies. Once you join the PALESA, you may also withdraw (take back) your consent at any time and leave the study. If you decide to leave the study, please tell the study staff right away.

CO-ENROLMENT

Co-enrolment is when you take part in more than one study. This is not safe for you and can also affect the studies you are taking part in. We prevent this by using an electronic system called the Biometric Co-Enrolment Prevention System (BCEPS) that uses a fingerprint reader to identify you. You will need to place your fingers onto the fingerprint reader which will enter your fingerprints onto BCEPS. This system will then check if your fingerprints are stored on the system for any other studies. Only a few members of the study team can see the information in BCEPS using a secure password. This is done at the beginning of your visit and is covered on a separate BCEPS informed consent form.

WHO WILL BE IN THIS STUDY?

Approximately 50 sexually active, non-pregnant and HIV negative AGYW aged 16-20 (inclusive) who used PrEP and stopped use within the past 6 months will be asked to join one of two study groups.

- Study group 1: ~25 AGYW who will self-assess their HIV risk using a risk assessment and self-test for STIs using STI test kits to trigger PrEP restart and
- Study group 2: ~25 AGYW who will only self-assess their HIV risk using a risk assessment to trigger PrEP restart

The group an AGYW joins is decided using a process called randomization. Randomization is like throwing a dice. Just like nobody knows on which side a dice will land until it lands, nobody will know which group you will be put in until the randomization is done (including the study staff).

WHAT PROCEDURES WILL BE DONE FOR THIS STUDY?

If you take part in PALESA you will be in the study for ~6 months. This will include 7 visits some of which will be done in person like today and some virtually (e.g., over the phone).

Visit	**Type**
Screening and enrolment	In person
Months 1, 2, 4, 5	Virtual
Months 3 and 6	In-person
PrEP re-start	In Person

Your first visit (screening and enrolment) will happen today after you read this form (or have this form read to you), discuss and understand the information, and sign or mark this form indicating your agreement to take part. The procedures done at this visit will let us know if you can join this study.

SCREENING AND ENROLLMENT PROCESS

It is expected that all screening procedures will be done today. However, you may need to come back to complete the screening process. Some tests may need to be repeated.

The following procedures will happen during your screening visit today:

- You will be provided with study information and asked for your agreement to take part. That is what this form is for
- You will be asked to confirm where you live and how to contact you. This will help us contact you if we need to provide you with study information or remind you about your study visits
- We will talk to you about your reasons for wanting to join this study and how you see your risk of getting STIs and/or HIV
- You will be assigned a study number which will be used during the study on your study documents and samples. This will help maintain confidentiality as your name will not be directly linked to your study information
- We will ask you questions about yourself to help us describe the AGYW population in this study
- We will ask you for a urine sample to test for pregnancy. This urine sample may also be used to test for urinary tract infection (UTI) if you have symptoms.
- We will collect blood from your arm to test for HIV (~1 teaspoon/2ml) and you will receive counselling on your HIV result and how to protect yourself from HIV and STIs. We will also offer you condoms.
- You will receive contraceptive counselling and offered contraception to help you prevent pregnancy
- We will ask you questions about your health including your previous PrEP use, any STI symptoms you may have and any medicines you might be taking
- You will be asked some questions about potential for intimate partner violence and social harms to check if study participation will be safe for you
- A study nurse or doctor will collect swabs from your vagina and endocervix (inner part of the cervix) to test for common STIs (Chlamydia, Gonorrhoea and Trichomonas). They will use a speculum (a metal or plastic device) to help gently open the vagina and collect these swabs. Before this is done (and while you are still clothed), the nurse or doctor will explain this procedure to you, show you the speculum if you would like to see it and answer any questions you may have. They will also ensure you are in a comfortable position before proceeding with the specimen collection.
- You will receive your STI test results and provided with treatment. You will also be provided with a partner notification card for your partner/s so he can get treatment at a local clinic. If he is willing to come to our clinic, he can also get treatment here.
- The study doctor or other staff member will then decide if you are eligible to take part in PALESA

If you are not eligible for the study, your visit will stop, and you will be provided with any referrals that are needed.

