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Co-occurrence of shedding Herpes Simplex Virus type-2 (HSV-2), Human Papilloma Virus (HPV) and Human Immunodeficiency Virus 1 (HIV-1) in the female genital tract among HIV-infected women

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PREAMBLE

1. Plagiarism Declaration

I, ……, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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2. Acknowledgement

I would like to express my deepest gratitude and acknowledgement to the following people for their support and contribution towards the completion of this thesis, without them, this thesis would never have been completed:

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3. Thesis Abstract

Introduction: Human Immunodeficiency Virus remains as one of the largest pandemics in the world, with the prevalence of more than 70% of HIV-infected individual reside in Sub-Saharan Africa. Moreover, other sexually transmitted viral infection such as Human Papillomavirus and Herpes Simplex Virus also show a high prevalence in Sub-Saharan Africa. Recent studies show the presence of other viral STI in the genital region may have increased HIV shedding in the genital region. However, it not clearly known if the presence of ART or HIV may affect the shedding of other viral STI in the genital region and if the combination of other viral STI treatment and ART is necessary to treat an individual with multiple STI infection.

Methods: This is a secondary data analysis study, based on analysing the data collected from a single-site, double-blinded randomized control study (2-IUD study). The research site was the Gugulethu Community Health Centre, Cape Town, South Africa and samples were collected between 2014 and 2018. Analysis was conducted on genital tract specimens of study participants obtained via the Menstrual Cup (MC) and Endocervical Swabs (ECS), collected at baseline, 3 and 6 months' follow up visit from randomly selected 52 ART-Naïve participants and 56 age-matched women from the ART-Using group of the primary study. Logistic regression models were constructed to measure the associations between possible risk factors and viral STIs. Results are presented as odds ratios (OR) with 95% confidence intervals (CI).

Results: ART-Naïve women had higher rates of HIV shedding in the genital tract at each visit. However, more than half of women using ART, most of them virally suppressed, had detectable genital HIV at one or more visits. Most of the participants showed pre-exposure to HSV-2, but shedding of HSV-2 was substantially less common. HPV was detected in 72% of the participants, with no significant difference by ART status. Overall, 70.3% of samples had at least one viral pathogen detected - 60.4% among ART-Using women compared to 82.8% in ART-Naïve women ($P<0.001$). Compared to ART-Naïve women, ART-Using women were significantly less likely to have co-occurrence of viral shedding overall. However, ART-Using women with higher VL had levels of viral co-occurrence similar to those of ART-Naïve women.

Conclusion: Our analysis demonstrated that the ART-Using women were less likely to shed HIV, HSV-2, HPV and viral STI co-infection in the genital tract compared to ART-Naïve women. This may be be driven by plasma VL levels where ART-Using women with lower VL are less likely to shed these viruses compared to women with elevated VL, including those not on ART.

4. List of Abbreviation

2IUDnCT	2-IUD study conducted in Cape Town
AIDS	Acquired Immune Deficiency Syndrome
aOR	Adjusted Odd Ratio
ART	Antiretroviral Therapy
ARV	Antiretroviral Treatment Drugs
C-IUD	Copper T-380 Intrauterine Device
CI	Confidence Interval
CT	*Chlamydia trachomatis*
CVL	Cervical Vaginal Lavage
^{o}C	Degree Celsius
ECS	Endocervical Swab
G	Gravitational force
g	Gram
HIV	Human Immunodeficiency Virus (For the duration of this thesis, HIV refers to Human Immunodeficiency Virus 1, group M, subtype C)
HPV	Human Papilloma Virus
hrHPV	High-Risk Human Papilloma Virus
HREC	Human Research Ethic Committee
HSV-2	Herpes Simplex Virus type 2
ID	Identifier
IgG	Immunoglobulin G
IQR	Inter-Quartile Region
IUD	Intrauterine Device

L-IUD / LNG IUD	Levonorgestrel Intrauterine Device
lrHPV	Low-Risk Human Papilloma Virus
MC	Menstrual Cup
mm^3	cubic millimetre
mL	Millilitre
N	Number
NG	*Neisseria gonorrhoeae*
NHLS	National Health Laboratory Service
OR	Odd Ratio
P-Value	Probability Value
PBS	Phosphate-Buffered Saline
%	Percentage
PCR	Polymerase Chain Reaction
RBC	Red Blood Cells
RCT	Randomised Controlled Trial
RNA	Ribonucleic Acid
SD	Standard Deviation
STI	Sexually Transmitted Infection
TB	Tuberculosis
UCT	University of Cape Town
UNAIDS	Joint United Nations Programme on HIV/AIDS
VL	Viral Load
WHO	World Health Organisation

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PART A: Protocol

1. Introduction

1.1. Background

The Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome (HIV / AIDS) pandemic has affected the globe for the past few decades, posing detrimental health risks and financial burden globally, particularly severe in sub-Saharan Africa (1). For decades, a massive amount of researches and attempted interventions took place to combat and reduce HIV incidence and HIV-related mortality. Over the years, despite all the efforts, HIV prevalence among women in sub-Saharan Africa remains persistently high, particularly among younger women (2).

Recent findings have confirmed sexually transmitted infections (STI) are among one of the most well-established risk factors for HIV acquisition. A possible mechanism could be, upon STI infection, the protective mucosal barrier becomes more vulnerable for HIV to penetrate and access susceptible cells (3). This STI / HIV acquisition relationship can also be bidirectional as HIV infected individuals have been shown to be more susceptible to acquire other sexually transmitted pathogens. This is most likely due to the fact that HIV infected individuals were more immune-compromised which allow opportunistic STI to occur (4).

Herpes Simplex Virus type 2 (HSV-2) is one of the most prevalent sexually transmitted pathogen worldwide (5). Symptomatic herpes infections express in the form of genital ulceration disease; and when being asymptomatic, the viruses stay dormant inside the host and cannot be cleared by the host immune system. Incidence and prevalence of HSV-2 are particularly high in sub-Saharan Africa, of which coincide with the high prevalence of HIV in

sub-Saharan Africa. Similarly, Human Papilloma Virus (HPV) is another highly prevalent sexually transmitted pathogen worldwide, the majority of cervical cancer can be linked to persistent high-risk HPV (hrHPV) infection. Cervical cancer is the most common cancer among young women in sub-Saharan Africa (6). Literature has shown HIV infected individual is more likely to acquire HSV-2 and HPV and leads to further complications such as cervical cancer (6, 7).

Following the massive rollout of Anti-Retrovirus Treatment (ART) programme, individuals who live with under-controlled HIV progression, increases in South Africa. Individual who are on ART can potentially control HIV viral load and largely increase the life expectancy of the HIV-infected individual.

This then poses the question, individuals who were enrolled in the ART programme, shown viral suppression, with the semi-restored immune system, are they less susceptible to other sexually transmitted viral infection comparing to those that weren't on the treatment or shown viral suppression.

A Randomised Controlled Trial (RCT) is currently ongoing; to compare the HIV-1 viral shredding in the genital tract between two different intrauterine devices (IUD), hormonal and non-hormonal, among Cape Town HIV-positive women who are on ART programme and who are not yet ready for ART programme. The study was investigated by UCT, Public Health Department, study participants were followed for a duration of 24 months. A nested study was conducted within this randomized controlled trial to compare STI occurrence between participants who are on ART programme and who were not on ART programme at enrolment.

1.2. Study Aim

The aim of this study is to compare the occurrence and co-occurrence of viral STI in HIV positive women who are on ART to that in HIV positive women who are ART-Naïve.

1.3. Objectives

1.3.1. Primary Objective

Describe the occurrence and co-occurrence of genital HIV, HSV-2 and high-risk HPV in female genital tract to identify the following:

1.3.2. Secondary Objectives

a. Risk factors for detection of genital HIV, HSV-2 and hrHPV individually, focusing on comparing between ART-Naïve and ART-Using participants or possibly viral suppression status.

b. Risk factors for co-occurrence of genital HIV, HSV-2, and HPV, focusing on comparing ART-Naïve and ART-Using participants or possibly viral suppression status.

2. Methodology

2.1. Study Design

The study design of this investigation was based on a single-site, double-blinded randomised controlled study (2-IUD study). The objective of the primary 2-IUD study, aims to evaluate the safety of hormonal levonorgestrel intrauterine device (L-IUD) and the copper T-380 intrauterine device (C-IUD) with respect to HIV progression between HIV-positive participants who were on ART at enrolment and HIV-positive participants who were not eligible for ART at enrolment by measuring the HIV viral load in the plasma and genital tract. Upon enrolment, study participants were randomized to one of the IUD types and followed up for a period of 24 months. The study took place at the Gugulethu Community Health Centre, Cape Town, South Africa between 2014 to 2018.

For our investigation, we propose to conduct a secondary analysis of data on the specimens that were already-collected from the primary RCT, including from baseline prior to installation of IUDs, and corresponding follow-up study specimens (3, 6 months).

2.2. Study Population and Sampling

The study population of the primary 2-IUD study was HIV positive women in South Africa, between the age of 18 to 40 years old.

The inclusion criteria for the primary study are as follow:

- Age 18 to 40
- Willing to provide written informed consent to be screened and participate in the 2-IUD study.

- Interested and willing to use either IUD as a family planning method.
- Willing to participate in all aspects of the study and to comply with study procedures and visits, for 24 months.
- Has documented HIV infection
- For those fall under ART-Naïve arm:
    - Not ART eligible at the time of enrolment as per South African ART guideline. Referral to ART initiation will occur per local guideline.
    - No symptoms of AIDS, pregnant or newly diagnosed Tuberculosis (TB).
    - At least 6 months post-delivery and not pregnant or desiring pregnancy for the next 30 months.
- For those fall under ART-Using arm:
    - Clinical records indicated ART usage.
    - Laboratory measure showed ART use and present evidence of viral suppression at enrolment (plasma HIV viral load < 1000 copies/mL).
    - At least 6 months post-delivery and not pregnant or desiring pregnancy for the next 30 months.

In total, 288 women have been recruited, 154 ineligible for ART at entry and 134 using ART at the entry for the primary study.

For our secondary data analysis, we proposed to randomly select a subset of participants from each arm. Investigate data collected from baseline, 3 months and 6 months follow up visits.

2.3. Measurement

The outcome of interest in this study is the viral STI status in the genital region of the female participants. The STIs of interest are HSV-2 and HPV respectively. For detection purposes, menstrual cup specimens and endocervical secretion specimens were obtained from the study participants at each visit. Collected specimens from sites were transported to the Medical Microbiology Lab at the University of Cape Town for further processing and stored at -80 degree Celsius freezer prior to the supplementary study. Collected specimens were then tested below:

2.3.1. Detection of quantitative HSV-2 in the genital tract

Menstrual cup specimens, previously collected and stored, are to be sent off to National Health Laboratory Service at Groote Schuur Hospital for quantitative HSV-2 detection, using Altona HSV 1/2 PCR kit.

2.3.2. HPV status confirmation and genotyping

Endocervical secretion specimens are to be used for HPV genotyping via Roche Linear Array HPV Genotyping Assay, manufactured by Roche Molecular Diagnostic. Linear Array Assay can detect 37 high and low-risk HPV genotype with B-globin testing as an internal control. The test is to be conducted via HPV accredited lab.

2.4. Data Collection

The data for this secondary analysis will be taken from the 2-IUD demographic and medical case report forms (appendix III), where the data were collected from face to face interview

during the time of visits (enrolment, 3 months and 6 months follow up visit). At each visit, after the interview, specimens were collected from the participants and sent off to respective laboratories, National Health Laboratory Service (NHLS) and Medical Microbiology Lab of University of Cape Town, for testing and storage. Variables of interest for this secondary analysis are depicted in Table A-1.

3. Data Management and Analysis Plan

Completed questionnaire from the parent study has already been entered into a password-protected database. Relevant data to be used in this secondary data analysis dissertation will be transferred onto a password protected external hard-drive. All data relevant to the study will be kept at the University of Cape Town when not in use.

Collected data will be analyzed using STATA software, with Linear Mix Model Algorithm and all statistical tests will be evaluated with statistical significance denoted by P=0.05. Data including HSV-2 viral load, HPV genotype and other possible variables such as HIV viral load will be taken into consideration to compare between ART and non-ART participants.

Table A-1: List of variables to be used for analysis

VARIABLE NAMES	TYPE OF VARIABLES	CATEGORICAL
DEMOGRAPHIC		
AGE	Numerical	
WEIGHT	Numerical	
EDUCATIONAL STATUS	Categorical – binary	< Grade 10, Grade 10 and above
OCCUPATIONAL STATUS	Categorical - binary	Employed, Unemployed
RELATIONSHIP STATUS	Categorical - binary	Single, in relationship
CLINICAL CHARACTERISTICS		
NUMBER OF YEAR SINCE HIV DIAGNOSIS	Numerical	
PAST TB HISTORY	Categorical - binary	Past TB presence, No past TB
CD4 COUNT AT ENROLMENT	Numerical	
ART STATUS	Categorical - binary	On ART, not on ART
PLASMA HIV VIRAL LOAD	Numerical / Categorical	Suppressed, not suppressed
GENITAL HIV VIRAL LOAD	Numerical / Categorical	Suppressed, not suppressed
HIGH-RISK HPV	Categorical – binary	Positive, not detected
HSV-2 VIRAL LOAD	Categorical – binary	Positive, not detected
HSV-2 IGG	Categorical – binary	Positive, not detected
TRICHNOMONAS	Categorical – binary	Positive, not detected
GONORRHEA	Categorical – binary	Positive, not detected
CHLAMYDIA	Categorical – binary	Positive, not detected
BACTERIAL VAGINOSIS	Categorical – binary	Positive, not detected

4. Ethics Approval

4.1. Description of risks and benefits

The parent study has received ethics approval from University of Cape Town since 2014 (Appendix I). Annual renewal for the year 2018, during which this dissertation was conducted,

can be found in the appendices (Appendix I). This secondary analysis will go through the UCT-HREC for ethic approval.

In this dissertation, one does not directly come into contact with the study participants. All data received came as an encrypted data that does not include the identity of the participants and one will not review the actual participant folders. Hence this poses a limited risk of harming or losing the anonymity of the participant for the study.

The secondary analysis does not have any direct benefit or harm on the study participants, as it does not come into contact with the participants directly. Study itself only utilizing the collected data from the parental study which may provide future research benefit for the better understanding of the HIV and STI relationship.

4.2. Informed consent process

Participants of this supplementary study were consented through the parental study (2-IUD study) consent process (Appendix II). The informed consent process was done with an interviewer in the local language (isiXhosa) with a standardized from. The standardized form was translated from English to isiXhosa and back to English by different ixiXhosa speaker to ensure fidelity. At the start of informed consent process, the study staff will describe the portion of the study involved in that specific consent, outlining all procedures and associated time commitments, duration of participation, risks and benefits of participation, and staff contact information. The study coordinator will be available to address any questions or concerns. The participation was strictly voluntary.

5. Potential Limitation

Certain characteristics of interest, that may have affected the risk of exposure to STI requires self-report during the initial questionnaire interview. Characteristics such as date or partner association may have been incorrectly answered during the interview. Hence may have inflated or deflated the comparative analysis.

Furthermore, analysis conducted over 6 months period (baseline, 3 months and 6 months follow up visits) may not completely reflect the true association of STI occurrence and co-occurrence due to the nature of viral shredding.

6. References

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PART B: Literature Review

1. Introduction

Human Immunodeficiency Virus 1 (HIV) remains one of the largest pandemics in the world. At World AIDS Day on 1 December 2018, the Joint United Nations Programme on HIV/AIDS (UNAIDS) published that in 2017, 37 million people globally were living with HIV, of which only 21 million have access to HIV antiretroviral therapy. In 2017 alone, 1.8 million people were found to be newly infected with HIV and about 1 million people died from HIV related disease (1). A disturbing fact indicated that Sub-Saharan Africa only accounts for less than 20% of the global population, yet it contributed to more than 70% of the global HIV prevalence (2). In South Africa during 2017, UNAIDS reported that 7.2 million people were living with HIV while 270 000 people were diagnosed to be newly infected with HIV and 110 000 people died from HIV-related diseases. (3). Currently only 61% of HIV positive individuals who live in South Africa are receiving antiretroviral therapy (ART) (3).

Antiretroviral treatment programme has been developed and implemented as the primary tool to suppress the HIV viral load in infected individuals to reduce mortality, morbidity and transmission. While researchers still attempt to develop a suitable vaccine for eradication of HIV, the focus has been on prevention of HIV-related diseases. (4-7). Similar to HIV, other viral sexually transmitted infections (STIs) such as Herpes Simplex Virus type 2 (HSV-2) and Human Papillomavirus (HPV) also have very high prevalence in Sub-Saharan Africa. HSV-2 causes genital ulcers, whereas persistent HPV infection has been linked to cervical cancer, both of which appear commonly in women living with HIV. Several studies have provided the rationale behind the high co-prevalence of STI and HIV. HIV infection reduces the efficiency of the host's immune system, and also disrupts and compromises the normal health-protective flora in the female genital tract. This allows HIV-infected women to become more susceptible

to other viral STIs which use the genital epithelial cells as an entry point (8-10). Moreover, viral STI co-infection particularly causes more severe damage in untreated HIV-women where a non-recovered and compromised immune system allows the viral STI to stay persistently in the genital region forming a stable viral reservoir. This then may progress to severe disease such as cervical cancer (11-13). Thus one of the objectives of HIV treatment is to prevent further STI damages.

ART is highly effective in causing HIV viral suppression and preventing HIV transmission (14). In 2014, the World Health Organisation (WHO) and their partners launched the 90-90-90 target: 90% of HIV-infected individuals have been tested and diagnosed; 90% of those that were tested have received antiretroviral therapy; and 90% of those who received treatments managed to achieve viral suppression (15). Increasing the coverage of antiretroviral therapy leads to a rise in the incidence of women with controlled HIV, a semi-restored immune system, which potentially reduces the danger of opportunistic infections and may boost life expectancy (14, 16). Studies have shown initiation of antiretroviral therapy results in rapid reductions of HIV viral load in plasma, leading to a decline in HIV-1 shedding (expulsion of viral particle after successful viral replication during host-cell infection) in the genital region, which potentially reduces the risk of transmission (17, 18). However, some studies also show that even with undetectable plasma viral load, women living with HIV can still shed viral particles in the genital region which pose an ongoing risk of transmission. The mechanisms underlying this are not well understood (19). In addition, it is not well understood whether ART can also decrease the shedding of other opportunistic STIs in the genital tract and whether there is any correlation with HIV shedding in the same region.

A massive ART treatment programme has been rolled out in South Africa since the early 2000s and resultant HIV incidence and related mortality have decreased significantly (20, 21). The achievement of ART therapy led in an rise in the life expectancy of HIV-infected individual due to the lifelong infection nature of HIV (20, 22). Recent studies showed that similarly sexually transmitted virus such as HSV-2 and HPV also remain significantly high in South Africa.

This then raises the question: are HIV-infected women, enrolled in the ART programme and possibly virally suppressed, shed less sexually transmitted viruses in the genital region and demonstrate more protection compared to those that not on the ART programme.

2. Literature search strategy

PubMed and Google Scholar were internet searches used to locate the literature for this review. The search was limited to English language publications with no restriction on the time period of publication. Search terms used in the search engines are indicated in Table B-1 below.

Table B-1: Search terms used in the literature review

Keywords	**Association or Keyword synonym**
HIV	Plasma HIV, Genital HIV, HIV viral load
Viral STI	HSV-2, HPV, STI
ART	HIV treatment, viral suppression

3. Summary and interpretation from the literature

3.1 HIV in the genital tract

Plasma HIV viral load (VL) is the major determinant of disease progression as well as viral transmission in HIV studies (23, 24). While plasma HIV VL is the main biomarker of HIV infection, genital tract HIV VL, or shedding of HIV in the genital region, can affect transmission during heterosexual contact (25-27). There is a direct correlation with plasma HIV VL and HIV shedding in the genital region, as individuals with higher plasma VL tend to have detectable HIV VL in the genital region (19, 25, 28).

The advent of ART has resulted in a huge reduction in HIV transmission and acquisition and ART has since been used as one of the key HIV prevention approaches (13, 14, 18, 29). Studies have shown that HIV-infected women receiving treatment have a considerable reduction of HIV viral load in their plasma and genital tract compared to untreated individuals. However, despite these reductions there are studies that report detectable HIV shedding in the genital tract despite undetectable HIV viral load in plasma (17, 19). This has implications for transmission of HIV to sexual partners during intercourse and in turn needs to be better understood.

There are sexually transmitted infections which are associated with HIV transmission and acquisition (30, 31). Individuals who showed symptomatic STIs in the genital region are more likely to acquire HIV during sexual intercourse. Similarly, individuals with HIV are also more likely to acquire other STIs (31). Furthermore it has also been shown that individuals who are HIV-positive and infected with other viral STIs are also more likely to shed HIV particles in the genital region and therefore increase the rate of HIV transmission (31, 32). Localised viral

infection, which refers to localisation in one area of the host, can potentially recruit HIV-infected leukocytes to the area as well as trigger a cytokine response which provides a further platform for HIV replication (19, 33). The combination of these effects enhances HIV replication and in turn increases viral shedding in the genital tract (19, 27, 32). This may be one of the factors that enhance HIV shedding in the genital region despite use of antiretroviral therapy.