If you are eligible to be in the study, the following will happen:

- We counsel you about the risks and benefits of oral PrEP.
- You will be offered an opportunity to be enrolled and randomized into PALESA.
- If you accept enrolment and once randomization is complete, you will be asked to complete a self-assessment of HIV risk in the clinic so the study staff can show you how it must be done
- If you are randomized to Group 1 (Group using STI test kits for self-testing and the self- assessment of HIV risk), you will
    - Be asked to self-collect a genital swab to be stored and tested later if you have a positive STI test during your self-testing
    - Receive instruction for STI self-testing
    - Receive kits for STI self-testing

FOLLOW-UP VISITS

MONTHS 1,2,4 AND 5 – VIRTUAL VISITS

Procedures will include the following

- We will confirm where you are living and how to contact you
- We will talk to you about what you are expected to do during the study, how to protect yourself from STIs, including HIV
- You will be asked some questions about potential for intimate partner violence and social harms to check if study participation is still safe for you. Counselling and referral will be provided if needed
- You will be asked to complete the self-administered behavioural risk assessment
- If you are in Group 1 (Group using STI test kits for self-testing and the self- assessment of HIV risk), you will be additionally asked to self-test for Chlamydia, Gonorrhoea and Trichomonas
- We will offer partner referral for STI management If needed
- We will schedule your next visit

MONTHS 3 and 6 – IN PERSON VISITS

Procedures will include the following

- We will confirm where you are living and how to contact you
- We will ask you for a urine sample to test for pregnancy. This urine sample may also be used to test for urinary tract infection (UTI) if you have symptoms
- We will collect blood from your arm to test for HIV (2ml) and you will receive counselling on your HIV result and how to protect yourself from HIV and STIs. We will also offer you condoms.
- You will receive contraceptive counselling and offered contraception to help you prevent pregnancy
- You will receive STI assessment and treatment
    - At month 3, we will ask you questions about any STI symptoms you may have and treat you based on your symptoms
    - At month 6, a study nurse or doctor will collect swabs from your vagina to test for common STIs (Chlamydia, Gonorrhoea and Trichomonas). The nurse or doctor will use a speculum (a metal or plastic device) to help gently open the vagina and collect the swabs. Treatment will be provided for any STIs you test positive for
- You will be asked some questions about potential for intimate partner violence and social harms to check if study participation is still safe for you. Counselling and referral will be provided if needed
- You will be asked to complete the self-administered behavioural risk assessment
- At Month 3, if you are in Group 1 (Group using STI test kits for self-testing and the self-assessment of HIV risk), you will be asked to self-collect a genital swab to be stored and tested later if you have a positive STI test during your self-testing
- We will offer partner referral for STI management If needed
- We will schedule your next visit (At month 3 only)

- At month 6 - If you restarted PrEP, we will also collect blood from your arm for dried blood spot (DBS) storage and plasma storage (2ml). If you become HIV positive during the course of this study, these samples will be used to check tenofovir levels in the blood at the time of seroconversion and for future assessment of antiviral resistance. We will also provide you with referral to a PrEP programme

PrEP RESTART – IN PERSON VISITS

Procedures will include the following

- We will confirm where you are living and how to contact you
- We will ask you for a urine sample to test for pregnancy. This urine sample may also be used to test for urinary tract infection (UTI) if you have symptoms
- We will collect blood from your arm to test for HIV (2ml) and you will receive counselling on your HIV result and how to protect yourself from HIV and STIs. We will also offer you condoms.
- We will ask you questions about any STI symptoms you may have and treat you based on your symptoms
- You will be asked some questions about potential for intimate partner violence and social harms to check if study participation is still safe for you. Counselling and referral will be provided if needed
- You may be asked to complete the self-administered behavioural risk assessment
- You will have blood collected from your arm for Creatinine (3.5 ml) and Hepatitis B testing (5ml)
- You will receive PrEP along with related counselling including adherence counselling
- We will offer partner referral for STI management If needed
- We will schedule your next visit

Additional procedures such as physical exams may be included at the doctor's discretion to make sure you are in good health. It is important for you to come to every study visit. If you cannot come to the visit, please tell the study staff as soon as possible so that the visit can be rescheduled.

IN-DEPTH INTERVIEW

At or just before your month 6 (exit visit), you may be offered an opportunity to take part in an in-depth interview (IDI) to discuss experiences of STI self-testing, self- assessment of HIV risk, and re-starting PrEP while taking part in PALESA (This will only be offered to up to 30 PALESA participants exiting the study). You may choose not to be interviewed. If you agree to be interviewed, you may be interviewed at or just before your month 6 visit.