3.2 HPV in the genital tract

HPV is one of the most prevalent sexually transmitted viruses among female populations worldwide, estimated at 11.7% worldwide (34, 35). In the recent meta-analysis shown on HPV information centre, sub-Saharan Africa have the highest HPV prevalence (24%) (34). South Africa showed high prevalence of HPV in women with healthy normal cervix, with no malignant lesion (17.9%) and particularly high prevalence in young adolescents (36, 37). The HPV infection starts soon after sexual debut, peaks in adolescence and rate decreased as age increased (36). Infection can later be cleared by the immune system but with the possibility of re-infection by the same HPV genotype. However, in some cases, persistent HPV infection can occur, in other words, failure by the immune system to clear infection could result in the development of cancer (38, 39). To date, several high-risk oncogenic HPV genotypes has already been identified, such as types 16, 18, 31, 33. Potential vaccines for various subtypes have been designed (40, 41).

Invasive cervical cancer has been correlated with HPV infection in the female genital tract. Invasive cervical cancer is the second most common cancer in women globally, mostly occurring in less developed countries (42). It is the second most common cancer in women

after breast cancer and is the most common cancer in women between age 15 to 44 in South Africa (36, 40). Cervical cancer has become one of the leading causes of death in South African women.

In most cases, HPV infection is commensal in the epithelial layer of the skin, cervix, anus or mucosal layer. Once infected in the region, the infection mechanism often causes lesions in the localised area (41, 43). Most of these infections do not linger and the virus is usually cleared by the host immune response. However, an invasive type such as type 16 and 18 together with other external factors, may cause persistent infection. As demonstrated in Figure B-1, HPV-based cervical cancer generally occurs in four stages: firstly, HPV infection; next a persistent infection of HPV; then the progression of clones of persistently infected cells to form a pre-cancerous lesion and finally the invasive cancer. Clinical symptoms are reversible at any time point in the first three stages, if HPV infection is treated and cleared. However, lack of screening in areas with poor infrastructure often allows detection at a very late stage of the cancer progression and hence treatment is difficult (41, 43).

In addition to growing HPV and cervical cancer incidence, HIV/AIDS infection has caused a major impact on the burden of HPV-associated diseases, particularly in South Africa. As indicated previously individuals with HIV positive status are more prone to HPV infection with progression to cervical cancer as HIV positive individuals are less likely to have the strong immune system required to clear HPV infection (44, 45). Moreover, HIV positive individuals are also more likely to be infected with multiple HPV genotypes which makes treatment difficult.

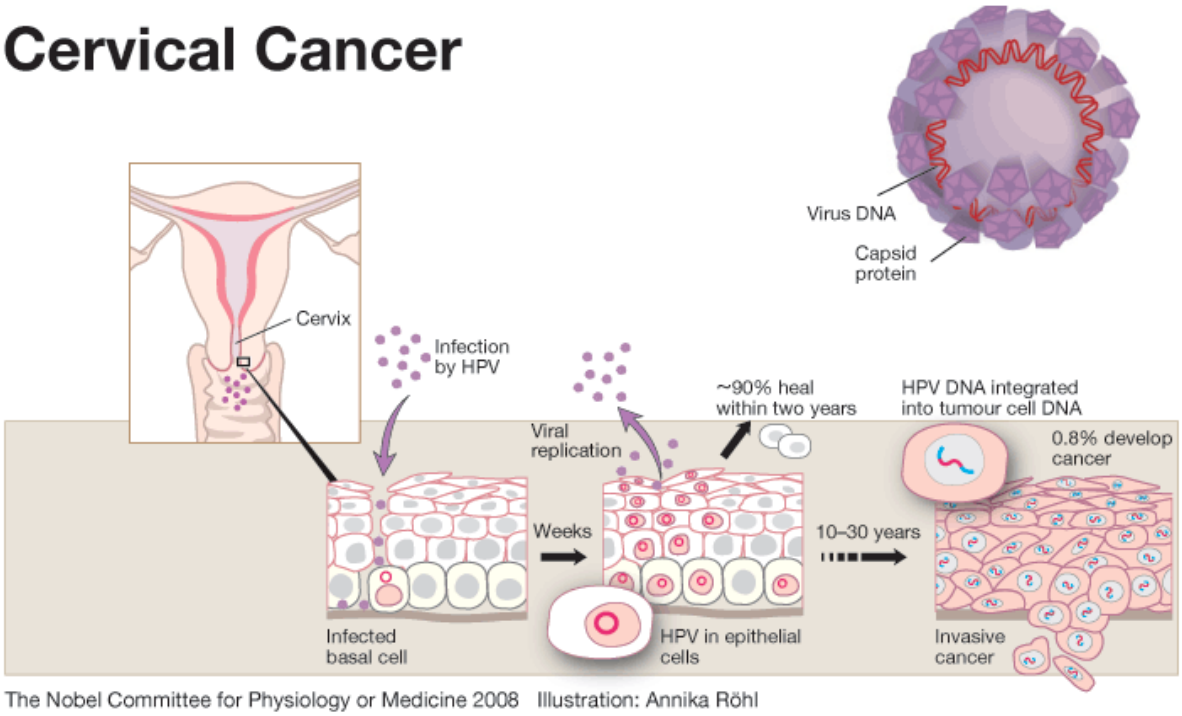

Figure B-1: Schematic diagram of HPV infection and c progression (46)

There is no direct evidence to show HIV accelerates the rate of cancer invasion or progression from pre-cancer to cancer. The effect of ART treatment on HPV remains inconclusive, although certain studies reported that with ART treatment, it is possible that individuals are now living longer with a constant higher risk of HPV acquisition and less immune defence in terms of HPV clearance comparing to HIV uninfected individual, thus increasing the risk of cancer progression (44, 47, 48).

3.3 HSV-2 in the genital tract

Herpes simplex virus type 2 (HSV-2) is one of the most prevalent sexually transmitted pathogens worldwide (49). Viral transmission can occur by sexual intercourse, through direct mucosal or skin contact (50, 51). Infection initiates from the epithelial cells under the skin layer and then moves to the nerve endings - sacral ganglion -where it resides, or in severe cases moves

to the central nervous system. Once infected, the infection is incurable and cannot be cleared by the immune system of the host. The infection lasts lifelong inside the host and can be identified with Immunoglobulin G (IgG) screening (52, 53). Disease symptoms can either be periodically symptomatic with the presence of a genital ulcer or mostly asymptomatic (see Figure B-2).

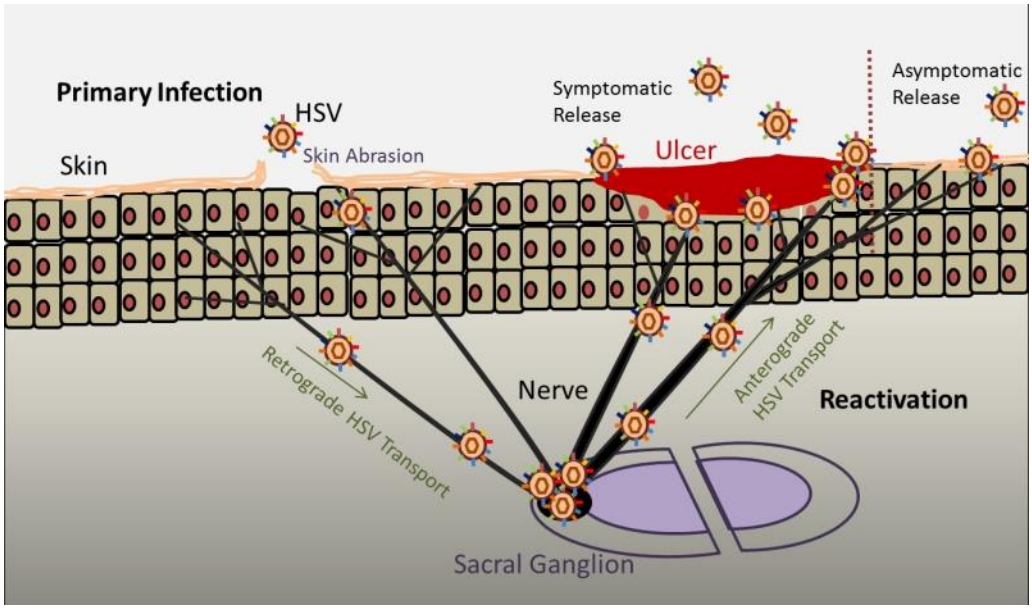

Figure B-2: Schematic diagram of HSV-2 infection and disease progression (54)

Being mostly asymptomatic, many people infected by HSV-2 are unaware of their status and therefore increase the risk of transmission via sexual intercourse (55). In 2012, it was estimated that the prevalence of HSV-2 among individuals between the ages of 15-49 is about 11% globally. In Africa a higher prevalence of 31.5%, coincided with a high prevalence of HIV (56). From a recent meta-analysis, the estimated prevalence of HSV-2 in women aged 15-24, ranges from 31.9% to 53.7% in the South African clinic- or community-based population. Due to the lifelong infection nature of HSV-2, the prevalence is a lot more higher as the age increase,

showing an estimated 77.8% in women aged 25-49 years old (57). This statistic matched with other HSV-2 prevalence studies conducted on South Africa populations (58, 59).

One of the main clinical symptoms of HSV-2 infection is the periodic re-occurrence of genital ulcers (56). Studies have shown that HSV-2 is currently the primary contributor to genital ulcers globally (60-62). Soon after initial infection, clinical symptoms of genital ulcer disease appear, with the possibility of reoccurrence (63-65). As time progress, the rate of re-occurrence decreases, however, this rate is variable due to other factors such as host immune response, sexual behaviour, other STDs or bacterial vaginosis (63, 65). Initially, HSV-2 viral shedding was thought only to occur during viral reactivation with the presence of clinical symptoms, and the viral particle was thought to have been shed from the genital ulcer directly. However, recent studies show that individuals with HSV-2 shed HSV-2 viral particles asymptomatically more frequently than those with clinical symptoms (51, 60, 63). In turn the true reactivation, as well as risk of viral transmission, are more frequent than what was originally perceived (60).

One of the major public health concerns associated with the high prevalence of HSV-2 is the increased risk of HIV acquisition (60). Studies have shown that prevalent HSV-2 increases the risk of HIV acquisition by 2- to 3-fold, and possibly much higher in some other settings (53, 60, 62). The possible mechanism could be that HSV-2 infection causes skin lesions, which provides an entry point for HIV (55, 60). Moreover, HSV-2 infection could also negatively impact the protective microflora lining the genital region, whereby a much weakened defensive barrier increases susceptibility to HIV acquisition (66, 67). In asymptomatic women, in the absence of genital ulcers, periodic HSV-2 shedding in the genital tract causes inflammation and recruits CD4+ T cells into the genital tract providing targets for HIV infection (66, 67).

Therefore, prevalent HSV-2, whether symptomatic or asymptomatic, may increases HIV acquisition. The relationship between HSV-2 and HIV is bidirectional as HIV-infected women have increased risk of HSV-2 acquisition by way of a similar bio-mechanism (55, 60).

Several studies have indicated that the presence of HSV-2 in HIV-infected individuals can potentially increase the shedding of HIV in the genital tract (68, 69). HIV-infected women were reported more likely to present symptomatic genital lesions/ulcerations or have longer shedding episodes or shed more HSV-2 viral particles compared to HIV-uninfected women (62, 67, 70). Moreover HIV viral particles are more likely to be shed through HSV-2 lesions and hence increase detection of HIV in the genital tract, and increase the rate of HIV transmission (68, 71). The rationale behind this could be that HSV-2 is less likely to be cleared after reactivation due to the host's compromised immune system from HIV infection. This in term, allows the prolonged activation of HSV-2, causing clinically symptomatic ulceration in the genital tract (65). Formation of ulcers triggers a particular cytokine response which in turn recruits more immune cells to a localised area (53, 55). This then provides more target for HIV infection and consequently more HSV-2 and HIV shedding the genital tract (55, 60). It was thought that HIV infection reduces the number of CD4 cells and thus enables HSV-2 to be reactivated more frequently. It was therefore initially hypothesised that using HIV antiretroviral therapy, the semi-restored count of CD4 T cells can then decrease the rate of HSV-2 activation. Recent studies however showed that the impact of ART on HSV-2 shedding was inconclusive. Some studies have shown that initiation of ART may slightly trigger more genital lesion, while others have shown no true changes in the general HSV-2 shedding in the genital tract of HIV-infected women (55, 60, 70, 72).

3.4 Effect of ART on co-occurrence of viral STI

Sexually transmitted infection (bacterial and viral) have already been established as one of the key risk factors associated with HIV acquisition (66, 69). Similarly, HIV-infected individuals are also more susceptible to other STIs as they are more immuno-compromised against opportunist infections. It is also not uncommon for HIV-infected individuals to acquire multiple different STIs at the same time point as the mode of transmissions are quite similar. Therefore more than one STI (bacterial and/or viral) can frequently be detected in an HIV infected individual (73, 74).

Studies have shown that the presence of other STIs can accelerate disease progression of HIV by increasing the shedding of HIV in the genital region, by increasing plasma HIV viral load, and by decreasing host CD4 cell counts (27, 32). Moreover, this is also bidirectional, as HIV, weakens host immune system, causing persistent STI infection, and potentially leads to cancer (HPV), or severe genital ulcer (HSV-2). It can be surmised that introduction of antiretroviral treatment can protect the host from further damages and partially restore the immune response. However, several complications with regards to the impact of antiretroviral treatment on other STIs have been reported (70, 72).

Highly active antiretroviral treatment can reduce HIV viral load at the plasma level as well as reduce shedding in the genital region, and thus reduce the rate of transmission. However, not enough evidence exists to show that ART can also reduce shedding of other STIs, and hence this can potentially compromise the effectiveness of ARV treatment. Although at the initial stage of ARV treatment HIV becomes less virulent other STIs still exist and continue to shed viral particles. This could result in recruitment of newly developed CD4 T cells to a localised

region due to immuno-inflammation. With additional CD4 T cells and immune activation and possible genital ulceration, this may allow HIV shedding to continue in the genital region and therefore increase the rate of transmission (73-75).

In most cases STIs are asymptomatic and in places where STI screening is not routine many individuals do not know their STI status. Ignorance of STI status can then potentially reduce the efficacy of the antiretroviral treatment programme leading to transmission of HIV. Other studies also showed that the success of the ART programme has increased the incidence of unprotected sexual intercourse as it has given the impression that HIV viral load is under control and transmission will not occur (75, 76). Therefore, the combination of not knowing STI status high risk, unprotected sexual behaviour resulted in increased incidence of STIs in the HIV-positive group. High prevalence of STI/HIV, resulted in reduced efficacy of treatment program and hence allowing the presence of HIV shedding in the genital tract, with undetectable HIV viremia in the plasma level and hence allowing transmission of HIV and STI to take place.

4. Conclusion

HIV shedding in the female genital tract is one of the primary risk factors in HIV transmission during sexual intercourse. Even with the introduction of ART, HIV shedding in the female genital tract is still detectable despite undetectable plasma viral load. This is a major concern for HIV transmission. Therefore, one of the major challenges is to understand the risk factors that cause HIV genital shedding with undetectable plasma HIV.

STIs in the genital tract has long been found to be associated with HIV infection. The presence of STIs increase the risk of HIV acquisition and the presence of HIV increase risk of other STI. Therefore, it is not uncommon to find HIV and other STIs co-occurring in the genital region. The routes of transmission are the same, where STI may damage mucosa and cause immune inflammation, recruiting CD4+ T cells. Although studies have shown that HIV/STI co-occurrence resulted in persistent infection and severe disease progression, not much of study has been done on the effect of HIV/STI co-occurrence on genital HIV shedding.

There are limited studies indicating that in the presence of other STIs, HIV shedding may increase in the genital tract. This may happen when STIs cause lesions in the genital tract, then recruit CD4 T cells to the localised region and thus increase HIV shedding in the genital tract. Not much has been verified however, and not much has been done to know whether asymptomatic STI can also boost shedding of HIV in the genital tract. This information is essential as it may explain an individual's HIV shedding phenomenon under ART with undetectable HIV viral load in the plasma. More and more studies have shown that more regular STI testing is essential in order to start early therapy, which will reduce the risk of other STI acquisitions. More importantly, for HIV-positive individuals, early STI therapy should be performed in conjunction with ART to avoid other STIs from decreasing the effectiveness of ART.

More studies need to be conducted in order to understand the role of other STIs in the genital region with regards to HIV shedding. One also needs to understand if there are other risk factors or influences which might act as viral suppression of ART.

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PART C: Manuscript

Co-occurrence of shedding Herpes Simplex Virus type-2 (HSV-2), Human Papilloma Virus (HPV) and Human Immunodeficiency Virus 1 (HIV-1) in the female genital tract among HIV-infected women

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1. Introduction

HIV-1 (refer to as HIV for the remainder of this manuscript) remains a major public health concern with more than 37 million infected individuals globally, more than 70% of whom live in sub-Saharan Africa (1-3). Furthermore, recent literatures show that young women between 15 to 24 years of age are twice as likely to be living with HIV than men of the same age (1, 4). At the level of both populations and individuals, antiretroviral therapy (ART) has altered fundamentally the course of HIV (5). ART use results in reduction of plasma HIV viral load (VL), the key biomarker of HIV disease progression (6, 7). After initiating ART, HIV-infected women experience a rapid decline of plasma HIV VL as well as reductions in HIV shedding in the female genital tract (8, 9). Reduced genital tract HIV reduces the potential of HIV transmission during heterosexual intercourse (8, 9). Hence, ART has been considered and utilised as an approach to preventing HIV transmission (8, 10). However, some studies found that even with undetected plasma HIV VL women can still have detectable HIV RNA in their genital tract (9, 11).

High rates of HIV co-infection with other sexually transmitted infections, particularly viral pathogens, are well documented (11-16). These infections share similar transmission routes and risk factors, and prevalent HIV infection can increase vulnerability to other viral pathogens such as Herpes Simplex Virus type 2 (HSV-2) and Human Papilloma Virus (HPV) (17, 18). Similarly, HSV-2 infection causes genital ulcers which provide a suitable entry point for other sexually transmitted infections (STIs) (19). There are limited data showing that HPV infection increases the risk of HIV acquisition but HIV and HPV co-infection is common and may lead to persistent HPV infection and, if untreated, to possible invasive cervical cancer particularly amongst those infected with highly invasive high risk HPV (hrHPV) (13, 20, 21).

HIV-infected women using ART may have suppressed HIV plasma viral load and reduced genital tract HIV shedding however other viral STIs may still be present in the genital tract. Several studies indicated that HIV-infected individuals with reasonably high CD4 counts, who were treated with ART demonstrated reduced incidence of hrHPV. Moreover, studies have indicated that hrHPV in ART-treated individuals was less persistent and less likely to develop invasive cervical lesions (22-24). Recent research showed that although initiation of ART may transiently increase HSV-2 shedding, longer periods on ART reduces the shedding of HSV-2 in the genital tract with fewer genital ulcers observed (25, 26). However, apart from reducing shedding and slowing disease progression, the introduction of ART does not prevent acquisition or transmission of other viral STIs (25, 27). Because viral pathogens such as HSV-2 and HPV present mostly asymptomatically, infections may not be detected clinically. It has been reported that localised HSV-2 and HPV infections, even if asymptomatic, may enhance shedding of HIV in the genital tract (28-32). This may limit the effects of ART in reducing HIV shedding as the presence of other viral pathogens in the female genital tract may promote HIV RNA shedding (14, 33).

Better understanding of the relationships between the shedding of common sexually transmitted viruses in the female genital tract are urgently needed. This information is crucial for HIV prevention as it may explain genital HIV shedding even with an undetectable HIV VL in the plasma. Furthermore, this may also raise awareness around the need to screen and treat other viral STIs in conjunction with ART use. The aims of this study are firstly to describe the occurrence and co-occurrence of viral STIs in women living with HIV using ART as compared to those who are not yet using ART, and secondly to determine factors associated with viral shedding in the female genital tract.

2. Methodology

2.1. Study Design

This is a secondary analysis of a single-site, double-blind randomised control study (NCT01721798). The original parent study aims to evaluate the safety of the progestin-containing levonorgestrel intrauterine device (LNG IUD) compared to the copper T-380 intrauterine device (C-IUD). At enrolment of the parental primary study, study participants were randomised to one of the IUD types and were followed up for a period of up to 24 months. The research site was the Gugulethu Community Health Centre, Cape Town, South Africa and samples were collected between 2014 and 2018.

For the purpose of this secondary study, our analysis was conducted on genital tract specimens of study participants obtained via the Menstrual Cup (MC) and Endocervical Swabs (ECS). Genital tract specimens were collected from baseline (prior to IUD insertion), and then at three- and at six months' follow-up visits. Of particular interest was the prevalence of risk factors for genital tract HIV, HSV-2 and HPV, separately and as co-infections.

2.2. Study Population and Sampling

The study population of the parent trial was HIV-infected women, between the ages of 18 and 40 years. Eligibility criteria included willingness to provide written informed consent, no planned pregnancy in the next 2 years, and willing to participate in all aspects of the study for 24 months including compliance with study procedures and visits. We randomly selected 52 ART-Naïve participants and 56 age-matched women from the ART-Using group. Figure C-1 shows how the study populations were derived.

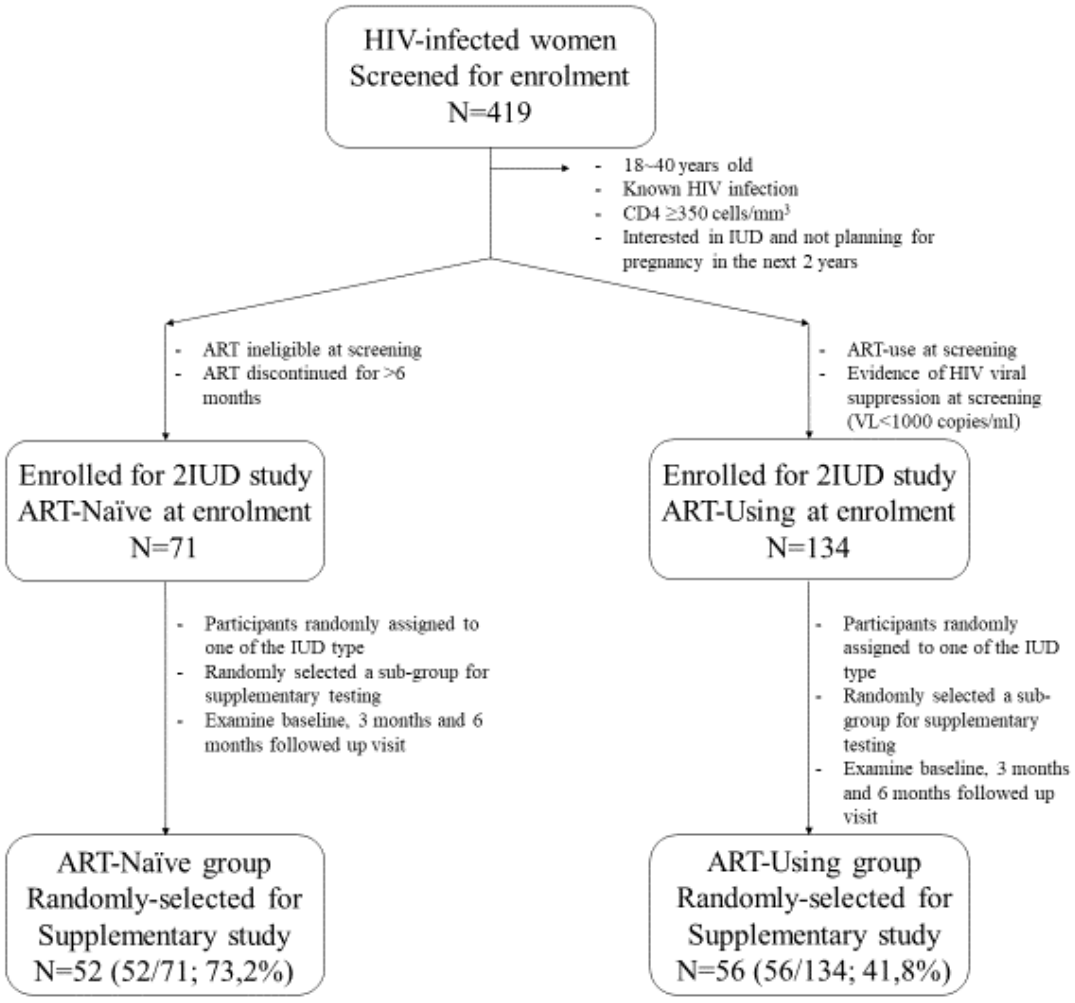

Figure C-1: Schematic diagram indicating the study population of the primary 2-IUD study and supplementary study

2.3. Specimen Collection

From the initial two type IUD (2-IUDnCT) study, three different genital tract samples (Menstrual Cup (MC) and Endocervical Swab (ECS)) were collected for HIV RNA detection at enrolment and months 3 and 6 visits. The collection procedure was described in a published paper (34) and is as follows:

For the MC specimens, the study participant either self-inserted or had a clinician insert an individually wrapped, single use Instead Softcup™ (Evofem Inc., San Diego, California, USA) at enrolment, months 3, and month 6. The MC was inserted to cover the cervix and was to

remain in place for at least 60 minutes before removal by a clinician and transference to a sterile 50-mL tube.

For the ECS specimens, a clinician collected endocervical fluid with elongated tapered flocked swabs (Copan Diagnostics, Murrieta, California, USA) during a pelvic examination. Each swab was allowed to absorb fluid inside the endocervical canal for 60 seconds, without rotating the swab to prevent microabrasion. Collected swabs were placed into individual cryovials with 1.5 mL phosphate-buffered saline (PBS).

For the Plasma specimens, whole blood was collected from eligible participants.

Collected specimens were sent to the Medical Microbiology Laboratory at the University of Cape Town for initial sample preparation and storage in a -80^{o}C freezer before viral pathogen and other testing by the afore-mentioned laboratory and the National Health Laboratory Service at Groote Schuur Hospital, Cape Town.

2.4. Specimen Processing

Specimen processing procedures have been published (34) and are described briefly below:

For the MC specimens, once collected from site, 50mL tubes containing MC specimens were weighed. The volume of secreted fluids was obtained by subtracting against the average weight of 50-mL tubes with an unused single-use Instead Softcup™. The Softcup with secreted fluids was centrifuged at 850G for 10 minutes in order to collect secretions at the bottom of the tubes. The contents were then resuspended in PBS, using the determined weight of secretions and assuming 1 g = 1 mL genital secretion to make a 10-fold dilution. Specimens were aliquoted and stored at −80°C.

For the ECS specimens, the sample (ECS with 1.5 mL PBS) was mixed and resuspended by using a vortex mixer for 1 minute. All fluid was removed from the swab by gently scraping the

swab head against the inside of the tube before discarding it. ECS samples were aliquoted and stored at −80°C.

For the Plasma specimens, collected whole blood specimens were centrifuged at 1500G for 10 minutes to separate the blood into an upper fluid layer (plasma) and lower red blood cells (RBC) layer. The plasma was then aliquoted and stored at -80℃.

2.5. Laboratory Testing for viral STIs

MC specimens were thawed and sent to the National Health Laboratory Service (NHLS) at Groote Schuur Hospital for quantitative HSV-2 detection using Altona HSV 1/2 PCR kit, and HIV-1 viral load detection using the Cobas Ampliprep / Cobas TaqMan system (Roche Diagnostics Ltd., Rotkreuz, Switzerland). Testing was conducted according to the manufacturer's manual. ECS specimens were tested for HPV via Roche Linear Array HPV Genotyping Assay (Roche Diagnostics Ltd., Rotkreuz, Switzerland). Linear Array Assay is capable of detecting 37 high and low-risk HPV genotypes with B-globin testing as an internal control. The test was conducted in the Molecular Virology Lab at the University of Cape Town.

HIV plasma VL were tested by NHLS during the parental study, using Abbott M2000SP/RT viral load assay (Abbott Diagnostics, Illinois, USA) with a lower limit of detection of 40 copies/mL. Plasma specimen from baseline were thawed and sent to NHLS for serology detection of HSV-2 using HerpeSelect® 1 and 2 Immunoblot IgG kit (FOCUS Diagnostic, Cypress, California, USA).

2.6. Laboratory Testing for bacterial STIs

Participant demographic and clinical data were collected via standardised interviews at each visit. In addition, *Neisseria gonorrhoeae* and *Chlamydia trachomatis* were tested in real-time using NG/CT Xpert® (Cepheid Diagnostics, Sunnyvale, California, USA) nucleic acid

amplification testing. OSOM® BV Blue and Trichomonas (Sekisui Diagnostics, Lexington, Massachusetts, USA) rapid diagnostic test (RDT) were used to test for *Trichomonas vaginalis* (bacterial vaginosis). Alere® Determine® Syphilis (Alere Diagnostics, San Diego, California, USA) rapid diagnostic testing was used to test for *Treponema pallidum* (syphilis).

2.7. Statistical Analysis

Data were analysed using STATA software (Version 14, Stata Corporation, College Station, Texas, USA). Analyses used two-sided tests at alpha = 0.05. Logistic regression models measured the associations between possible risk factors and viral STIs. Results are presented as odds ratios (OR) with 95% confidence intervals (CI). Because of the close causal relationship between HIV plasma VL and ART use, and that the vast majority of ART-Naïve women had elevated VL (see Supplementary Table 1), in analysis we combined these two variables into a single polytomous variable categorised as ART-Naïve on ART VL<50 copies/mL; ART VL 50-999 copies/mL; ART VL 1000-9999 copies/mL and ART VL ≥10000 copies/mL. Measures on each participant were repeated over time allowing for generalised estimating equations to account for intra-individual clustering of observations using the Huber-White (sandwich) estimator for standard errors (35). Adjusted models included variables either previously documented as confounders, or co-variates which appeared to be potential confounders in bivariate analysis (23, 30, 31, 36-39).

3. Results

Overall 108 women were included in the study: 52 ART-Naïve and 56 ART-Using participants. Table C-1 presents participant characteristics relevant to their ART status. The mean age in both groups was 31 years (similar by design), and 90% of participants had completed at least

Grade 10 education. At baseline, there were differences in demographic characteristics, with women on ART more likely to be married or cohabiting, and less likely to be employed compared to women not on ART.

Table C-1: Demographic characteristics and health indicators of 2IUDnCT study participants contributing specimens for genital tract viral pathogen analysis at baseline

DEMOGRAPHIC CHARACTERISTICS/ HEALTH INDICATORS	TOTAL PARTICIPANTS (N=108)	ART-USING PARTICIPANTS (N=56)	ART-NAIVE PARTICIPANTS (N=52)	P-VALUE
AGE (MEAN, SD)	31 (4.57)	31 (4.47)	31 (4.70)	P=1.000
WEIGHT (MEAN, SD)	75 (29.64)	71 (35.94)	80 (20)	P=0.114
HIGHEST LEVEL OF EDUCATION				
BELOW GRADE 10	11 (10%)	7(12.5%)	4 (8%)	P=0.409
GRADE 10 AND ABOVE	97 (90%)	49 (87.5%)	48 (92%)	
OCCUPATION STATUS				
UNEMPLOYED	72 (67%)	42 (75%)	30 (58%)	P=0.057
EMPLOYED (FULL / PART-TIME)	36 (33%)	14 (25%)	22 (42%)	
CURRENT PARTNERSHIP				
SINGLE	20 (18%)	4 (7%)	16 (31%)	P=0.002
IN RELATIONSHIP	88 (82%)	52 (93%)	36 (69%)	
NUMBER OF YEARS SINCE HIV DIAGNOSIS (AT STUDY SCREENING)				
MEAN (STANDARD DEVIATION)	6.47 (3.94)	6.96 (3.58)	5.92 (3.94)	P=0.157
PAST TB HISTORY				
NO TB HISTORY	91 (85%)	40 (73%)	51 (98%)	P<0.001
PREVIOUSLY DIAGNOSED WITH TB	16 (15%)	15 (27%)	1 (2%)	
CD4 COUNT (count/mm^3) AT ENROLMENT				
MEDIAN (INTER-QUARTILE REGION (IQR)) (ONLY ART-NAÏVE PARTICIPANTS)	638.13 (472.5 – 738)		638.13 (472.5 – 738)	
IUD DISTRIBUTION				
COPPER IUD	48 (44%)	24 (43%)	24 (46%)	P=0.730
LNG IUD	60 (56%)	32 (57%)	28 (54%)	

Table C-2 compares the plasma and genital tract viral measures between ART-Using and ART-Naïve groups during the 6-month study period. During the follow up, 8 participants from the ART-Using cohort missed one or both of the 3/ 6 months' follow-up visits (8/56, 14.3%) and 4

participants from the ART-Naïve cohort missed one or both of the 3/ 6 months' follow-up visits (4/52, 7.7%).

Table C-2: Viral pathogen markers over a six-month period among HIV-infected women who either use or do not use ART (N=108)

CLINICAL AND LABORATORY STATUS	TOTAL PARTICIPANTS (N=96)	ART-USING PARTICIPANTS (N=48)	ART-NAÏVE PARTICIPANTS (N=48)	P-VALUE
GENITAL HIV VIRAL LOADS				
BELOW THE LIMIT OF DETECTION/UNDETECTABLE	30 (33%)	21 (45%)	9 (21%)	P<0.001
DETECTED (>40 COPIES/ML) BUT NOT ON ALL THREE VISITS	43 (47%)	24 (51%)	19 (43%)	
DETECTED (>40 COPIES/ML) ON ALL THREE VISITS	18 (20%)	2 (4%)	16 (36%)	
MISSING/INVALID	5	1	4	
HSV-2 IGG (PLASMA AT BASELINE, ALL 108)				
UNDETECTED	6 (6%)	2 (4%)	4 (8%)	P=0.316
DETECTED	94 (94%)	49 (96%)	45 (92%)	
MISSING/INVALID	8	5	3	
GENITAL HSV-2 VIRAL LOADS (ALL)				
NOT DETECTED FROM ALL VISITS	64 (83%)	40 (85%)	24 (80%)	P=0.187
DETECTED IN ONE OF THE VISITS	11 (14%)	7 (15%)	4 (13%)	
DETECTED IN TWO OF THE VISITS	2 (3%)	0	2 (7%)	
DETECTED IN ALL THREE VISITS	0	0	0	
MISSING/INVALID	19	1	18	
MEDIAN (IQR) (LOG_{10} COPIES/ML)	3.35 (2.97 - 4.49)	3.24 (3.07 – 3.45)	4.38 (2.88 – 5.08)	P=0.497
TOTAL HPV				
NOT DETECTED FROM ALL VISITS	11 (28%)	8 (17%)	3 (21%)	P=0.310
DETECTED BUT NOT ALL THREE VISIT	31 (35%)	15 (33%)	16 (43%)	
DETECTED IN ALL THREE VISITS	48 (37%)	23 (50%)	25 (36%)	
INVALID / MISSING SPECIMENS	6	2	4	
HR HPV				
NOT DETECTED FROM ALL VISITS	25 (28%)	16 (35%)	9 (21%)	P=0.215
DETECTED BUT NOT ALL THREE VISIT	32 (35%)	13 (28%)	19 (43%)	
DETECTED IN ALL THREE VISITS	33 (37%)	17 (37%)	16 (36%)	
MISSING/INVALID	6	2	4	

ART-Naïve women had higher rates of HIV shedding in the genital tract at each visit. However, more than half of women using ART had detectable genital HIV at one or more visits. The HSV-2 IgG results show >90% prevalence of HSV-2 infection in both ART-Using and ART-Naïve groups however shedding of HSV-2 in the genital tract was substantially less common. The median log10 HSV-2 VL was 4.4 and 3.2 in ART-Naïve and ART-Using women respectively (p=0.50). HPV infection was detected in 72% of participants, with no significant difference by ART status and similar proportions of detection for HPV overall and high-risk subtypes.

Table C-3: Prevalence of multiple viral shedding in the genital tract and endocervical region

VIRAL STI	TOTAL PARTICIPANTS	ART-USING PARTICIPANTS	ART-NAÏVE PARTICIPANTS	P-VALUE
AT BASELINE				
NOT DETECTED	27 (27.3%)	23 (41.1%)	4 (9.3%)	P<0.001
ONE STI DETECTED	43 (43.4%)	24 (42.9%)	19 (44.2%)	
TWO STI DETECTED	26 (26.3%)	9 (16%)	17 (39.5%)	
THREE STI DETECTED	3 (3%)	0	3 (7%)	
AT 3 MONTHS FOLLOW UP				
NOT DETECTED	26 (29.2%)	19 (38%)	7 (17.9%)	P=0.010
ONE STI DETECTED	39 (43.8%)	24 (48%)	15 (38.5%)	
TWO STI DETECTED	20 (22%)	5 (10%)	15 (38.5%)	
THREE STI DETECTED	4 (4.5%)	2 (4%)	2 (5.1%)	
AT 6 MONTHS FOLLOW UP				
NOT DETECTED	29 (33%)	19 (39.6%)	10 (25%)	P=0.354
ONE STI DETECTED	38 (43.2%)	20 (41.7)	18 (45%)	
TWO STI DETECTED	17 (19.3%)	8 (16.7%)	9 (22.5%)	
THREE STI DETECTED	4 (4.5%)	1 (2%)	3 (7.5%)	
OVERALL				
NOT DETECTED	82 (29.7%)	61 (39.6%)	21 (17.2%)	P<0.001
STI DETECTED	194 (70.3%)	93 (60.4%)	101 (82.8%)	

In Table C-3, we demonstrate the shedding and co-occurrence of multiple viral pathogens in the female genital tract. Overall, 70.3% of samples had at least one viral pathogen detected - 60.4% among ART-Using women compared to 82.8% in ART-Naïve women (P<0.001).

Figure C-2 (a-c) presents Venn diagrams depicting the co-occurrence of viral pathogens at each visit by ART status. Most HSV-2 shedding occurred in the presence of detectable genital HIV and/or hrHPV at the same visit; there was also a high co-occurrence of genital HIV RNA shedding with hrHPV.

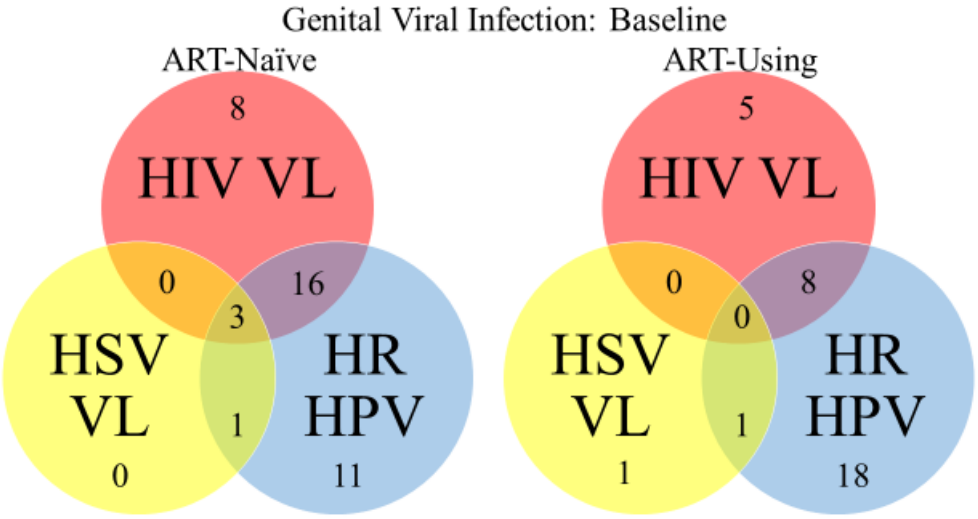

Figure C-2a: Venn Diagram showing the prevalence of multiple viral STI combinations at baseline, comparing ART-Naïve and ART-Using women

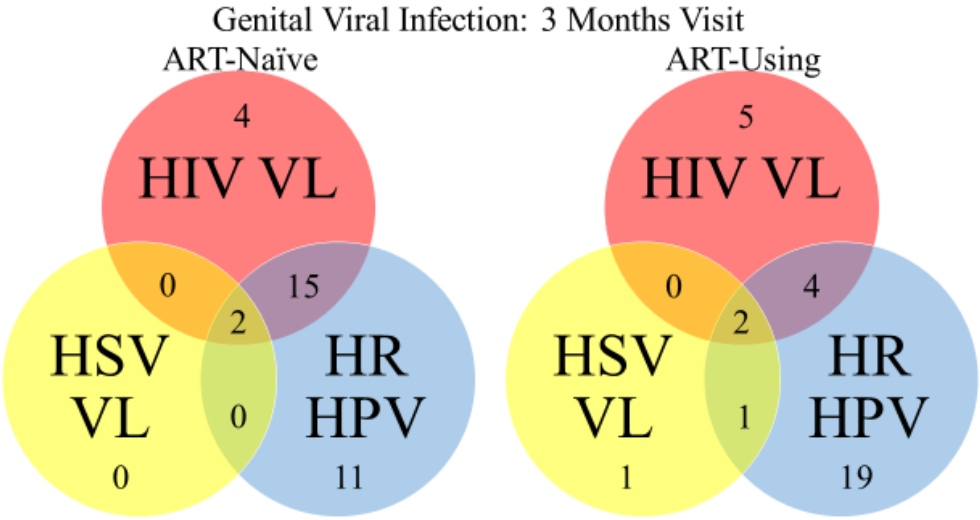

Figure C-2b: Venn Diagram showing the prevalence of multiple viral STI combinations at the 3 Months follow-up visit, comparing ART-Naïve and ART-Using women

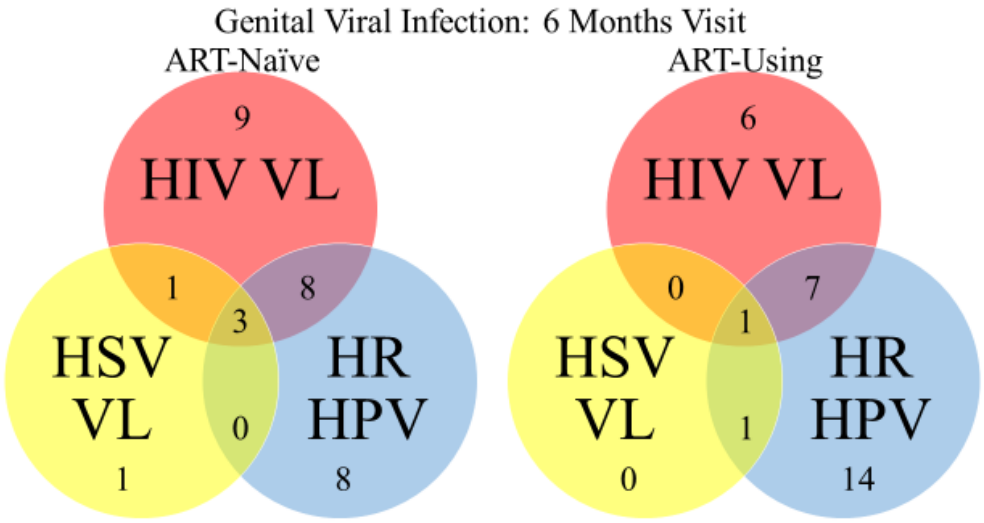

Figure C-2c: Venn Diagram showing the prevalence of multiple viral STI combinations at 6 Months follow-up visit, comparing ART-Naïve and ART-Using women

Table C-4 (a-c) shows the risk factors associated with the shedding into the genital tract of HIV, HSV-2 and HPV. No social or demographic factors were associated with individual pathogen detection. Chlamydia trachomatis (CT) increased the risk of HIV shedding (aOR=3.63, 95% CI: 1.07-12.31), whereas Neisseria gonorrhoeae (NG) was associated with twice the odds of hrHPV (aOR=1.93, 95% CI: 0.57-6.52) and Trichomonas vaginalis was associated with HSV-2 shedding (aOR=4.16, 95% CI: 1.31-13.20).