INTERIM/UNSCHEDULED VISITS

Interim/unscheduled visits and telephone contacts may be performed at any time during the study. Study staff will discuss with you the importance of contacting the clinic as soon as you experience any changes in your body, including symptoms of a UTI, RTI or STI or if you have queries or require counselling. Also, it is possible that you may be asked to come to the clinic for an unscheduled visit in the event of an abnormal test result; difficulties in sample shipping, processing, or testing or to have study procedures repeated; or for other reasons at your request or the studies requirement.

IF YOU BECOME INFECTED WITH HIV

Being in this study will not cause HIV infection. But there is always a chance that you can get HIV through sex or other activities. If you test HIV-positive, your result will be confirmed within the study. Once confirmed, you will stop using PrEP immediately, be discontinued from the study and referred immediately to adolescent friendly HIV treatment and care services in the community. If interested, we will inform you of other research studies you may be eligible for.

PREGNANCY

If you become pregnant during the study, you will not be stopped from taking part in the study. You will be counselled on HIV transmission risk during pregnancy, safety of PrEP use during pregnancy, and supported to make an informed decision about whether to continue PrEP during pregnancy.

We will refer you for antenatal care and other services for pregnant women. The study does not pay for this care, but dependent on the facilities used, these services may be free in the community.

RISKS AND/OR DISCOMFORTS

- You may feel uncomfortable responding to some questions in study questionnaires. You can choose not to answer any question if it makes you feel uncomfortable.
- You may feel discomfort or pain when your blood is drawn. You may feel dizzy or faint. You may have a bruise, swelling, small clot, or in rare cases, an infection where the needle goes into your hand or arm. Clinical staff are trained and experienced in blood draws and minimizing associated risk
- You may feel uncomfortable or worried learning about HIV/STI risk or talk about current or recent IPV during the study. Should this occur, study staff are trained to provide suitable counselling and link you to necessary counselling support, shelters, legal support and services.
- You may feel discomfort, pain or pressure when vaginal and endocervical samples are collected. You may have a small amount of vaginal bleeding or spotting which should stop shortly after the exam. Clinical staff are trained and experienced in vaginal and endocervical sample collection and lowering associated risk
- When conducting STI self-testing at home, you may reveal use of the test kits to others in the home and this could lead to social harm (negative effects) or intimate partner violence (IPV). To reduce the chances of this, you will be provided with study material that you can access on a cellphone or computer. You will be counselled to self-test in a private safe space and to consult with study staff if they have any fears or concerns about self-testing. Should any social harm related to study participation be reported, the study team will provide appropriate virtual and in person counselling, support and referrals as per your needs.
- There may be risk related to you taking STI test kits home. For this reason, the STI kits will be packaged carefully, and you will be counselled on strategies to safely store these kits.
- There is also the risk of you sharing kits with your friends/partners. You will receive counselling that this must not be done as your STI management will be informed by the test results and your taking of the treatment will be observed at the study site. Those who are not in the study will not be able to get within the study.
- Should you choose to take part in the In-depth interviews (IDI), this will involve minimal risk because you would be providing your opinions in a one-on-one discussion with a study staff member. As such a breach of confidentiality is unlikely. It is entirely up to you if you choose to participate in the IDIs and refusal to participate will have no impact on your care within the study. You can choose not to answer any question if it makes you feel uncomfortable.

BENEFITS

There are no direct benefits to you apart from access to HIV and pregnancy testing, STI testing and treatment, PrEP, contraceptives, condoms and applicable referrals if needed. The data from this pilot RCT will have potential to inform policy on PrEP re-start among AGYW using self-identified STIs as a marker of heightened risk

NEW INFORMATION

You will be told any new information learned during this study that may affect your willingness to stay in the study. We will also tell you when study results may be available, and how to learn about them.

WHY YOU MAY BE ASKED TO LEAVE THE STUDY

You may need to leave the study early without your permission if:

- The study is cancelled by the sponsors, funders, the local government or regulatory agency, or the Institutional Review Board (IRB)/Ethics Committee (EC). An IRB/EC is a committee that watches over the safety and rights of study participants.
- You are not able to comply with study procedures

- You are confirmed HIV positive
- As determined by the PIs/designee, you have any current or previous physical health, mental health or social issue or any other condition that the site investigator or designee decides would make study participation unsafe, or otherwise interfere with achieving the study objectives.

If you are removed from the study or choose to leave, we will ask you to come back for one final clinic visit.

ALTERNATIVES TO BEING IN THE STUDY

You may be able to join other studies here or in the community. There may be other places where you can go for HIV counselling and testing, family planning and PrEP access. We will tell you about those studies and those places if you wish.