Furthermore, ART treatment was associated with reduced shedding of HIV in the genital region (aOR=0.37, 95% CI: 0.15-0.94). While ART-Using women with VL<1000 copies/mL were significantly less likely to have HIV detected in the genital tract, ART-Using women with high plasma VL (>1000 copies/mL) showed no difference in the detection of HIV as compared to ART-Naïve women (Table C-4a). HSV-2 shedding in the genital tract showed a similar pattern (Table C-4c). While ART use reduced the odds of HSV-2 overall (aOR=0.47, 95% CI: 0.10-2.10), ART-Using women with a high plasma HIV VL had levels of shedding similar to ART-

Naïve women though not all associations achieved statistical significance. High-risk HPV shedding followed a similar pattern also (Table C-4b). Lastly, HSV-2 detection was associated with concurrent HIV and HPV detection across visits (aOR=2.61, 95% CI: 0.78-8.71 and aOR=3.51, 95% CI: 0.91-13.54, respectively).

Next, we investigated factors associated with co-occurrence of viral shedding in the female genital tract. Compared to ART-Naïve women, ART-Using women were significantly less likely to have co-occurrence of viral shedding overall (aOR=0.27, 95% CI: 0.10-0.72; Table C-5). Mirroring the findings involving individual viruses, this was driven by ART-Using women with VL<1000 copies/mL, and ART-Using women with higher VL had levels of viral co-occurrence similar to those of ART-Naïve women. In addition, both Neisseria gonorrhoeae and Chlamydia trachomatis increased the odds of detecting two or more viral pathogens (aOR=1.84, 95% CI: 0.43-7.90 and aOR=2.17, 95% CI: 0.68-7.01 respectively). At baseline, married women or women in a relationship had reduced odds of multiple viral pathogens co-occurring (aOR=0.6, 95% CI: 0.214-1.826).

Table C-4a: Unadjusted and adjusted logistic regression models of the association between undetectable HIV shedding and detectable HIV shedding in the genital tract

	UNADJUSTED MODELS*		ADJUSTED MODEL A **		ADJUSTED MODEL B***	
VARIABLES	**OR [95% CI]**	**P-value**	**aOR [95% CI]**	**P-value**	**aOR [95% CI]**	**P-value**
ART STATUS (ART-NAÏVE VS ART-USING)	0.267 [0.148, 0.478]	<0.001	0.372 [0.148, 0.936]	0.036		
ART AND PLASMA HIV SUPPRESSION						
ART-NAÏVE	Reference				Reference	
ART PLASMA HIV VL (0-49 COPIES/ML)*	0.203 [0.110, 0.375]	<0.001			0.213 [0.098, 0.463]	<0.001
ART PLASMA HIV VL (50-999 COPIES/ML)	0.390 [0.152, 1.004]	0.051			0.254 [0.086, 0.748]	0.013
ART PLASMA HIV VL (1000-9999 COPIES/ML)	0.390 [0.067, 2.270]	0.295			0.280 [0.037, 2.093]	0.215
ART PLASMA HIV VL (≥10000 COPIES/ML)	1.561 [0.315, 7.735]	0.586			1.543 [0.285, 8.351]	0.615
BASELINE DEMOGRAPHIC						
AGE	0.953 [0.891, 1.020]	0.166	0.939 [0.864, 1.020]	0.136	0.934 [0.858, 1.017]	0.115
WEIGHT	1.002 [0.992, 1.011]	0.729	0.996 [0.987, 1.006]	0.450	0.996 [0.987, 1.006]	0.440
HIGHEST LEVEL OF EDUCATION (<GRADE 10 VS GRADE 10 AND ABOVE)	1.460 [0.456, 4.678]	0.525	1.653 [0.591, 4.625]	0.339	1.796 [0.648, 4.974]	0.260
OCCUPATION STATUS (UNEMPLOYED VS EMPLOYED)	1.394 [0.755, 2.576]	0.288	1.070 [0.537, 2.132]	0.847	1.063 [0.528, 2.140]	0.864
CURRENT PARTNERSHIP (SINGLE VS IN RELATIONSHIP	0.532 [0.246, 1.152]	0.109	0.663 [0.260, 1.686]	0.388	0.695 [0.272, 1.774]	0.447
NUMBER OF YEARS SINCE HIV DIAGNOSIS (AT STUDY SCREENING)	1.002 [0.921, 1.090]	0.963	1.003 [0.915, 1.100]	0.953	0.993 [0.906, 1.089]	0.884
PAST TB HISTORY (NO VS PAST TB)	0.672 [0.321, 1.407]	0.292	1.144 [0.424, 3.087]	0.790	1.176 [0.431, 3.209]	0.751
IUD (NO IUD VS WITH IUD)	1.050 [0.693, 1.590]	0.819	0.941 [0.549, 1.616]	0.826	0.901 [0.520, 1.561]	0.709
BACTERIAL STI						
TRICHOMONAS (NOT DETECTED VS DETECTED)	1.255 [0.594, 2.651]	0.553	1.184 [0.426, 3.291]	0.746	1.117 [0.395, 3.161]	0.835
GONORRHEA (NOT DETECTED VS DETECTED)	2.572 [1.031, 6.421]	0.043	1.354 [0.394, 4.646]	0.630	0.933 [0.285, 3.060]	0.909
CHLAMYDIA (NOT DETECTED VS DETECTED)	5.724 [1.687, 19.427]	0.005	2.883 [0.862, 9.646]	0.086	3.628 [1.070, 12.307]	0.039
BACTERIAL VAGINOSIS (NOT DETECTED VS DETECTED)	1.174 [0.550, 2.506]	0.678	1.001 [0.421, 2.381]	0.998	1.068 [0.444, 2.575]	0.882

VIRAL STI						
HIGH RISK HPV (NOT DETECTED VS DETECTED	1.830 [1.060, 3.160]	0.030	1.309 [0.736, 2.328]	0.360	1.326 [0.739, 2.377]	0.344
GENITAL HSV-2 (NOT DETECTED VS DETECTED)	3.438 [1.179, 10.024]	0.024	2.767 [0.876, 8.739]	0.083	2.940 [0.886, 9.757]	0.078

*Unadjusted model: Logistic regression model on each variate only, clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

**Adjusted model A: Logistic regression model on outcome of HIV shedding in the genital tract (no shedding vs shedding), adjusted for all other co-variates (ART status, no plasma HIV VL), clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

***Adjusted model B: Logistic regression model on outcome of HIV shedding in the genital tract (no shedding vs shedding), adjusted for all other co-variates (ART status combined with plasma HIV VL), clustered using participant ID, to pool all data collected from participant between baseline to 6 month visit.

Table C-4b: Unadjusted and adjusted logistic regression models of the association between no detectable hrHPV and detectable hrHPV in the cervical region

	UNADJUSTED MODELS*		ADJUSTED MODEL A**		ADJUSTED MODEL B***	
VARIABLES	**OR [95% CI]**	**P-value**	**aOR [95% CI]**	**P-value**	**aOR [95% CI]**	**P-value**
ART STATUS (ART-NAÏVE VS ART-USING)	0.610 [0.320, 1.164]	0.134	0.615 [0.237, 1.595]	0.318		
ART AND PLASMA HIV SUPPRESSION						
ART-NAÏVE	Default Reference				Default Reference	
ART PLASMA HIV VL (0-49 COPIES/ML)*	0.583 [0.296, 1.150]	0.120			0.548 [0.230, 1.308]	0.175
ART PLASMA HIV VL (50-999 COPIES/ML)	0.713 [0.229, 2.220]	0.559			0.557 [0.129, 2.397]	0.432
ART PLASMA HIV VL (1000-9999 COPIES/ML)	1.267 [0.217, 7.378]	0.793			1.017 [0.103, 10.087]	0.989
ART PLASMA HIV VL (≥10000 COPIES/ML)	0.792 [0.151, 4.140]	0.782			0.514 [0.073, 3.630]	0.505
BASELINE DEMOGRAPHIC						
AGE	0.990 [0.927, 1.059]	0.779	1.005 [0.935, 1.081]	0.884	1.006 [0.935, 1.081]	0.879
WEIGHT	0.997 [0.984, 1.009]	0.582	0.997 [0.984, 1.010]	0.632	0.997 [0.984, 1.010]	0.641
HIGHEST LEVEL OF EDUCATION (<GRADE 10 VS GRADE 10 AND ABOVE)	1.165 [0.360, 3.762]	0.799	1.380 [0.374, 5.085]	0.629	1.440 [0.390, 5.319]	0.585
OCCUPATION STATUS (UNEMPLOYED VS EMPLOYED)	1.003 [0.499, 2.013]	0.994	0.648 [0.298, 1.408]	0.273	0.646 [0.294, 1.417]	0.275
CURRENT PARTNERSHIP (SINGLE VS IN RELATIONSHIP	0.803 [0.346, 1.863]	0.610	0.846 [0.320, 2.237]	0.736	0.849 [0.325, 2.214]	0.737
NUMBER OF YEARS SINCE HIV DIAGNOSIS (AT STUDY SCREENING)	0.985 [0.903, 1.074]	0.726	0.990 [0.891, 1.099]	0.846	0.993 [0.894, 1.102]	0.892
PAST TB HISTORY (NO VS PAST TB)	1.047 [0.399, 2.747]	0.926	1.148 [0.361, 3.646]	0.815	1.129 [0.326, 3.904]	0.848
IUD (NO IUD VS WITH IUD)	0.813 [0.580, 1.140]	0.819	0.841 [0.579, 1.220]	0.361	0.848 [0.584, 1.230]	0.385
BACTERIAL STI						
TRICHOMONAS (NOT DETECTED VS DETECTED)	1.998 [0.774, 5.158]	0.153	1.714 [0.596, 4.924]	0.317	1.639 [0.591, 4.547]	0.343
GONORRHEA (NOT DETECTED VS DETECTED)	2.526 [0.807, 7.908]	0.111	1.851 [0.614, 5.584]	0.274	1.925 [0.568, 6.518]	0.293
CHLAMYDIA (NOT DETECTED VS DETECTED)	1.146 [0.369, 3.567]	0.813	1.049 [0.281, 3.913]	0.943	1.047 [0.280, 3.909]	0.946
BACTERIAL VAGINOSIS (NOT DETECTED VS DETECTED)	1.267 [0.634, 2.531]	0.503	1.043 [0.482, 2.263]	0.913	1.008 [0.456, 2.227]	0.984
VIRAL STI						

GENITAL HIV (NOT DETECTED VS DETECTED	1.830 [1.060, 3.160]	0.030	1.308 [0.733, 2.336]	0.364	1.331 [0.739, 2.397]	0.341
GENITAL HSV-2 (NOT DETECTED VS DETECTED)	4.25 [1.206, 14.973]	0.024	3.632 [0.989, 13.337]	0.052	3.650 [0.982, 13.568]	0.053

*Unadjusted model: Logistic regression model on each variate only, clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

**Adjusted model A: Logistic regression model on outcome of hrHPV shedding in the genital tract (no shedding vs shedding), adjusted for all other co-variates (ART status, no plasma HIV VL), clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

***Adjusted model B: Logistic regression model on outcome of hrHPV shedding in the genital tract (no shedding vs shedding), adjusted for all other co-variates (ART status combined with plasma HIV VL), clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

Table C-4c: Unadjusted and adjusted logistic regression models of the association between no detectable HSV-2 shedding and presence of shedding in the genital tract

	UNADJUSTED MODELS*		ADJUSTED MODEL A**		ADJUSTED MODEL B***	
VARIABLES	**OR [95% CI]**	**P-value**	**aOR [95% CI]**	**P-value**	**aOR [95% CI]**	**P-value**
ART STATUS (ART-NAÏVE VS ART-USING)	0.490 [0.180, 1.335]	0.163	0.465 [0.103, 2.103]	0.320		
ART AND PLASMA HIV SUPPRESSION						
ART-NAÏVE	Default reference				Default reference	
ART PLASMA HIV VL (0-49 COPIES/ML)*	0.443 [0.146, 1.340]	0.149			0.501 [0.122, 2.056]	0.338
ART PLASMA HIV VL (50-999 COPIES/ML)	1.284 [0.263, 6.266]	0.757			1.742 [0.228, 13.302]	0.593
ART PLASMA HIV VL (1000-9999 COPIES/ML)	1 (omitted)				1 (omitted)	
ART PLASMA HIV VL (≥10000 COPIES/ML)	1 (omitted)				1 (omitted)	
BASELINE DEMOGRAPHIC						
AGE	1.011 [0.917, 1.115]	0.822	0.985 [0.881, 1.102]	0.791	0.986 [0.878, 1.107]	0.810
WEIGHT	1.006 [0.988, 1.025]	0.524	1.003 [0.986, 1.021]	0.732	1.004 [0.986, 1.023]	0.648
HIGHEST LEVEL OF EDUCATION (<GRADE 10 VS GRADE 10 AND ABOVE)	1.636 [0.227, 11.782]	0.625	0.836 [0.140, 4.974]	0.844	0.729 [0.139, 3.827]	0.709
OCCUPATION STATUS (UNEMPLOYED VS EMPLOYED)	1.609 [0.577, 4.491]	0.364	1.854 [0.597, 5.752]	0.285	2.133 [0.654, 6.955]	0.209
CURRENT PARTNERSHIP (SINGLE VS IN RELATIONSHIP	0.511 [0.156, 1.671]	0.266	0.900 [0.201, 4.040]	0.891	0.909 [0.193, 4.274]	0.904
NUMBER OF YEARS SINCE HIV DIAGNOSIS (AT STUDY SCREENING)	1.104 [0.914, 1.333]	0.304	1.062 [0.887, 1.273]	0.508	1.060 [0.880, 1.277]	0.541
PAST TB HISTORY (NO VS PAST TB)	1.095 [0.324, 3.704]	0.884	1.998 [0.429, 9.295]	0.378	1.544 [0.320, 7.444]	0.589
IUD (NO IUD VS WITH IUD)	1.152 [0.418, 3.174]	0.785	1.512 [0.428, 5.346]	0.521	1.510 [0.428, 5.324]	0.521
BACTERIAL STI						
TRICHOMONAS (NOT DETECTED VS DETECTED)	3.631 [1.310, 10.060]	0.013	4.628 [1.464, 14.629]	0.009	4.163 [1.312, 13.203]	0.015
GONORRHEA (NOT DETECTED VS DETECTED)	0.901 [0.106, 7.633]	0.924	0.562 [0.035, 9.115]	0.685	0.867 [0.048, 15.786]	0.923
CHLAMYDIA (NOT DETECTED VS DETECTED)	1.038 [0.161, 6.693]	0.969	0.321 [0.071, 1.453]	0.140	0.325 [0.071, 1.479]	0.146
BACTERIAL VAGINOSIS (NOT DETECTED VS DETECTED)	1.786 [0.565, 5.647]	0.324	1.920 [0.485, 7.599]	0.353	2.240 [0.532, 9.437]	0.272
VIRAL STI						

GENITAL HIV (NOT DETECTED VS DETECTED	3.438 [1.179, 10.024]	0.024	2.562 [0.777, 8.447]	0.122	2.609 [0.782, 8.710]	0.119
HIGH RISK HPV (NOT DETECTED VS DETECTED	4.25 [1.206, 14.973]	0.024	3.540 [0.939, 13.344]	0.062	3.512 [0.911, 13.540]	0.068

*Unadjusted model: Logistic regression model on each variate only, clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

**Adjusted model A: Logistic regression model on outcome of HSV-2 shedding in the genital tract (no shedding vs shedding), adjusted for all other co-variates (ART status, no plasma HIV VL), clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

***Adjusted model B: Logistic regression model on outcome of HSV-2 shedding in the genital tract (no shedding vs shedding), adjusted for all other co-variates (ART status combined with plasma HIV VL), clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

Table C-5: Unadjusted and adjusted logistic regression models of the association between one or less viral STI and more than one viral STI in the genital tract

	UNADJUSTED MODELS*		ADJUSTED MODEL A**		ADJUSTED MODEL B***	
VARIABLES	**OR [95% CI]**	**P-value**	**aOR [95% CI]**	**P-value**	**aOR [95% CI]**	**P-value**
ART STATUS (ART-NAÏVE VS ART-USING)	0.289 [0.146, 0.570]	<0.001	0.273 [0.104, 0.716]	0.008		
ART AND PLASMA HIV SUPPRESSION						
ART-NAÏVE	Default reference				Default reference	
ART PLASMA HIV VL (0-49 COPIES/ML)*	0.257 [0.123, 0.538]	<0.001			0.235 [0.097, 0.572]	0.001
ART PLASMA HIV VL (50-999 COPIES/ML)	0.315 [0.101, 0.983]	0.047			0.250 [0.063, 0.988]	0.048
ART PLASMA HIV VL (1000-9999 COPIES/ML)	1 (omitted)				1 (omitted)	
ART PLASMA HIV VL (≥10000 COPIES/ML)	1.176 [0.295, 4.680]	0.819			0.665 [0.117, 3.787]	0.646
BASELINE DEMOGRAPHIC						
AGE	1.013 [0.946, 1.085]	0.701	1.008 [0.936, 1.086]	0.830	1.006 [0.933, 1.084]	0.881
WEIGHT	1.002 [0.992, 1.012]	0.699	0.998 [0.987, 1.008]	0.634	0.997 [0.987, 1.008]	0.617
HIGHEST LEVEL OF EDUCATION (<GRADE 10 VS GRADE 10 AND ABOVE)	1.109 [0.321, 3.835]	0.871	0.963 [0.256, 3.626]	0.955	0.959 [0.253, 3.637]	0.951
OCCUPATION STATUS (UNEMPLOYED VS EMPLOYED)	1.343 [0.642, 2.810]	0.434	1.002 [0.450, 2.230]	0.997	1.009 [0.453, 2.248]	0.982
CURRENT PARTNERSHIP (SINGLE VS IN RELATIONSHIP	0.334 [0.134, 0.832]	0.019	0.610 [0.210, 1.773]	0.364	0.625 [0.214, 1.826]	0.390
NUMBER OF YEARS SINCE HIV DIAGNOSIS (AT STUDY SCREENING)	1.045 [0.946, 1.154]	0.388	1.053 [0.947, 1.171]	0.340	1.045 [0.936, 1.166]	0.435
PAST TB HISTORY (NO VS PAST TB)	0.786 [0.360, 1.718]	0.546	1.392 [0.465, 4.172]	0.555	1.476 [0.462, 4.717]	0.511
IUD (NO IUD VS WITH IUD)	0.836 [0.528, 1.322]	0.443	0.825 [0.490, 1.388]	0.468	0.798 [0.477, 1.333]	0.388
BACTERIAL STI						
TRICHOMONAS (NOT DETECTED VS DETECTED)	1.255 [0.594, 2.651]	0.553	1.403 [0.484, 4.068]	0.533	1.491 [0.532, 4.179]	0.448
GONORRHEA (NOT DETECTED VS DETECTED)	2.572 [1.031, 6.421]	0.043	2.216 [0.483, 10.157]	0.306	1.836 [0.427, 7.895]	0.414
CHLAMYDIA (NOT DETECTED VS DETECTED)	5.724 [1.687, 19.427]	0.005	1.868 [0.580, 6.012]	0.295	2.174 [0.675, 7.005]	0.193
BACTERIAL VAGINOSIS (NOT DETECTED VS DETECTED)	1.174 [0.550, 2.506]	0.678	0.977 [0.401, 2.378]	0.959	1.059 [0.429, 2.614]	0.901

*Unadjusted model: Logistic regression model on each variate only, clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

**Adjusted model A: Logistic regression model on outcome of viral STI shedding in the genital tract (one or less vs 2 or more viral STI), adjusted for all other co-variates (ART status, no plasma HIV VL), clustered using participant ID, to pool all data collected from participants between baseline to 6 month visit.

***Adjusted model B: Logistic regression model on outcome of viral STI shedding in the genital tract (one or less vs 2 or more viral STI), adjusted for all other co-variates (ART status combined with plasma HIV VL), clustered using participant ID, to pool all data collected from participant between baseline to 6 month visit.

4. Discussion

In this cohort of HIV-infected women HIV, HSV-2 and HPV were prevalent in the genital tract of more than half of participants and were closely associated with HIV plasma VL. In the ART-Naïve group the shedding of HIV appeared considerably higher than in the ART-Using group suggesting that ART use may have an effect on HIV shedding in the genital tract. However genital shedding of HIV was still detectable even in women using ART- a finding with implications for ongoing HIV prevention efforts.

Our analysis demonstrated that the ART-Using (virally suppressed) women were less likely to shed HIV, HSV-2 and HPV in the genital tract compared to ART-Naïve women. This may be driven by plasma VL levels where ART-Using women with lower VL are less likely to shed these viruses compared to women with elevated VL, including those not on ART. The bidirectional, mutualistic relationship between HIV and other viral STIs has been well documented (14, 29, 32) however our data are novel in showing a direct correlation between plasma VL and shedding of viral STIs in the female genital tract.

The prevalence of low-risk and high-risk HPV types was high in this cohort where 37% of women were detected with HPV consistently across study visits. This high prevalence of HPV in HIV-infected women is well-documented in South Africa (40, 41). Past studies have shown that HPV, particularly high-risk HPV, tends to be more persistent in HIV-infected females and has been suggested to increase the risk of progressive invasive cancer (42-44). However, data on the effects of ART on HPV shedding remain inconclusive. Interestingly, in our cohort no significant differences in rates of detection were found between the ART-naïve and ART-treated group for either total or high-risk HPV detection. Similarly, in the regression models, no variables, including co-infections, were associated with HPV detection (for both low-risk and high-risk).

While 94% of the cohort was IgG positive for HSV-2 reflecting previous infection, HSV-2 shedding in the genital tract was uncommon, involving only17% of women. This relatively low prevalence has been reported by other studies and is in keeping with the biology of HSV-2 where genital shedding is episodic (19, 45). In addition, although HSV-2 appeared to be a risk factor that increases high-risk HPV shedding, our analysis is inconclusive given the low prevalence of HSV-2 shedding in this cohort. HSV-2 as a risk factor for HPV shedding thus remains an important issue for further research.

We found a high prevalence of viral STI co-infection in the genital tract in this cohort, mainly involving HIV and HPV together, particularly in ART-Naïve women. This correlates with the past literature in regard to the bidirectional relationship between HIV and other viral STIs (21, 30), with ART-Using women appearing less likely to shed more than one viral STI in the genital tract. This is not surprising as ART treatment leads to a reduction in plasma HIV viral load and restores the host's immune system, thereby reducing the risks of viral shedding.

Apart from ART use and plasma viral load, we identified few other potential predictors of HIV, HSV-2 and HPV in the genital tract. Data showed that the presence of Chlamydia increased the risk of HIV shedding. Consistent with these data, other studies indicated that both Gonorrhea and Chlamydia may increase HIV shedding and result in increased risk of HIV transmission (30, 46). Related to this, several studies have explored the connection between bacterial infections in the female genital tract and persistent infection of HPV (23, 47, 48). In these data, Gonorrhea appeared associated with increased hrHPV shedding; while this did not achieve statistical significance, the association between bacterial STI and hrHPV in the female genital track is an important avenue for future research. Our study showed that the presence of either Trichomonas or Bacterial Vaginosis lead to increased risk of shedding of HSV-2 in the genital tract (Table C-4c). Although the association of Bacterial Vaginosis in our cohort was not statistically significant, this association is in keeping with previous research that reported comparable result (49-51). Interestingly, Chlamydia was a strong risk factor for both the shedding of HIV and the co-occurrence of viral STI in the genital region. However, there was no significant association between Chlamydia and HSV-2 and high-risk HPV. Future work needs to be carried out to understand what role Chlamydia plays that may result in recruiting other STIs, and particularly HIV, into the genital region as this potentially poses a high risk of HIV transmission despite the use of ART treatment.

These data should be interpreted in light of several strengths and limitations. The low prevalence of HSV-2 shedding in this cohort is not unusual, but limited our power to detect associations involving this virus. In addition, while these data are novel in their prospective examination of viral co-infections, the short duration of follow-up limited our ability to document true persistence or remission of HPV (52, 53). Finally, while the measurement of plasma HIV VL is a major strength of this work, we did not have CD4+ cell counts routinely available, limiting our ability to understand how overall immune deficiency may influence

viral shedding. Finally, the data come from a trial of IUD types, and while IUD types did not affect shedding of any of the three viruses, and all analyses were adjusted for trial arm, it is important to remember that the measures here included this contraceptive type.

In conclusion, ART use is as a critical factor that reduces shedding of HIV in the genital tract of women living with HIV, and although not statistically significant when adjusted for other factors, the presence of both HSV-2 and HPV may increase the risk of HIV shedding. Taken together, these results suggest that ART plays a major role in reducing the co-occurrence of STIs in the female genital tract.

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Appendix I –
Ethic Approval and Renewal

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)		
☑ Approved	☑ Type of review: Expedited	☐ Full committee
This serves as notification that all changes and documentation described below are approved.		
Signature Chairperson of the HREC		Date 14/12/2016

Note: All major amendments must include a final **PI Synopsis** justifying the changes for the amendment.
Please note that incomplete amendment submissions will not be reviewed.

Comments from the HREC to the Principal Investigator:

Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	12 December 2016		
HREC REF Number	283/2012		
Protocol title	Comparison of Two IUDs among Cape Town HIV-positive Women: A Randomized Controlled Trial Assessing Safety of Registered Products in South Africa		
Protocol number (if applicable)	FHI 360 Study 10369		
Principal Investigator	Landon Myer		
Department / Office Internal Mail Address	CIDLR, School Of Public Health and Family Medicine		
1.1 Is this a major or a minor amendment? (see FHS000hlp) Major (tick box) Minor (tick box)		☐ Major	✓ Minor
1.2 Does this protocol receive US Federal funding?		✓ Yes	☐ No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval?		☐ Yes	☐ No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval. This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.
Protocol version 9.0 dated 30 November 2016

3. Protocol status (tick ✓)

✓	Open to enrolment
☐	No participants have been enrolled
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

	Protocol
☐	Study objectives, design (including investigator's brochure, clinical activities, study length)
☐	Study instruments, questionnaires, interview schedules
☐	Sample size
☐	Recruitment methods
☐	Eligibility criteria (inclusion and exclusion criteria)
☐	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
✓	Data collection/ analysis
☐	Principal Investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013)
☐	Consent form and information sheet
☐	Recruitment materials (e.g. advertisements)
☐	Administrative (e.g. change in sponsor's name, change in contact information)

☐	Other. Please specify:

4.1 In your opinion, will there be any **increase** in risk, discomfort or inconvenience to participants?	☐ Yes	✓ No
If yes, please provide a detailed justification/explanation:		

4.2 What follow-up action do you propose for participants who are already enrolled in the study?	
☐	Inform current participants as soon as possible
☐	Re-consent current participants with revised consent/assent forms (append)
✓	No action required
☐	Other. Please describe:

5. Detailed description of the change(s)

Please attach, for each amendment, a summary of all changes which clearly indicates:

i. Old wording (e.g. ~~strikethrough~~ text, CHANGED FROM and CHANGED TO)

ii. New wording (e.g. *italicized*, **bold**, tracked)

iii. Detailed rationale/ justification/ explanation for each change

6. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.

Signature of PI		Date	12/12/16

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

HUMAN RESEARCH ETHICS COMMITTEE
14 MAR 2017
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) **This serves as notification of annual approval, including any documentation described below.**			
☑ Approved	Annual progress report	Approved until/next renewal date	27/03/18
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	14/3/2017

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	13 March 2017 (Report includes period up to 09 March 2017)		
HREC REF Number	283/2012	Current Ethics Approval was granted until	27 Mar 2017
Protocol title	Comparison of Two IUDs among Cape Town HIV-positive Women: A Randomized Controlled Trial Assessing Safety of Registered Products in South Africa		
Protocol number (if applicable)	FHI 10369		
Are there any sub-studies linked to this study?	☐ Yes ✓No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Prof Landon Myer		
Department / Office Internal Mail Address	CIDER, School of Public Health and Family Medicine		

HUMAN RESEARCH ETHICS COMMITTEE
13 MAR 2017
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

1.1 Does this protocol receive US Federal funding?	✓ Yes	☐ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	✓ No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	☐ Yes	✓ No

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) **This serves as notification of annual approval, including any documentation described below.**			
☐ Approved	Annual progress report	Approved until/next renewal date	27.3.2019
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	5/3/2018

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	26 February 2018 (Report includes period up to 14 February 2018)		
HREC REF Number	283/2012	Current Ethics Approval was granted until	27 Mar 2018
Protocol title	Comparison of Two IUDs among Cape Town HIV-positive Women: A Randomized Controlled Trial Assessing Safety of Registered Products in South Africa		
Protocol number (if applicable)	FHI 10369		
Are there any sub-studies linked to this study?	☐ Yes ✓No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note**: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Prof Landon Myer		
Department / Office Internal Mail Address	CIDER, School of Public Health and Family Medicine		

1.1 Does this protocol receive US Federal funding?	✓ Yes	☐ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	✓ No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	☐ Yes	✓ No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

06 March 2019

HREC REF: 106/2019

Prof L Myer
Public Health & Family Medicine
Office 5.51, Level 5
Falmouth Building, FHS

Dear Prof Myer

PROJECT TITLE: CO-OCCURRENCE OF HSV-2, HPV AND HIV IN THE FEMALE GENITAL TRACT AMOUNG HIV INFECTED WOMAN (SUB-STUDY 283/2012) (MASTERS CANDIDATE: MR N HU)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 March 2020.

However, it is noted that the parent study (HREC/REF:283/2012) approval expires on 27.03.2019. Please note that up to date approval for HREC REF:283/2012 and this study must be maintained.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Mr Nai-Chung Hu will also be involved in this study.

Please quote the HREC REF number in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

signature removed to avoid exposure online

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 106/2019

Appendix II –
Informed Consents Documents

INFORMED CONSENT FOR TRIAL SCREENING

Name of Research Study:	Comparison of Two IUDs among Cape Town HIV-positive Women: A Randomized Controlled Trial Assessing Safety of Registered Products in South Africa
Site Principal Investigator:	Prof. Benjamin Landon Myer
FHI 360 Medical Monitor:	Dr. Catherine Todd
Sponsor:	FHI 360, Durham, North Carolina, USA
Funder:	Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health; Preventive Technologies Agreement, United States Agency for International Development

Introduction

This consent form contains information about the screening process for the intrauterine device (IUD) trial. The IUD trial is a research study. In order to be sure that you are informed about the screening process, we are asking you to read this consent form. If you are unable to read this consent form, a study staff member will read and explain it to you. Someone other than the study staff will be present during this procedure. If you agree to take part in this screening, you will be asked to sign this form or make your mark in the presence of a witness. You are only agreeing to be screened for the ability to join, but not to enter the IUD trial, with this consent. Your understanding and agreement is necessary before the screening process may start.

This consent form might contain some words that are unfamiliar to you. Please ask us to explain anything that you do not understand.

General information about the research

We are from the Desmond Tutu human immunodeficiency virus (HIV) Centre at the University of Cape Town. We are doing a research study to compare two IUDs (also called loops) among HIV-positive women. The two IUDs will be the levonorgestrel intrauterine device (LNG IUD) (called Mirena) and the copper IUD. HIV-positive women in Cape Town will be in the trial. We want to find out if the two IUDs are similar in safety and acceptability for HIV-positive women. Both IUDs are equally effective at preventing pregnancy.

An IUD is a small T-shaped flexible device about the length of an egg that is inserted into the womb. The IUD is very good at preventing pregnancy for 5 – 10 years. Both IUDs work mainly by stopping the man's sperm from reaching the woman's egg. The IUD can be removed at any time if a person decides they want to become pregnant. The IUD may change menstrual bleeding patterns after insertion.

Neither IUD protects against HIV or other sexually transmitted infections. The best way to prevent HIV infection and other infections is through the use of a barrier method such as the male condom.

This form gives information to help you decide if you want to take part in screening to find out if you are eligible to join the IUD research study. You can ask any questions to help you decide

whether to be a part of the study or not. You may ask questions about the purpose of the research, what will be done during study visits, the possible risks and benefits and anything else about the research or this form that is not clear. When all of your questions are answered, you can decide if you would like to take part in this screening part of the study or not. We will give you a copy of this form.

Your part in the research study

We are asking you to take part in this screening because you are a woman 18 to 40 years old, inclusive, with known HIV infection and willing to answer screening questions and have some tests. We plan to talk to about 1000 women in this screening part of the study. This part of the study is being done to see if you are eligible to join the longer IUD study. You may or may not be able to join the longer IUD study, which will last up to 24 months. The screening process will be only your visit today and will last for about 3 hours.

If you decide to volunteer for this screening part of the research:

- We will ask you questions about your medical history contraceptive use, living situation, sexual behavior and thoughts about family planning.

- We will review your medical chart and your other accessible medical records at this clinic for results of confirmation of your HIV status, your last CD4 cell count or viral load, Pap smear, and other information. We may ask you to bring documents with these results from other clinics if you have received care at other sites. If you agree to be screened for this study, we ask that you open a folder at the Gugulethu Community Health Centre (GCHC). Some of your medical information collected through this study will be recorded in this folder; however, you will not be identified as a study participant in your GCHC folder.

- If we cannot document your HIV status with your medical records, we will ask you to have HIV counseling and a test at the study clinic today.

- You will give urine for a pregnancy test. If you are pregnant, you cannot participate in the study and will be referred for care. Also, if you plan to become pregnant in the next two years, you cannot participate in the study.

- We will contact you by telephone if it is necessary to return to the clinic for test results and referrals for appropriate care.

- You will have your blood collected and it will be tested for syphilis and, if you are not taking antiretroviral therapy (ART), a CD4 count.

- You will have an individual risk-reduction counseling session.

- If you are currently menstruating, you will be asked to come again for the remainder of the screening. You will be provided with another appointment for 2 days after bleeding has stopped.

- You will have a physical exam including a pelvic exam. A pelvic exam looks at the part of your womb that the doctor can see when looking into the vagina. We will take samples to test for infections passed through sex. We will give you free treatment for yourself and your partner(s) for any of the curable infections passed through sex that we find during your exam.

- You will be asked questions about your understanding of the screening.

- You will provide your contact information.

- If you are eligible, an enrollment visit will be scheduled for you. It is important to know that all women who take part in the screening process may not be able to enroll in the IUD study. If you are scheduled for an enrollment visit and do not attend, we may call, text message (SMS), or visit you at your home to schedule follow-up and see if you would still like to participate in the study.

- If you are not eligible or decide to withdraw from the study after screening begins, we would like to ask you a few brief questions about your age and family planning method choice before you leave.

- You will sign this consent form or make your mark in front of a witness, if you decide to take part in this screening.

If you do not want to do any of these procedures or tests, you do not have to take part in this screening. Your participation in this screening is voluntary. If you do not take part in the screening, you cannot take part in the longer IUD study.

Whether or not you decide to participate in this screening will not affect your treatment and care at this clinic or other clinics.

Possible risks

Your participation in this part of the study will involve some risks. Some of the questions we ask will be of a personal nature, which may make you uncomfortable.

With the blood draw, there may be slight pain when a needle is inserted into your arm to get the blood sample. There may be minor bruising or pain that may last for up to 2-3 days at the site of the blood draw. Although rare, you may become lightheaded (feel dizzy) or faint when you have blood drawn, and there is a very small risk of infection at the site from where we take your blood.

We will minimize the risks of bruising or infection by cleaning your skin before using a needle to draw blood. We will use a new needle for each person. We will also apply pressure and a bandage to the site after we are done. These discomforts are usually small. If you get an infection because of the blood draw, we will treat you here.

The visit will involve collecting cells inside the vagina with a swab and may feel uncomfortable and you may experience a bit of spotting afterward.

Possible benefits

You will receive free condoms. We will demonstrate how to use them.

You will receive individual risk-reduction counseling.

You will be screened and we will give you and your partner free treatment for any of the curable infections passed through sex that we find during your exam for free.

There are no other direct benefits to participating, but if you need referral for additional services, we will assist with this. The information you give may help us to understand ways to improve IUD use for women living with HIV in the Cape Town area.

Choosing to be in this study

You do not have to join this research study if you do not want to. If you join, you can leave at any time. You also have the right to refuse to answer any specific questions, or to end the interview at any time without penalty.

If you choose not to take part in the screening, the staff will ask you to participate in a portion of the study for women not interested in participating in the IUD trial. If you do not want to sign the consent form today, you are welcome to return at a later date if you decide you want to be screened. Once we start the screening process, if you decide to stop, you cannot take part in the screening process again.

If you are eligible but are not able to come for enrollment within 28 days of your screening visit, you will need repeat the enrollment process, including consent, before you can enroll in the IUD study.

Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. This includes all medical record reports we review to determine whether you can join the IUD trial. These record documents will be kept in a chart that is kept in a locked office; only study staff will be able to see this chart. We will do everything we can to keep your data secure, but complete confidentiality cannot be promised. Your name will not appear in any study reports or on any blood samples. Despite all of our efforts, unanticipated problems such as a stolen computer could occur, although it is highly unlikely. Your specimens and questionnaire answers will be assigned a code number, and separated from your name or any other information that could identify you.

The following individuals and/or agencies will be able to look at and copy your research records (such as this consent form, completed questionnaires, lab results, etc.):

- The investigator, study staff and other medical professionals who may be evaluating the study;
- Authorities from the University of Cape Town, including the Institutional Review Board (IRB);
- Authorities from FHI 360, including the Protection of Human Subjects Committee (PHSC);

- The United States Food and Drug Administration ('FDA') and/or the Office of Human Research Protections ('OHRP');
- The sponsors of this study, NIH, USAID, including persons or organizations working with or owned by the sponsor;
- Other South African government regulatory agencies.

Compensation

You will receive compensation valued at 150 Rand at this screening visit. This is for your time and travel costs.

If there is anything that is unclear or if you need further information, please ask us and we will provide it. Do you have any questions?

Contacts for more information

If you have any questions or are hurt while taking part in this research study, you should contact:

Dr. B. Landon Myer
School of Public Health and Family Medicine
Faculty of Health Sciences, University of Cape Town (UCT)
Tel: +27 21 406 6661 or the study clinic at 074-931-6740
Email: Landon.Myer@uct.ac.za

If you are sick or have a health problem due to taking part in the screening process, you will not have to pay to see study staff. If you need more help, we will refer you to other clinics, where you may have to pay.

Your Rights as a Participant

Before a research study can be carried out, it must be approved by an ethics committee. An ethics committee is a group of people who review details of a proposed research study and determine whether the research may be conducted. Their main goal is to help protect participants.

This protocol has been approved by the ethics committees of:

- The University of Cape Town and
- FHI 360 (Protection of Human Subjects Committee).

If you have any questions about how you are being treated by the study your rights as a research participant, you may contact:
UCT Ethics Committee
Prof. Marc Blockman

Chair, Human Research Ethics Committee
Faculty of Health Sciences, UCT

You may also contact:
FHI 360 Protection of Human Subject Committee
P. O. Box 21059
Durham, NC 27703, USA

Tel: +1 919 405 1445
Email: phsc@fhi360.org

If you have questions about this trial you should first discuss them with your doctor or the ethics committee (contact details as provided on this form). 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 Medicines Control Council (MCC) at:

The Registrar of Medicines
Medicines Control Council
Department of Health
Private Bag X828
PRETORIA
0001

Fax: (012) 395 9201

e-mail: mogobm@health.gov.za

VOLUNTEER AGREEMENT

I understand that the purpose of this part of the study is to find participants for a research study titled "Comparison of Two IUDs among Cape Town HIV-positive Women." The study will compare two IUDs among HIV-positive women.