EMERGENCY CARE AND HOSPITALISATION

If you have a medical emergency during the time you are taking part in this study, please seek emergency care at the nearest hospital and inform the doctor treating you that you are taking part in this study. That doctor is welcome to call the study staff for information. This includes the time of up to 1 month after you have completed your time in the study. Please inform the study staff of your time in the hospital as soon as possible.

COSTS TO YOU

There is no cost to you for study visits, PrEP, physical exams, laboratory tests or other procedures. We can give you treatment for STIs other than HIV free of charge while you are in the study, or we can refer you for available treatment.

REIMBURSEMENT

You will receive R400 for your time, inconvenience, and expense to and from the clinic on completion of your in-person clinic study visits and R150 on completion of your virtual visits. This is in accordance with the South African Health Products Regulatory Authority requirements. You may also receive up to R150 for any study related visits which occur in between your normally scheduled visits, depending on your travel and procedures to be completed. Payment will occur electronically, and you will need to have your cell phone with you to ensure this process can occur.

CONFIDENTIALITY

We will make every effort to keep your information private and confidential. Study visits will take place in private. To keep your information confidential, your study information will be written down with a unique study identification number and not your name, address or any other information that could identify you. Only this number will be on your study documents and only clinic staff will be able to link this number to your name. We will keep the information about your study visits in a secure place that only certain people can access for the purposes of this study. We will only enter your information into computers protected by passwords and will not include information that could identify you. If you are selected to participate in an in-depth interview, you can choose not to answer questions at any time. We will keep the audio recordings and materials from all interviews confidential and will only use study numbers or fake names. We store the recordings for 2 years after publication of the study results or 6 years if there is no publication.

During this study, research staff from Wits RHI will record the information you provide during your study visits. This information may include, but is not limited to, basic information about you such as your date of birth, race, ethnic group, religion, level of education, income and employment history, marital status, and your medical history. This information will be shared with the study partners, which may include but not be limited to the parties listed below, however there will no personal identifiers such as your name or ID number included. This will ensure the information you provide is not directly linked to you. These partners will not be allowed to use your information for any other purpose other than the study and/or

in terms of your consent provided and may not transfer your information to any other party other than those partners taking part in the study and with our approval, as well as that of the Ethics Committee.

Data collected from you will not be shared without your permission. Your personal information may be disclosed if required by law. For example, if we learn something that would immediately put you or others in danger, the study staff must take steps to keep you and others safe. This means that we must share any information with the authorities (hospital, police, or social services) that tells us you may be in danger. For example, if you tell us that you plan to hurt or kill yourself, hurt or kill someone else, or if you tell us that someone is abusing or neglecting you.

It may be necessary, depending upon local and national health requirements, for study staff to report communicable diseases identified among PALESA Study participants. If you are suspected of having a communicable disease other than HIV based on clinical examination, you may be treated on site or be referred to a local clinic for further assessment.

The study staff will only use your fingerprints and personal information to verify that you are not taking part in any other research studies on BCEPS. This study will not use your name or identify you personally in any publication.

Your records may be reviewed by:

- Study team at the University of Alabama Birmingham
- Study team at the University of California San Francisco
- Representatives of the US National Institute of Mental Health:
- Other US, local and international regulatory entities
- Members of the study protocol team and external advisors
- South African Health Products Regulatory Authority
- University of the Witwatersrand Human Research Ethics Committee (Wits HREC)
- National Health Research Ethics Committee (NHREC)
- Members of an Independent Data Safety Monitoring Board who review this clinical trial
- Study monitors
- Study staff

All these organizations/institutions will be requested to comply with the Protection of Personal Information Act and its Regulations ("POPIA") in their handling of your personal information.

You have the right to request corrections to your personal information if it is inaccurate. You also have the right to limit the collection and use of your personal information under certain circumstances (for example, if you think that the information is inaccurate). If you have a complaint regarding the use of your personal information, you can file your complaints with South Africa's Information Regulator using their website (https://inforegulator.org.za/complaints/) or by sending an email to POPIAComplaints@inforegulator.org.za or enquiries@inforegulator.org.za. You may also contact the Deputy Information Officer of Wits Health Consortium (Pty) Ltd by sending an email to popia@witshealth.co.za.