I have read the information in the informed consent form, or it has been read to me. I have had the opportunity to ask questions about it, and the questions that I have asked have been answered to my satisfaction. I consent voluntarily to be screened for possible participation in the IUD study. I understand that this session is screening for possible entry into the IUD study and I am only consenting to screening at this time. I understand that I have the right to withdraw from this screening session at any time without affecting the care that I can get at this clinic or other clinics.

Printed Name of Volunteer	**Date**
Signature (or mark) of Volunteer	**Date**

If a volunteer cannot read the form for herself, a witness must sign here:

I was present while all information in this consent form, including the benefits, risks and procedures were read to the volunteer. All questions were answered and the volunteer has agreed to take part in the research.

Printed Name of Witness	**Date**
Signature of Witness	**Date**

I certify that all information in this consent form, including the nature and purpose, the potential benefits, and possible risks associated with participating in this study have been explained to the volunteer.

Printed Name of Person Who Obtained Consent	**Date**
Signature of Person Who Obtained Consent	**Date**

A signed copy of this consent form was offered to the participant.

Initials of Person Who Obtained Consent	**Date**

VERBAL INFORMED CONSENT FOR DECLINERS/INELIGIBLE

Name of Research Study:	Comparison of Two IUDs among Cape Town HIV-positive Women: A Randomized Controlled Trial Assessing Safety of Registered Products in South Africa
Site Principal Investigator:	Prof Landon Myer
FHI 360 Medical Monitor	Dr. Catherine Todd
Sponsor:	FHI 360, Durham, North Carolina, USA
Funder:	Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health; Preventive Technologies Agreement, United States Agency for International Development

We are from the Desmond Tutu HIV Centre at the University of Cape Town. We are collecting information from women who declined entry or are ineligible for entry into the Intrauterine Device (IUD) trial during the screening process. We want to find out their thoughts about IUDs and other birth control methods.

Your participation in this part of the study is voluntary. Whether or not you decide to participate in this study will not affect your treatment and care at this clinic or other clinics.

If you decide to participate:

- You will meet with a study staff for about 10 minutes to complete a brief anonymous questionnaire.
- We will ask about your thoughts of IUDs and other birth control methods.
- We will ask about your past and current contraceptive use and other basic information such as your age and education.
- Your name will not be collected or recorded; the information will be completely anonymous.
- You do not have to join this study if you do not want to. If you do join, you can refuse to answer any questions, or to end the interview at any time without penalty.
- The information you provide may help us to find ways to improve IUD use. The information may improve family planning use for women living with HIV in Cape Town.

Possible risks

Your participation in this part of the study may involve risks. Some of the questions we ask will be of a personal nature, which may make you uncomfortable.

Possible benefits

There are no direct benefits to participating. If you need referral for additional services, we will assist with this.

Data Confidentiality

No information will be collected during this study that can identify you by name. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely. Your responses will be assigned a code number separate from the screening process, and your name will not be collected.

The following individuals and/or agencies will be able to look at and copy your research records:

- The investigator, study staff and other medical professionals who may be evaluating the study;
- Authorities from the University of Cape Town, including the Institutional Review Board (IRB);
- Authorities from FHI 360, including the Protection of Human Subjects Committee (PHSC);
- The United States Food and Drug Administration ('FDA') and/or the Office of Human Research Protections ('OHRP');
- The sponsors of this study, NIH, USAID, including persons or organizations working with or owned by the sponsor;
- Other South African government regulatory agencies.

Compensation

You will not receive compensation for participating in this portion of the study.

If there is anything that is unclear or if you need further information, please ask us and we will provide it. Do you have any questions?

Contacts for more information

If you have any questions or are hurt while taking part in this research study, you should contact:

Dr. B. Landon Myer
School of Public Health and Family Medicine
Faculty of Health Sciences, University of Cape Town (UCT)
Tel: +27 21 406 6661 or the study clinic at 074-931-6740
Email: Landon.Myer@uct.ac.za

Your Rights as a Participant

Before a research study can be carried out, it must be approved by an ethics committee. An ethics committee is a group of people who review details of a proposed research study and determine whether the research may be conducted. Their main goal is to help protect participants

This protocol has been approved by the ethics committees of:

- The University of Cape Town and
- FHI 360 (Protection of Human Subjects Committee).

If you have any questions about how you are being treated by the study your rights as a research participant, you may contact:
UCT Human Research Ethics Committee
Prof. Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, UCT
Tel: +27 21 406 6338

You may also contact:
FHI 360 Protection of Human Subject Committee
P. O. Box 21059
Durham, NC 27703, USA
Tel: +1 919 405 1445
Email: phsc@fhi360.org

If you have questions about this trial you should first discuss them with your doctor or the ethics committee (contact details as provided on this form). 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 Medicines Control Council (MCC) at:

The Registrar of Medicines
Medicines Control Council
Department of Health
Private Bag X828
PRETORIA
0001

Fax: (012) 395 9201

e-mail: mogobm@health.gov.za

VERIFICATION OF VOLUNTEER AGREEMENT

I was present while all information in this informed consent, including the benefits, risks and procedures, were read to the volunteer. All questions were answered and the volunteer has verbally agreed to take part in this research.

Printed Name of Witness	**Date**
Signature of Witness	**Date**

I certify that all information in this consent form, including the nature and purpose, the potential benefits, and possible risks associated with participating in this study have been explained to the volunteer.

Printed Name of Person Who Obtained Consent	**Date**
Signature of Person Who Obtained Consent	**Date**

A signed copy of this consent form was offered to the participant.

Initials of Person Who Obtained Consent	**Date**

INFORMED CONSENT FOR TRIAL ENTRY

Name of Research Study:	Comparison of Two IUDs among Cape Town HIV-positive Women: A Randomized Controlled Trial Assessing Safety of Registered Products in South Africa
Site Principal Investigator:	Prof. Benjamin Landon Myer
FHI 360 Medical Monitor:	Dr. Catherine Todd
Sponsor:	FHI 360, Durham, North Carolina, USA
Funder:	Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health; Preventive Technologies Agreement, United States Agency for International Development

Introduction

This consent form contains information about the intrauterine device (IUD) trial. The IUD trial is a research study. In order to be sure that you are informed about the research study, we are asking you to read this consent form. If you are unable to read this consent form, a study staff member will read and explain it to you. Someone other than the study staff will be present during this procedure. If you agree to take part in this study, you will be asked to sign this form or make your mark in the presence of a witness.

This consent form might contain some words that are unfamiliar to you. Please ask us to explain anything that you do not understand.

General information about the research

We are from the Desmond Tutu HIV Centre at the University of Cape Town. We are doing a research study to compare two IUDs ("loops") among HIV-positive women. The two IUDs will be the levonorgestrel IUD (LNG IUD) (called Mirena) and the copper IUD. HIV-positive women in Cape Town will be in the trial. We want to find out if the two IUDs are similar in safety and acceptability for HIV-positive women. The IUDs are equally effective at preventing pregnancy.

An IUD (also called a loop) is a small T-shaped flexible device about the length of an egg that is inserted into the womb. The IUD is very good at preventing pregnancy for 5 – 10 years. Both IUDs work mainly by stopping the man's sperm from reaching the woman's egg. The IUD can be removed at any time if a person decides they want to become pregnant. The IUD may change menstrual bleeding patterns after insertion, including causing menstrual bleeding to stop. This is not harmful to you and does not change likelihood of future fertility.

Neither IUD protects against human immunodeficiency virus (HIV) or other sexually transmitted infections. The best way to prevent HIV and other infections is through the use of a barrier method such as the male condom.

You have completed the screening visit for this study and are eligible at this point to take part in the study. This form gives information to help you decide if you want to take part in a research study. The purpose of today's enrollment visit is to explain all the details of the trial to you, review all your test results to confirm that you can take part in the study, obtain your consent to take part, and enroll you.

You can ask any questions to help you decide whether to be a part of the study or not. You may ask questions about the purpose of the research, what will be done during study visits, the possible risks and benefits and anything else about the research or this form that is not clear. When all of your questions are answered, you can decide if you would like to take part in this study or not.

Your part in the research study

288 women will take part in this study. You have successfully completed the medical screening part of this study and are being asked to join the study. Women in the study are 18 to 40 years old with known HIV infection and either a CD4 count greater than the level for antiretroviral therapy (ART) eligibility by Western Cape Province guidelines with no acquired immune deficiency syndrome (AIDS)-defining conditions or taking ART with no HIV virus in blood at the last test. It is important for you to know that you must have a negative pregnancy test before joining this trial and have no plans to get pregnant in the next 2.5 years.

Women in the study will be put into different groups. Each woman will receive one of the IUDs to use for 2 years. The IUD that you get will be chosen by a computer, and half of the women will get an LNG IUD and half of the women will get a copper IUD. Participants will have a 50/50 chance (like tossing a coin) of being placed in one of two groups. But you will not know which kind of IUD you get. This does not mean that one IUD is less effective than the other as both are equally effective at preventing pregnancy. We do not know if there is a difference in safety between the two IUDs, which is why we are doing this study. Which IUD you get will be told to you at the end of the study or sooner if there is a scientific reason to do so.

Taking part in this study will last up to 24 months and will include 5 visits after today. Each visit will last about 2 to 3 hours on 6 separate days, including today.

If you decide to volunteer for this study, the schedule of study visits and the procedures that will be done at each visit are as follows:

Enrollment/ Insertion visit

- At today's visit you should ask any questions about the study and anything you may not understand. Before you sign this consent form, please be sure that you understand what this study is about and what you will be asked to do. You will be asked questions about your understanding of the study. You will sign this consent form or make your mark in front of a witness, if you decide to take part in this study. You will be given a copy of the informed consent form.
- You will give a urine sample for a pregnancy test. If you are pregnant, you cannot take part in the study and will be referred for care.
- You will be randomly assigned by the computer to use one of the IUDs.
- We will ask you to insert a menstrual cup into the vagina to collect cells. The cup will be removed later by the nurse-practitioner during your examination.

- We will ask you personal questions about various areas, including your medical history, your current living and economic situation, your sexual relationships, and your attitudes about birth control and childbearing, within a baseline questionnaire.
- You will have your blood collected to check blood count to check for anemia and HIV viral load.
- You will have an individual risk-reduction counseling session.
- You will have a pelvic exam. A pelvic exam looks at the part of your womb that the doctor can see when looking into the vagina. We will remove the menstrual cup and take several sample of cells from your cervix and vagina, using swabs and a small amount of liquid. We will insert the IUD.
- You will receive counseling on symptoms and warning signs of IUD expulsion and pelvic inflammatory disease.

Follow-up visits

You will return to the clinic for a follow-up visit at 3, 6, 12, 18 and 24 months. You will be called a few days before your appointment as a reminder and, if you are bleeding, you will be asked to delay your visit until bleeding has stopped for at least 2 days. You will be asked to not insert anything in the vagina or have sexual intercourse for three days before each visit. We may call, text message (SMS), or visit you at home if you do not come for an appointment or to remind you of an upcoming appointment.

At each visit:

- You will be asked questions about your health, sexual behavior, and thoughts about using the IUD.
- You will give urine for a pregnancy test.
- You will have your blood collected to test for syphilis and check viral load.
- You will have a pelvic exam to check IUD position and collect cervical and vaginal cells with swabs to test for infections passed through sex. We will give you free treatment for any of the curable infections passed through sex that we find during your exam. We may not be able to do the testing for all infections immediately following your visit and will freeze those samples for possible testing at a later date.
- We will provide you with a disposable menstrual cup and ask you to place it in your vagina at the beginning of your visit. The cup will be removed at the time of examination and the nurse practitioner will take several samples of cells with swabs.
- You will have an individual risk-reduction counseling session.
- You will update your contact information if it changes.

In addition at follow-up visits at 6, 12, 18, and 24 months:

- You will have your blood collected to check blood count, viral load, and, if not on ART, CD4 count. You should always follow up at your home clinic for updated viral load testing.

We will periodically review your medical chart and your other accessible medical records for any new laboratory results, including plasma viral loads if you are using ART, and other information that applies to your safety in this study. We may ask you to bring documents from other clinics if you have received care at other sites.

If you do not want to do any of these procedures or tests, you do not have to take part in this study. Your participation in this study is voluntary. If you choose to take part in this study, you cannot take part in another study that involves a biomedical intervention, like new types of ART medicine. Please discuss your participation in another study with study staff to determine eligibility.

It is very important that you come to each scheduled visit. If you think you cannot keep your scheduled clinic visits over the next two years, please consider not taking part in this study.

If you are not taking ART, if your CD4 count drops below the eligibility level for ART based on local guidelines or you develop AIDS-defining conditions during the study, you will be referred to a clinic for free HIV care and treatment services. If this happens, you will be given a choice about whether you would like to keep your IUD or have it removed. You may remain in this study. If you are taking ART and are found to have increasing HIV levels in your blood based on plasma viral load results, you will be referred to your clinic for medication counseling and possible change. If this happens, you will be given a choice about whether you would like to keep your IUD or have it removed. You may remain in this study.

You can come at any time for an unscheduled visit for IUD removal or for any other medical problem. If you decide to have the IUD removed, you may remain in the study with the same follow-up schedule and may change to a different method of birth control. We may interview you with questions about the IUD and why you chose to have it removed. If you become pregnant after IUD removal, we will refer you for appropriate care in the public sector health system. Obstetric care is not provided through the study.

The 24 hour telephone number with which you can reach the study doctor or another authorized person will be provided to you before you complete the first visit. If you have any problems, please call the 24 hour telephone number and study staff can assist you in making an appointment. If you decide to leave the study before it is completed, you may keep the IUD.

At the end of the study, you will be given the choice to keep your IUD in or have it removed. If you choose to keep it, we will tell you what type of IUD you have and how long it will remain effective for preventing pregnancy. You will need to visit your regular clinic and obtain a new IUD or other form of birth control when the period of effectiveness for your IUD is finished. We may call you after the end of the study visits to follow up on any medical conditions you experience during the study. You may come for care related to these issues at the study clinic after you complete all study visits.

Future use of specimens

We are specifically looking at the IUD in this study. However, the information (data) and samples being collected from all participants may also help answer other questions about HIV, other infections, or safety of other family planning methods. We may want to use your questionnaire information, blood and/or genital tract sample(s) so that other research studies can be done during or after this research study for up to 3 years.

The researchers do not plan to contact you or your regular doctor with any results from tests done on your stored samples. Should a rare situation come up where the researchers decide

that a specific test result could help your health, the researchers will try to notify your study doctor. Your study doctor will try to contact you.

Your samples may be shipped to another country for storage and/or testing, because some of the tests may not be available in South Africa. Only approved researchers will have access to the samples and they will not have any information that identifies you.

You can be in the IUD study and not agree to have these samples stored. You can withdraw your consent for the storage of your samples at any time.

There are no additional risks involved in the long-term storage of samples compared to those in IUD study.

Your participation in this research may benefit other women in the future by answering important research questions about HIV infection.

There are no costs to you for agreeing to have your samples stored.

You will not receive any additional compensation if you agree to have your samples stored long-term. Some research using blood or other samples allows the researchers to make medical tests or treatments that may have commercial value. If this happens, there are no plans to pay you for any products or treatments that are made, or for using your samples.

Permission for use of coded specimens:

Please initial below to indicate whether or not you give permission for your data and specimens to be used for research in addition to the core study.

_____(initial) I agree to have my specimens and data stored for future research by the investigators who are conducting this study or other research collaborators in related areas.

_____(initial) I do not consent to the use of my blood/genital tract sample for any reason outside of this specific study.

Possible risks

Your participation in this part of the study will involve some risks, which include:

- Possible changes in the chance of HIV transmission to your male sexual partner. We do not know how use of the study IUDs affects the chance of infecting a sex partner with HIV. You should always use condoms during sex, and condoms will be offered to you at each study visit.
- Excessive bleeding with the copper IUD is a risk.
- Possible changes in your HIV disease with the LNG IUD. We know that the copper IUD does not affect HIV disease, but we do not know whether the LNG IUD does affect HIV disease.

Other risks include problems that can happen with IUD insertion, like creating a hole in the uterus, having the IUD ejected from the uterus, pregnancy, and pelvic inflammatory disease. The IUD may also increase or decrease your menstrual bleeding. Heavy bleeding is possible and is a risk of the copper IUD and study staff should be notified with any bleeding similar to the

heaviest day of a normal period for 7 or more days. The risk of these events or conditions is quite low.

Pregnancy with the IUD in place is very rare. If you get pregnant with the IUD in place, an ultrasound will be performed right away to find the location of the IUD and of the pregnancy. Depending on the location of the pregnancy and whether the IUD is still in the uterus, you will be counseled on your options.

With the blood draw, there may be slight pain when a needle is inserted into your arm to get the blood sample. There may be minor bruising or pain that may last for up to 2-3 days at the site of the blood draw. Although rare, you may become lightheaded (feel dizzy) or faint when you have blood drawn, and there is a very small risk of infection at the site from where we take your blood.

We will minimize the risks of bruising or infection by cleaning your skin before using a needle to draw blood. We will use a new needle for each person. We will also apply pressure and a bandage to the site after we are done. These discomforts are usually small. If you get an infection because of the blood draw, we will treat you here.

The visit will involve collecting cells inside the vagina with a swab and possibly with a liquid. This process may feel uncomfortable and you may experience a bit of spotting afterward.

There is no known risk associated with menstrual cups. There may be slight discomfort if the cup is not inserted correctly. You will be provided with clear instructions on how to insert the cup.

Some of the questions we ask will be of a personal nature, which may make you uncomfortable.

There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study. If there are any future findings regarding the safety or acceptability of the IUDs we are investigating for HIV-positive women, we will also notify you.

Possible benefits

You will not have to pay for the LNG IUD, if you receive this IUD by chance, in this study, or for any tests that we do.

You will receive free condoms. We will demonstrate how to use them.

You will receive individual risk-reduction counseling with trained staff about the need for condom use for sexually transmitted infection and HIV transmission prevention, tips for negotiating condom use, and we will give you male and/or female condoms, if you wish.

We will give you free treatment for any of the curable infections passed through sex that we find by nurse diagnosis or, where possible, infection tests, during your exams.
There are no other direct benefits to being in the study. If you need referral for more care somewhere else, we will assist with this, but you may have to pay for care at other clinics. We

will not provide payment for injuries or complications resulting from being in the study but will provide or refer for appropriate care. Your participation in this research may benefit other women in the future by helping us understand IUD safety and acceptability in HIV positive women.

Choosing to be in this study

You do not have to take part in this study to get treatment for your condition. You may continue with routine HIV care and receive family planning methods at the Desmond Tutu HIV Center and/or Gugulethu Community Health Centre with no penalty. Whether or not you decide to join this study will not affect your treatment and care at this clinic or any other clinic.

Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, but complete confidentiality cannot be promised. Your name will not appear in any study reports or on any blood samples. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely. Your specimens and questionnaires will be assigned a code number, and separated from your name or any other information that could identify you.

The following individuals and/or agencies will be able to look at and copy your research records (such as this consent form, completed questionnaires, lab results, etc.):

- The investigator, study staff and other medical professionals who may be evaluating the study;
- Authorities from the University of Cape Town, including the Institutional Review Board (IRB);
- Authorities from FHI 360, including the Protection of Human Subjects Committee (PHSC);
- The United States Food and Drug Administration ('FDA') and/or the Office of Human Research Protections ('OHRP');
- The sponsors of this study, NIH, USAID, including persons or organizations working with or owned by the sponsor;
- Other South African government regulatory agencies.

Study staff may request copies of your medical records if you receive any treatment at any other facility. We will request your permission to look at these records.

Compensation

You will receive compensation valued at 150 Rand at this visit. You will receive compensation valued at 150 Rand at each study visit. This is for your time and travel costs. There is no compensation for missed visits.

WHAT ABOUT INSURANCE?
There are no experimental medicines being used in this study. Therefore no insurance has been obtained. However you will be protected in terms of the study staffs' personal malpractice insurance or that of the university's insurance cover in the event of injury or illness that is caused by you taking part in this study (details of this insurance cover are attached in appendix at the end of this document).

Leaving the Research

You may leave this research study at any time. If you decide to stop taking part, please tell the study staff why you wish to leave.

Also, you may be asked to leave the research if:

- The research doctor or study staff feel it is best for you, or
- You are not able to follow the study procedures, or
- The research is stopped. If the research is stopped, you may be asked additional questions about your participation in the study. You may choose not to answer these questions if you wish.

We will tell you if we learn something new about the IUD that could affect your choice to stay in the study. When you are no longer in the research, you will still be able to receive care at this clinic.

If there is anything that is unclear or if you need further information, please ask us and we will provide it. Do you have any questions?

Contacts for more information

If you have any questions after you leave the clinic, or if you are hurt while taking part in this research study, you should contact:

Dr. B. Landon Myer
School of Public Health and Family Medicine,
Faculty of Health Sciences, University of Cape Town (UCT)
Tel: +27 21 406 6661 or the study clinic at 074-931-6740
Email: Landon.Myer@uct.ac.za

If you are sick or have a health problem due to taking part in the study, you will not have to pay to see study staff. If you need more help, we will refer you to other clinics, where you may have to pay.