YOUR RIGHTS AS A RESEARCH PARTICIPANT

- Voluntary: Your participation in this study is entirely of your own free will and you can refuse to take part or stop at any time without stating any reason. If you choose not to join or to leave the study, you can still join other studies you are eligible for at this clinic.
- If you decide to stop taking part in the study, the study staff will encourage you to come to the clinic for one final visit to check on your health. You can still access to medical care at your local clinic. If you want the results of the study after the study is over, let the study staff members know.

- You may also take back your permission for the collection and use of information about you by informing the Wits RHI research team. If you decide to leave the study or if you take back your permission for the collection and use of information about you, your participation in the study will end and the study staff will stop collecting information from you.
- New findings: The study clinic staff will provide you with any additional information that becomes available during the study, which may affect your willingness to continue in the study.

ETHICAL APPROVAL OF THIS STUDY

This study is being done in accordance with the Declaration of Helsinki (last update October 2013), which deals with the recommendations guiding doctors in biomedical research involving human participants as well as the Department of Health Guidelines for the South African Good Clinical Practice: Clinical Trial Guidelines (2020) and has received ethical approval from the University of the Witwatersrand Human Research Ethics Committee. Copies of these documents can be obtained from me if you wish to review them.

PROBLEMS OR QUESTIONS

If you have any questions about the study, who to contact at the study site, or if you have a research related injury or any other problems related to the study, please feel free to contact the clinic staff by visiting the clinic between 08:00 to 16:30 or phoning on 011 358 5424 (clinic hours) or 083 783 3574 (after hours). If you feel that you require more information than the clinic staff can provide you, please contact one of the people listed below:

Prof Thesla Palanee – Phillips Principal Investigator Wits RHI, Research Centre No. 7 Esselen Street, Hillbrow Tel: 011 358 5471 Emergency Number: 083 783 3574	Ms. Krishnaveni Reddy Co-Principal Investigator Wits RHI, Research Centre No. 7 Esselen Street, Hillbrow Tel: 011 358 5470	Ms Angeline Mzolo Counsellor Supervisor Wits RHI, Research Centre No. 7 Esselen Street, Hillbrow Tel: 358 5424/067 072 7010

If you want any information regarding your rights as a research participant, or if you have complaints regarding this study, you may contact Prof. Clement Penny, Chairperson of the University of the Witwatersrand Human Research Ethics Committee (Wits HREC), which is an independent committee established to help protect the rights of research participants.

Prof. Clement Penny Chairperson for the University of the Witwatersrand Human Research Ethics Committee University of the Witwatersrand Tel: 011 717 2301

DATE AND TIME OF COMPLETION OF INFORMED CONSENT DISCUSSION:

DD	**MMM**	**YYYY**

:
Time *(24 hour clock)*

NOTIFICATION OF PERSONAL DOCTOR:
Please indicate if you would like us to inform your personal doctor about your participation in this study.

Please sign or place your mark/thumbprint next to the option you choose

Yes, I want you to inform my personal doctor *(Staff to obtain personal doctor contact details)*	_____ Participant's signature/mark or thumbprint
No, I do not want you to inform my personal doctor	_____ Participant's signature/mark or thumbprint
I do not have a personal doctor	_____ Participant's signature/mark or thumbprint

INFORMED CONSENT:

- I hereby confirm that I have been informed by the study staff member_____ *(Print full name)*, about the nature, conduct, benefits and risks of PALESA
- I have also received, read (or had read to me) and understood the above written information (Participant Informed Consent Form for Young Women Aged 18 to 20 Years) regarding the PALESA study.
- I am aware that the results of the study, including personal details regarding my ethnicity, race, sex, age, medical conditions, date of birth, initials and diagnosis will be anonymously processed into a study report and my deidentified personal information may be shared as set out in this Informed Consent Form.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

Signature of participant:

Print name					
Signature/mark or thumbprint					
Date of signature/mark or thumbprint				Time of signature/mark or thumbprint *(24-hour clock)*	:
	DD	MMM	YYYY		

Signature of witness (if applicable):

If the volunteer cannot read, this form must be read to the volunteer in the presence of a witness exactly as it is written, in the volunteer's local language. The witness must then sign this form to agree that the correct information was given to the volunteer and that the volunteer voluntarily agrees to take part in this study

Print name					
Signature					
Date of signature				Time of signature *(24-hour clock)*	:
	DD	MMM	YYYY		

Signature of study staff taking consent:

Print name					
Signature					
Date of signature				Time of signature *(24-hour clock)*	:
	DD	MMM	YYYY		