Your Rights as a Participant

Before a research study can be carried out, it must be approved by an ethics committee. An ethics committee is a group of people who review details of a proposed research study and determine whether the research may be conducted. Their main goal is to help protect participants.

This protocol has been approved by the ethics committees of:

- The University of Cape Town and
- FHI 360 (Protection of Human Subjects Committee).

If you have any questions about how you are being treated by the study your rights as a research participant, you may contact:
UCT Ethics Committee
Prof Marc Blockman

Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape Town
Tel: +27 21 406 6338

You may also contact:
FHI 360 Protection of Human Subject Committee
P. O. Box 21059
Durham, NC 27703, USA
Tel: +1 919 405 1445
Email: phsc@fhi360.org

If you have questions about this trial you should first discuss them with your doctor or the ethics committee (contact details as provided on this form). 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 Medicines Control Council (MCC) at:

The Registrar of Medicines
Medicines Control Council
Department of Health
Private Bag X828
PRETORIA
0001

Fax: (012) 395 9201

e-mail: mogobm@health.gov.za

VOLUNTEER AGREEMENT

I understand that the purpose of the research study titled "Comparison of Two IUDs among Cape Town HIV-positive Women," is to compare the safety of two IUDs among HIV-positive women.

I have read the information in the informed consent form, or it has been read to me. I have had the opportunity to ask questions about it, and the questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study. I understand that I have the right to withdraw from the study at any time without affecting the care that I can get at this clinic or other clinics.

Printed Name of Volunteer	**Date**
Signature (or mark) of Volunteer	**Date**

If a volunteer cannot read the form for herself, a witness must sign here:

I was present while all information in this consent form, including the benefits, risks and procedures were read to the volunteer. All questions were answered and the volunteer has agreed to take part in the research.

Printed Name of Witness	**Date**
Signature of Witness	**Date**

I certify that all information in this consent form, including the nature and purpose, the potential benefits, and possible risks associated with participating in this study have been explained to the volunteer.

Printed Name of Person Who Obtained Consent	**Date**

Signature of Person Who Obtained Consent **Date**

A signed copy of this consent form was offered to the participant.

_____ _____

Initials of Person Who Obtained Consent **Date**

Details of UCT's no-fault insurance

What if Something Goes Wrong?

The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from your participation in the study. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI) in the event of an injury or side effect resulting directly from your participation in the study. You will not be required to prove fault on the part of the University.

The University will not be liable for any loss, injuries and/or harm that you may sustain where the loss is caused by

- The use of unauthorised medicine or substances during the study
- Any injury that results from you not following the protocol requirements or the instructions that the study doctor may give you
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the study medication
- An injury that results from negligence on your part

By agreeing to participate in this study, you do not give up your right to claim compensation for injury where you can prove negligence, in separate litigation. In particular, your right to pursue such a claim in a South African court in terms of South African law must be ensured. Note, however, that you will usually be requested to accept that payment made by the University under the SA GCP guideline 4.11 is in full settlement of the claim relating to the medical expenses.

An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.

INFORMED CONSENT FOR FINAL STUDY VISIT & IUD CONTINUATION TELEPHONE FOLLOW-UP

Name of Research Study:	Comparison of Two IUDs among Cape Town HIV-positive Women: A Randomized Controlled Trial Assessing Safety of Registered Products in South Africa
Site Principal Investigator:	Prof. Benjamin Landon Myer
FHI 360 Medical Monitor:	Dr. Catherine Todd
Sponsor:	FHI 360, Durham, North Carolina, USA
Funder:	Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health; Preventive Technologies Agreement, United States Agency for International Development

Introduction

This consent form contains information about the final study visit for women not in the 24-month visit window at the last day of scheduled follow-up due to study closure or did not complete their 24 month visit by the last day for scheduled study visits of June 8, 2018. This consent also contains information about follow-up calling for women already participating in the intrauterine device (IUD) trial. The purpose of today's visit is to explain changes in the study if you were not yet eligible or did not complete your 24-month visit. The study is closing and you will not be able to complete the 24-month visit. Today, we will tell you which IUD you received and ask you if you wish to continue using the IUD. If you decide to continue your IUD, we request your consent to call you when you are eligible for the 24-month visit to ask if you are still using your IUD. The IUD continuation call is part of the current research study. In order to be sure that you are informed about the changes to the final study visit and the additional follow-up calling as part of the research study, we are asking you to read this consent form. If you are unable to read this consent form, a study staff member will read and explain it to you. Someone other than the study staff will be present during this procedure. If you agree to take part in this study, you will be asked to sign this form or make your mark in the presence of a witness.

General information about the research

We are from the Desmond Tutu HIV Centre at the University of Cape Town. We are doing a research study to compare two IUDs ("loops") among HIV-positive women and you are currently participating in that study.

The study is now ending and this has happened before some participants were able to come for their 24-month visit or before they were eligible for their 24-month visit. This change has happened for budget reasons and we have no reason to believe there are any safety concerns with the IUD you are using.

This form gives information to help you decide if you want to take part in the final study visit and added telephone call follow-up. We are asking you, as someone who is not yet eligible for or did not complete the 24-month visit, if you would be willing to complete the final study visit. If so and you want to continue the IUD, we are also asking you if you would be willing to receive a telephone call at the 24-months visit date to ask about your IUD use.

You can ask any questions to help you decide whether to continue with this part of the study or not. You may ask questions about the purpose of the research, what will be done during the call, the possible risks and benefits and anything else about the research or this form that is not clear. When all of your questions are answered, you can decide if you would like to take part in this study or not. You will sign this consent form or make your mark in front of a witness, if you decide to take part in this study. You will be given a copy of the informed consent form.

Your part in the research study

Today's visit will last for about 30-60 minutes. Around 20 women will be involved in this part of the study. If you decide to volunteer for the final study visit, the visit details are as follows:

- You will be asked questions about your health, sexual behavior, and thoughts about using the IUD.
- We will follow-up on any outstanding medical issues and provide a referral for any issues that have not yet resolved.
- We will tell you which IUD you received and you will be given the choice to keep your IUD in or have it removed.
    - If you choose to keep it, we will tell you how long it will remain effective for preventing pregnancy and test you for pregnancy if you wish.
    - If you chose to remove the IUD, we will remove it during this visit and perform a pregnancy test. We will also counsel with available methods and provide you with your selected method or a referral as applicable.
- We will test you for any reproductive infections if you wish.
- If you decide to continue your IUD, we request your consent to call you when you are eligible for the 24-month visit to ask if you are still using your IUD.

If you do not want to do any of these procedures or tests, you do not have to take part in this study. Your participation in this study is voluntary.

If you have decided to keep your IUD and are not yet eligible for your 24-month visit, with your consent you may receive 1-2 follow-up telephone calls in a few months that will last about 20 minutes. Around 20 women will be involved in this part of the study. If you decide to volunteer for this part of the study, the call details are as follows:

Follow-up Call:

- You will be asked to provide best telephone numbers and times at which to reach you in a few months when you are eligible for the 24-month visit.
- At around 24 months after you received the IUD, the study manager or a female study representative will call you. They will identify themselves as being from UCT and then ask if it is you.

- You will be asked some basic questions, like your birthdate, to confirm it is really you with whom they are speaking.
- The person calling will then ask you a series of questions about whether you are using the IUD and if you are satisfied with it. If you have had the IUD removed between today's visit and the call, they will ask when and why it was removed and what you are now using for family planning.
- You may request an additional call if you are unable to complete the questionnaire at the time of the first call.
- If you are having any problems, you may discuss them with the study member who calls you and they can suggest follow-up at your home clinic to address the problem.

Permission to be called at 24-month post study insertion:

Please initial below to indicate whether or not you give permission for the additional follow-up calls.

_____(initial) I agree to have the follow-up calls as described above.

_____(initial) I do not consent to the follow-up calls as described above.

Possible risks

Your participation in this part of the study will involve some risks, which include:

- Possible disclosure of your participation in the study to others answering your telephone. We will make every effort to confirm your identity with full name and birth date before we start the questionnaire.

Some of the questions we ask will be of a personal nature, which may make you uncomfortable.

Possible benefits

If you opt to have testing for reproductive infections, we will give you free treatment for any of the curable infections passed through sex that we find by nurse diagnosis or, where possible, infection tests.

You will receive free condoms. We will demonstrate how to use them.

There are no other direct benefits to being in this part of the study. If you need referral for care, we will assist with this, but you may have to pay for care at other clinics. Your participation in this research may benefit other women in the future by helping us understand IUD acceptability in HIV positive women.

Choosing to be in this study

You do not have to take part in this study to get treatment for your condition. You may continue with routine HIV care and receive family planning at the Desmond Tutu HIV Center and/or Gugulethu Community Health Centre with no penalty. Whether or not you decide to join this part of the study will not affect your treatment and care at this or any other clinic.

Confidentiality

Any information collected during this part of the study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, but complete confidentiality cannot be promised. Your name will not appear in any study reports or on any blood samples. Despite all of our efforts, unanticipated problems such as another person answering your phone or a stolen computer may occur, although it is highly unlikely. Your questionnaires will be assigned a code number, and separated from your name or any other information that could identify you.

The following individuals and/or agencies will be able to look at and copy your research records (such as this consent form, completed questionnaires, etc.):

- The investigator, study staff and other medical professionals who may be evaluating the study;
- Authorities from the University of Cape Town, including the Institutional Review Board (IRB);
- Authorities from FHI 360, including the Protection of Human Subjects Committee (PHSC);
- The United States Food and Drug Administration ('FDA') and/or the Office of Human Research Protections ('OHRP');
- The sponsors of this study, NIH, USAID, including persons or organizations working with or owned by the sponsor;
- Other South African government regulatory agencies.

Study staff may request copies of your medical records if you receive any treatment at any other facility. We will request your permission to look at these records.

Compensation

You will receive compensation valued at 150 Rand at this visit. This is for your time and travel costs.

You will not receive compensation for the follow-up phone calls.

Leaving the Research

You may leave this research study at any time. If you decide to stop taking part, please tell the study staff why you wish to leave.

Also, you may be asked to leave the research if:

- The research doctor or study staff feel it is best for you, or
- You are not able to follow the study procedures, or
- The research is stopped. If the research is stopped, you may be asked additional questions about your participation in the study. You may choose not to answer these questions if you wish.

We will tell you if we learn something new about the IUD that could affect your choice to stay in the study.

If there is anything that is unclear or if you need further information, please ask us and we will provide it. Do you have any questions?

Contacts for more information

If you have any questions after you leave the clinic, or if you are hurt while taking part in this research study, you should contact:

Dr. B. Landon Myer
School of Public Health and Family Medicine,
Faculty of Health Sciences, University of Cape Town (UCT)
Tel: +27 21 406 6661 or the study clinic at +27 21 633 9735
Email: Landon.Myer@uct.ac.za

Your Rights as a Participant

Before a research study can be carried out, it must be approved by an ethics committee. An ethics committee is a group of people who review details of a proposed research study and determine whether the research may be conducted. Their main goal is to help protect participants.

This protocol has been approved by the ethics committees of:

- The University of Cape Town and
- FHI 360 (Protection of Human Subjects Committee).

If you have any questions about how you are being treated by the study your rights as a research participant, you may contact:
UCT Ethics Committee
Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape Town
Tel: +27 21 406 6338

You may also contact:
FHI 360 Protection of Human Subject Committee
359 Blackwell Street, Suite 200
Durham, NC 27701 USA
Tel: +1 919 405 1445
Email: phsc@fhi360.org

If you have question about this part of the study you should first discuss them with your doctor or the ethics committee (contact details as provided on this form). 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 Medicines Control Council (MCC) at:

The Registrar of Medicines
Medicines Control Council
Department of Health
Private Bag X828

PRETORIA
0001

Fax: (012) 395 9201
e-mail: mogobm@health.gov.za

VOLUNTEER AGREEMENT

I understand that the purpose of the research study titled "Comparison of Two IUDs among Cape Town HIV-positive Women," is to compare the safety of two IUDs among HIV-positive women. I further understand that I, as an already-consented study participant, am being asked to participate in the final study visit and to participate in additional phone calls to discuss IUD use.

I have read the information in the informed consent form, or it has been read to me. I have had the opportunity to ask questions about it, and the questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this part of the study. I understand that I have the right to withdraw from the study at any time without affecting the care that I can get at this clinic or other clinics.

Printed Name of Volunteer	**Date**
Signature (or mark) of Volunteer	**Date**

If a volunteer cannot read the form for herself, a witness must sign here:

I was present while all information in this consent form, including the benefits, risks and procedures were read to the volunteer. All questions were answered and the volunteer has agreed to take part in the research.

Printed Name of Witness	**Date**
Signature of Witness	**Date**

I certify that all information in this consent form, including the nature and purpose, the potential benefits, and possible risks associated with participating in this study have been explained to the volunteer.

Printed Name of Person Who Obtained Consent	**Date**

Signature of Person Who Obtained Consent	**Date**

A signed copy of this consent form was offered to the participant.

Initials of Person Who Obtained Consent	**Date**

Appendix III –
Questionnaires and Data CRF

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

Pre-ART Baseline Questionnaire: 2IUDnCT

#	**Umbuzo /Question** ***[To be read verbatim]***	**Impendulo** ***/ Answer*** **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo** ***/ Write in***	**Gqitha** ***Skip***	**Ikhowudi Yempendulo** ***Code***
Siyabulela ngokuthatha inxaxheba nokugqiba inkqubo yohluzo. Namhlanje ndiza kubuza imibuzo ngembali yempilo, indlela ophila ngayo, kunye neembono zakho ngocwangciso ntsapho. Siza kuthetha sobabini mhlawumbi ixesha elingaphezulwana kwemizuzu engama 60. Ukuba akuwuqondi umbuzo ndicela undazise, sikwazi ukuxoxa ngawo. *Thank you for participating and completing the screening process. Today, I am going to ask you some questions about your health history, current living situation, and ideas about family planning. We will probably talk together for a little over an hour. If you don't*				
Demographic Information (200s)				
201	*Umhla wakho wokuzalwa?* *What is your date of birth?* Mingaphi iminyaka yakho? *What is your age?*	DOB: l_l_l / l_l_l_l / l_l_l_l_l *(dd/mmm/yyyy)* l__l__l iminyaka */ years*		
202	Loluphi ulwimi olu phambili olisebenzisayo ekhaya? *What is the primary language you use at home?*	1…..IsiXhosa */ Xhosa* 2…..IsiZulu */ Zulu* 3…..IsiBhulu */ Afrikaans* 4…..Isingesi */ English*		_____
203	Sithini isimo sakho sobudlelwane neqabane? *What is your current partnership status?*	1….Andinamntu *Single/ no steady partner/boyfriend* 2….Sitshatile sihlala kunye/*Married and live together* 3….Sitshatile asihlali kunye *Married, live apart* 4….Sihlala kunye asitshatamga *Live together, not married* 6 …Ndineqabane lwisisigxina, asihlali kunye/ *Steady*		_____
204	Uya sebenza ngoku? *Are you currently employed?*	0…. Hayi */ No* 1…. Ewe, manqaphanqapha */ Yes, part-time* 2…. Ewe, isigxina */ Yes, full time*		_____
205	Hlobo luni lwendlu ohlala kuyo? *What type of house do you live in?*	1…..Imbacu / ityotyombe *Informal dwelling / hokkie* 2…. ndihlala endlini*/ Live in a home* 3….Ifleti / indlu kamasipala *Flat / municipal housing*		_____

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Place **Enrolment PTID** label here

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#	**Umbuzo /Question** ***[To be read verbatim]***	**Impendulo** ***/ Answer*** **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo** ***/ Write in***	**Gqitha** ***Skip***	**Ikhowudi Yempendulo** ***Code***
206	Bangaphi abatwana nabantu abadla abahlala endlini yakho? *How many adults and children live in your house?*	|_|_| abadala (kuquka nawe) *adults (including yourself))* |_|_| abantwana */ children*		_____ _____
207	Liliphi elona banga eliphezulu oligqibileyo eskolweni? *What is the highest level of school you have completed?*	Grade (1-12): |___|		_____
		or Standard (1-10): |___|		_____
		or Imfundo ephakamileyo (cacisa) *Post secondary (explain)* _____		
208	Ingaba ungumfundi ngoku? *Are you currently a student?*	0…. Hayi */ No* 1…. Ewe, manqaphanqapha */ Yes, part-time*		_____
209	Unawo amanzi ahamba ngopipe endlini yakho?	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
210	Unayo indlu yangasese egungxulwayo?	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
211	Unawo na umbane endlini yakho? *Do you have electricity in your house?*	0…. Hayi */ No* 1…. Ewe, owam okanye igenerator */ Yes, my own or a generator* 2…. Ewe owam osuka kummelwane /		_____
212	Unaye umabona-kude osebenzayo endlini yakho?	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
213	Unayo ifowuni ohamba uyiphethe esebenzayo?	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
Menstrual, pregnancy and fertility history (300s) ***Uqhuba kakuhle.Siza kubuza ngoku ngamava akho ngokuya exesheni.***				
301	Wawuneminyaka emingaphi ukuqala kwakho ukuya exesheni? *How old were you when you started your menses?*	|_|_| iminyaka /years		_____

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#	**Umbuzo /Question** ***[To be read verbatim]***	**Impendulo / *Answer*** **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo / *Write in***	**Gqitha** ***Skip***	**Ikhowudi Yempendulo *Code***
302	Kwinyanga ezintathu ezidlulileyo, zingaphi intsuku phakathi kosuku lokuqala lokuya exesheni nosuku lokuqala phambi kokuya exesheni kwinyanga elandeleyo? *In the last three months, about how many days were there between the first day of your menstrual cycle and the first day of your next*	|_|_|_| iintsuku /days 999….andiyi exesheni /ukuya exesheni manqaphanqapha kuhlobo locwangciso ntsapho endilidebenzisayo (BCM) *Amenorrheic / not menstruating / irregular menses on current BCM*	999→306	_____
303	Kwezinyanga zi-3 zidlulileyo uqhele ukopha intsuku ezingaphi xa usiya exesheni? *In the last 3 months, for how many*	|_|_| iintsuku /days		_____
304	Ungayichaza njani imini owopha kakhulu ngayo (khetha eyona mpendulo)? *How would you describe a "heavy bleeding" day?* ***[Do not read responses, circle those that are mentioned by the respondent]***	1… Ngamaxa enditshintsha ngawo iiphedi *By the number of times I change my menstrual product*		_____
		2….Xa ndibona amahlwili *By whether I see blood clots*		_____
		3….Xa ndinentlungu okanye ezinye ingqaqambo *By whether I have cramping or other pain*		_____
		4….Xa ndiphumela kwiphedi nokuba ndiyitshintshe amaxa amaninzi		_____
		5… Ezinye cacisa / *Other (specify):* _____		_____
305	Ngosuku owophe ngalo, uyitshintsha kangaphi ipadi? *On one of these heavy days, about*	|_|_| inani lamaxesha / *times*		_____

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#	**Umbuzo /Question** ***[To be read verbatim]***	**Impendulo** ***/ Answer*** **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo** ***/ Write in***	**Gqitha** ***Skip***	**Ikhowudi Yempendulo** ***Code***
306	Ungakuchaza njani ukuya kwakho exesheni kwezinyanga zi-3 zidlulileyo? *In the last 3 months, how would you describe your bleeding pattern overall?* ***[Read each of these options and have them select <u>one</u> best answer]***	1…. Ukuya exesheni ngokwesiqhelo iintsuku ezi 3 ukuya kwezi 7 kungekho kopha phakathi kwalamaxesha *Regular menstruation of 3-7 days with no bleeding in between these times* 2…. Manqapha nqapha (nganeno kwamatyeli amabini kweli xesha)*Infrequent (less than 2 bleeding events in this time)* 3…. Ukopha qho, amatyeli angaphezulu kwesiqhelo okuya exesheni(ngaphezu kwamatyeli amane >=ngaphezu kwentsuku ezimbini kwinyanga ezintathu ezidlulileyo) / *Frequent bleeding events that are more frequent than menstruation (more than 4 events (>=2 days) in last 3 months)* 4…. Ukopha ngokutsalileyo (mhlawumbi ityeli elinye litsale iintsuku ezilishumi nangaphezulu); kungenzeka ngokongezelelekileyo kunokuya exesheni ngokwesiqhelo / *Prolonged bleeding (at least one event lasting >=10 days); may occur in addition to regular menstruation* _____ 5… Ukuchaneneka kwesiqhelo	6→308	_____

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307	Kwinyanga ezintathu ezidlulileyo, ingaba oku kulandelayo kuye kwenzeka na kuwe? **(funda nganye)**			
A1	Amantsi esisu anxulumene nokutya, ukuchama nokuyangasese. *Lower abdominal pain related to*	0…. Hayi */ No* 1…. Ewe */ Yes*		
B	Ukopha kakhulu / amahlwili xa usexesheni	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
C	Ukopha manqaphanqapha (ukungayi exesheni nyanga zonke	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
C1	Ukopha okungaqhelekanga (ukuya exesheni kanye nangaphezulu enyangeni enye)	0…. Hayi */ No* 1…. Ewe */ Yes*		
D	Ukopha phakathi kwentsuku zakho zokuya exesheni okanye amachaphaza egazi (ukopha kwenzeke ngaphezu kwentshuku ezimbini phambi kokuya exesheni nasemva kokuya exesheni kwaye kungeyonxalenye yokuya kwakho exesheni. *Bleeding in between your menstrual*	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
E	Ezinye chaza Other, explain _____	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
308	Uyathanda ukuya exesheni? *Do you like having periods?*	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
309	Ukuba ungakhetha, ungathanda ukuya kangaphi exesheni? *If you could choose, how often would you like to have a period?*	0…Andifuni */ Never* 1….Ngenyanga*/ Monthly* 2… Emva kwenyanga ezintatu *At least every 3 months* _____ 3….Ezinye chaza */ Other (specify):*		_____
310	Wawukhe wasebenzisa ucwangciso ntsapho olwamisa ukuya kwakho exesheni?	0…. Hayi */ No* 1…. Ewe */ Yes*		_____

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Ngoku ndizakubuza imibuzo malunga nolwazi lwakho ngokhulelo? ***Now I am going to ask you some questions about your experiences with pregnancies.***			
311	Wakhe wakhululelwa? *Have you ever been pregnant?*	0…. Hayi / No 1 … Ewe / Yes	0→ skip to 316	_____

Previous Pregnancy History

312 **(Ukuba Ewe)Kumitho ngalunye uqale ngolokugqibela, nceda cacisa oku kulandelayo**: ***[If Yes] for each pregnancy starting with the most recent please specify the following:***

	A. **Unyaka [isiphumo]** *Year [of outcome]*	B. **Isiphumo?** *Outcome?* 1= Ukuzala usana oluphilayo */live birth* 2= Ukukhutswa kwesisu ngenjongo /*induced abortion* 3= Ukuphuma kwesisu/ozelwe engaphili */miscarriage- still birth*	C. **Isini?** *Sex?* 1 = inkwenkwe *male* 2= Intombi *femal e*	D. **Isimo sentsholongwane sosana ngexesha ezalwa?** *HIV status of child at birth?* 0 = alikho ichaphaza /*negative* 1 = likhona ichaphaza */ positive* 99 = Andazi, aluka vavanywa usana *unknown: child untested*	E. **Luyaphila ngoku**? *Currently alive?* 0= Hayi */no* 1= Ewe */yes* ***Ukuba 1, gqithela kumitho olulandelayo. Ukuba alukho olunye, yiya ku 313***	F. **Ubudala ngelixa esweleka?** *Age at death?* ***Cacisa iinyanga okanye iminyaka*** ***[indicate in months or years]*** ***Gqithela kumitho olulandelayo. Ukuba alukho lolunye, yiya ku 313*** ***[Go to next pregnancy. If no other pregnancy go to 313]***
1						
2						
3						
4						
5						
6						

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
313	Kukhulelo lwakho lwangaphambili, wawukhe wadibana nezinye zezingxaki zilandelayo? [Funda ngezantsi uphedulo] *During your previous pregnancy or pregnancies did you ever experience any of the following? [Read list to participant]*			
A	Ukopha kakhulu de uthiwe igazi	0…. Hayi */ No*		_____
B	Uqhaqho lokubeleka *Need for Cesarean section*	0…. Hayi */ No*		_____
C	Ukunyukelwa yi Highblood/ elumithweni / *High blood pressure/ pre*	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
D	Ukuxhuzula kwilixa lokusondela ukubeleka / *Seizures around time of birth/*	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
E	Ulwasuleleko ngelixesha ubelekayo okanye emva	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
F	Ukrazuko ebufazini okwenze ukuchama,ukuzithuma,okanye ukwabelana ngesondo	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
314	Ukuya kwakho exesheni kuye kwatshintsha enyakeni emva nje kokukhulelwa? *Did your menses change within the year*	0…. Hayi */ No* 1…. Ewe */ Yes* 99… Andazi */ I don't know*	0→ 316 99→ 316	_____
315	Ukuba ngu Ewe, njani? If yes, in what way?	1….Ukuya exesheni kunqabile *Menses became less regular* 2….Ukuya exesheni kubenje ngesiqhelo */ Menses became more regular* 3….Ukuya exesheni akujiyanga / akuthathanga xesha elide */ Menses became lighter or didn't last as long* 4….Ukuya exesheni kakhulu / kwathatha ixesha elide /		_____
316	Wakhe wacetyiswa ukuba ungabinabantwana ngenxa yezizathu zempilo yakho? *Have you ever been advised for*	0…. Hayi */ No* 1…. Ewe */ Yes* 99… Andazi */ I don't know*		_____

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Place **Enrolment PTID** label here

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
Olu luhlu lulandelayo lwemibuzo lungeengcinga zakho ngoku nokuba uziva njani ngokuba nabantwana kwixesha elizayo. Ukuba umbuzo ukwenza ungakhululeki, nceda ndixelele sixoxe ngawo. Unako ukusala ukuphendula loo mbuzo. *The next set of questions is about your CURRENT thoughts and feelings*				
317	Ungathanda ukuba nomntwana/abantwana, okanye ukheta ukungabi nabantwana konke konke? *Would you like to have (a/another) child, or would you prefer not to have*	0….Andifuni konke konke *No more / none* 1….Ndiyamfuna omnye umntwana *Have a/nother child* 99…Andazi / andiqinisekanga *Undecided/don't know*	0→ 320 99→ 320	_____
318	Ungathanda ukulinda ixesha elingakanani ukususela ngoku phambi kokuba ubenomnye umntwana/ubenabanye abantwana? *How long would you like to wait from now before the birth of a/nother child?*	|___|___| iminyaka */ years* *or* |___|___| iinyanga*/ months*	**Ukuba ngaphantsi kweminyak a emi 2, yazisa umphathi wovavany**	Yrs: _____ Mos: _____
319	Bangaphi abantwana (abongezelelekileyo) onqwenela ukuba nabo kwixesha elizayo?	|___|___| Bantwana */ children*		_____
320	Likhe waxoxa ngomnqweno wakho wokufuna ukuba nabanye abantwana okanye umnqweno wakho wokungafuni ukuba nabantwana neqabane lakho lokugqibela obunalo/onalo? *Have you discussed your desire to*	0…. Hayi / *No* 1…. Ewe /*Yes*		_____
321	Ingaba ukuba nesifo seHIV sakutshintsla kwizigqibo zakho zokuba nomntwana/okanye ukungabi namntwana? *Did*	0…. Hayi / *No* 1…. Ewe /*Yes*		____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

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#	**Umbuzo** */ Question* ***[Funda ngohlobo ebhalwe ngalo /To be read***	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** ***Skip***	**Ikhowudi Yempendulo**
322	Ingaba IHIV ithe yabangela ukuba utshintshe izigqibo zokuba uzakumfumana nini na umntwana/omnye umntwana? *Did HIV diagnosis change your decision about WHEN to have (a)nother child?*	0…. Hayi / *No* 1…. Ewe indenze ndafuna ukuba naye ngokukhawuleza. /*Yes, made me want to have one sooner* 2…. Ewe indenze ndafuna ukulinda ixesha elide *Yes, made me want to wait longer* -8….Andifuni abanye abantwana		____

Sexual Health and HIV (400s)

Olu luhlu lulandelayo lwemibuzo luzakubuza ngempilo yakho yesondo namava esondo, ngamava akho ngezesondo kwanesimo sakho seHIV. Ukuba ufuna ixesha elongezelelweyo ukuphendula lemibuzo okanye uziva ungakhulelekanga, nceda undixelele. *The next section of questions will ask about your sexual*

401	Wawuneminyaka emingaphi ukuqala kwakho ukwabelana ngesondo? *How old were you the first time you had*	|___|___| iminyaka */ years*		____
402	Mangaphi amaqabane akho esondo owakhe wanawo ebomini? *How many sexual partners have you had in your lifetime?*	|___|___| inani labantu *persons* ***[If they cannot give an exact number, ask them to estimate]***		____
403	Mangaphi amaqabane akho esondo okhe wanawo kulo nyaka uphelileyo? *How many sexual partners have you had in the last year?*	|___|___| inani labantu *Persons* ***[If none enter 00]***	00→ 412	____
404	Unalo iqabane elisisigxina lokwabelana	0…. Hayi / *No* 1…. Ewe / *Yes*	0→ 406	____
405	Kukangaphi wena neqabane lakho elisisigxina nisebenzisa ikhondom kwezi nyanga zi 3 zigqithileyo? *How often did you use condoms with your steady partner in the last 3 months?*	1….Rhoqo */ always* 2….Phantse onke amaxesha *(>75%) almost all the time (>75%)* 3….Maxesha onke (50% - 75%) *most of the time* (50% - 75%) 4….Ngamanye amaxesha (25% - 50%)		____

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#	**Umbuzo** */ Question* ***[Funda ngohlobo ebhalwe ngalo /To be read***	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** ***Skip***	**Ikhowudi Yempendulo**
406	Ingaba unawo amanye amaqabane obelana ngawo ngesondo? *Do you currently have any (other) sexual partners?*	0…. Hayi */ No* 1…. Ewe */Yes*	0→ 408	____
407	Ukuba ewe, kukangaphi usebenzisa ikhondom neliqabane kwezinyanga zintathu zidlulileyo? *If yes, how often did you use condoms with this partner/these partners in the last 3 months?*	1….Rhoqo */ always* 2….Phantse onke amaxesha *almost all the time (>75%)* 3….Maxesha onke *most of the time* (50% - 75%) 4….Ngamanye amaxesha		____
408	Xa usebenzisa iikhondom, zeziphi ezona zizathu zibalulekileyo zokuba usebenzise ikhondom? *When you use condoms, what are the most important reasons you use condoms?* ***Sukufunda okubhaliweyo, qwalasela okuphuma kumthathi nxaxeba*** ***[Do not read responses, note all the responses that are stated by the participants]***	0…Andisebenzisi ikhondom*/ I don't use condoms*		____
		1 …Ukuthintela ukumitha/andifuni mntwana		____
		2….Isimo sentsholongwane seqabane asaziwa */ Partner's HIV status unknown*		____
		3….Iqabane alinachaphaza lentsholongwane */ Partner HIV negative*		____
		4….Iqabane liphila nentsholongwane; ukukhusela ulwasuleleko		____
		5….Ukhuselo kwizifo ezifumaneka ngokwabelana ngesondo/intsholongwane		____
		6….Iqabane liyagxininisa ukusebenzisa ikhondom */ Partner insists to use them*		____
		7….Ixhala lokuba ucwangcisontsapho aluthembekanga ngokupheleleyo/alusebenzi ngokupheleleyo */ Concerned birth control method is unreliable/ not*		____
		8….Andifuni iqabane lazi ukuba ndisebenzisa olunye uhlobo locwangcisontsapho */ Don't*		____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
		9….Okunye(bhala) */ Other (write in)*: _____		____
409	Xa uqikelela wabelana kangaphi ngesondo kwezinyanga zintathu zidlulileyo? *In the last 3 months, about how often did you have sexual intercourse?*	0….Khange, ndabelane ngesondo kwezi nyanga zi 3 zigqithileyo *Not sexually active in the last 3 months* 1….Ngaphantsi kwenyanga *<1 per month* 2….Kanye – kathathu ngenyanga *1-3 times per month* 3….Kanye ngeveki / *1 per week* 4….Kabini ukuya kathathu evekini		____
409a	Zingaphi iintsuku ogqibele ngazo ukwabelana ngesondo? *How many days ago did you last have sexual intercourse?*	_____days (Enter 99 if participant does not remember)		
409b	Ingaba iqabane lakho lisebenzise ikhondom yotata okanye wena usebenzise eyotata okugqibela kwakho ukwabelana ngesondo? *Did your partner use a male condom or*	0….Hayi */ No* 1….Ewe */Yes* 99…Andikhumbuli/andazi *.I don't know/ recall*		
	Ngoku, ndingakubuza imibuzo malunga netsholongwane kagawulayo nokhathalelo. *Now I would like to ask you some questions about your HIV diagnosis and care*			
412	Uzaze nini ukuba uphila neHIV? *When were you diagnosed with HIV?*	|____|____|____|month |____|____|____|____| year ***[If participant unsure, please show them calendar and ask them to estimate. If they really do not know the month, enter***		Mo_____ Yr _____
413	Uqale ukuzazi ukuba uneHIV ngexesha ubukhulelwe? *Were you first diagnosed with HIV*	0….Hayi */ No* 1….Ewe */Yes*		____

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#	**Umbuzo** ***/ Question*** ***[Funda ngohlobo ebhalwe ngalo /To be read***	**Impendulo** ***/ Answer Key*** **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** ***Skip***	**Ikhowudi Yempendulo**
414	Uye watshintsha indlela yocwangisontsapho ngenxa yokuphila nentsholongwane? *Did you change your birth control method due to your HIV diagnosis?*	0….Hayi */ No* 1….Ewe */Yes*	0→ 416	____
415	Ukuba Ewe, ngoba? *If yes, why?*	_____ _____		____
416	Ukuya kwakho exesheni kuye kwatshintsha wakuzazi ukuba uphila neHIV?	0…. Hayi */ No* 1…. Ewe */ Yes*	0→ 418	____
417	Ukuba ngu ewe, njani? *[If yes], how?*	1….Ukuya exesheni kunqabile *Menses became less regular* 2….Ukuya exesheni kubenje ngesiqhelo */ Menses became more regular* 3….Ukuya exesheni akujiyanga/ akuthathanga xesha elide */ Menses became lighter or didn't last as long* 4….Ukuya exesheni kakhulu / kwathatha ixesha elide */ Menses became heavier/ lasted*		____
418	Kwinyanga ezi 6 ezidlulileyo, kukangaphi ubonana nomnikezi wezempilo kule kliniki ngokhathalelo lwakho lweHIV? In the last 6 months, how many	|___|___| kangaphi/*times*		____

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419	Usichazile isimo sakho sentsholongwane kwaba...? *Have you disclosed your HIV status to…?*			
A	Abantwana */ your children*	0…. Hayi / No 1…. Ewe /Yes		____
B	Mama */ mother*	0…. Hayi / No 1…. Ewe /Yes		____
C	Tata */ father*	0…. Hayi / No 1…. Ewe /Yes		____
D	Utatomkhulu/makhulu */grandparents*	0…. Hayi / No 1…. Ewe /Yes		____
E	Umnakwenu/dadewenu */ Brothers or sisters*	0…. Hayi */ No* 1…. Ewe */ Yes*		____
F	Iqabane lokugqibela okanye langokulokwabelana ngesondo	0…. Hayi */ No* 1…. Ewe */ Yes* -8 Not applicable		____
420	Uyasazi isimo sentsholongwane kagawulayo seqabane lakho langoku okanye lokugqibela ubunalo?	0…. Hayi / No 1…. Ewe /Yes		____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

	Contraceptive History (500s) **Ngoku ndizakubuza imibuzo eyongeziweyo malunga namava akho ngocwanciso-ntsapho.**			
501	Ngaphambi kokungenela oluphando, wakhe weva nge IUD okanye iloop? *Prior to joining this study, had you ever heard of the IUD or loop?*	0…. Hayi */ No* 1…. Ewe */ Yes*		____
502	Wakhe weva ngolunye uhlobo locwangciso-ntsapho olufakelwayo olubizwa ngokuba yi-implant?	0…. Hayi */ No* 1…. Ewe */ Yes*		____
503	**Wena okanye iqabane lakho nakhe nazisebenzisa na i….** Have you or your partner ever **used**….. .			
A	Ipilisi / eziselwayo *Pill or Oral Contraceptive*	0….Hayi */ No* 1….Ewe */ Yes*		____
B	Net-en / naliti (istofu senyanga ezi 2) *Net-en/2 monthly injectable*	0….Hayi */ No* 1….Ewe */ Yes*		____
C	Idepo naliti (istofu senyanga ezi 3) *DepoProvera/3 monthly Injectable*	0….Hayi */ No* 1….Ewe */ Yes*		____
D	Isivalo-mlomo sesibeleko (loop) *IUD (Loop)*	0….Hayi */ No* 1….Ewe */ Yes*		____
E	Ikhondom yamadoda *Male condom*	0….Hayi */ No* 1….Ewe */ Yes*		____
F	Ikhondom yabafazi *Female condom*	0….Hayi */ No* 1….Ewe */ Yes*		____
G	Isivalo nzala samadoda *Male sterilization*	0….Hayi */ No* 1….Ewe */ Yes*		____
H	Ukurhoxisa ubudoda phambi kokuchama imbewu yobudoda	0….Hayi */ No* 1….Ewe */ Yes*		____
I	Okunye (chaza) / *other method (explain)* _____	0….Hayi */ No* 1….Ewe */ Yes* 99…Adiginisekanga / *Not sure*		____
504	Uye watshintsha uhlobo locwangciso ntsapho kwezi nyanga zi 12 zidlulileyo?	0…. Hayi */ No* 1…. Ewe */ Yes*	0→ 506	____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
505	Ukuba ewe, kutheni / If Yes, why? *[Ungazifundeli ngaphandle iiopshini Rhangqa konke umthathi nxaxheba akuxelela kona]* [*DO NOT READ OPTIONS. CIRCLE ALL THAT THE PARTICIPANT IS TELLING YOU HERSELF]*	1….Ndifuna ukukhulelwa		____
		2….Andabelani ngesondo *Not sexually active*		____
		3….Ndohlukene neqabane *Broke up with partner*		____
		4….Ukopha kakhulu/ mangaphangan		____
		5….Ndandingayi exesheni rhoqo		____
		6….Ukuba nentlungu nengqaqambo xa ndiqwacha ni/n		____
		7….Luyandityebisa */ Gained weight*		____
		8….Luyandibhityisa */ Lost weight*		____
		9….Iqabane alifuni sisebenzise ucwangciso ntsapho lwangaphambili */ Partner did not*		____
		10…Andazi ukuba uhlobo locwangciso ntsapho luza kusichaphazela njani isifo sam seHIV / Did not know how the		____
		11… Ndixhalabile lulosuleleko */ Worried abour risk of infections*		____
		12….Ezinye, cacisa */ Other, specify:* _____		____
506	Ugqibele nini ukusebenzisa ucwangciso ntsapho ngaphambi kwanamhlanje? *When was the last time you used a contraceptive method before today?* UMYALEZO KUMSEBENZI: ikhondom lolunye uhlobo locwangciso ntsapho. Ukuba ibisisitofu (DMPA okanye NET-EN, yongeza inani eliqikelelweyo	|___|___| iinyanga */months ago* **00 = Ukuba ngeneno kwenyanga enye ukuza kuthi ga namhlanje, xa ubuza kubuyela istofu esilandelayo** ***00 = if less than 1 month ago*** ***Bhala "24" iinyanga ukuba***		____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
507	Loluphi uhlobo locwangciso- ntsapho obulusebenzisa ngaphambi kwanamhlanje? *What is the last contraceptive method you used before today?* ***Khetha ibenye. Ukuba usebenzise ikhondom nolunye uhlobo locwangciso, khetha olunye uhlobo]*** ***[STAFF NOTE: Select only one. If they used a condom plus another method, choose the non-condom method]***	1….Ipilisi / eziselwayo */ Pill or Oral Contraceptive* 2….Net-en inaliti yenyanga ezimbini *Net-en 2 monthly injectable* 3….Idepo inaliti yenyanga ezintathu *DepoProvera 3 monthly Injectable* 4….Isivalo-mlomo sesibeleko (loop) *IUD (Loop)* 5….Isiciko somlomo wesibeleko *Diaphragm* 6….Ikhondom yamadoda */ Male condom* 7….Ikhondom yabafazi */ Female condom* 8….Isivalo nzala samadoda *Male sterilization* _____ 9….Ukurhoxisa ubudoda phambi		____
508	Ngeloxesha, iqabane lakho belisazi ukuba usebenzisa olu hlobo? *At that time, did your*	0…..Hayi */ No* 1…..Ewe */ Yes* 99…Andazi */ I don't*		____
509	Ungaluncoma uhlobo lwakho lokugqibela locwangciso- ntsapho kwisihlobo okanye kwilungu losapho lwakho*? Would you recommend your last method of birth control to a friend or family member*?	1….Ewe, ngokuqinisekileyo *Yes, I would definitely recommend it* 2….Ewe, ndingazama *Yes, I would probably recommend it* 3….Andiqinisekanga */ I am unsure* 4….Hayi, andinako		____
510	Ukuba olu phandobelungaqhu beki ubuzakuba nomdla kangakanani wokuqhubekeka usebenzisa uhlobo lwakho lokugqibela lo wangciso-	1….Ukuba nomdla kakhulu kakhulu ndingaqhubeka */ Extremely willing* 2…Ukubanomdla kakhulu */ Very willing* 3….Ukubanomdla nje */ Somewhat willing* 4…Ukungabinamdla tu */ Not at all*		____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo** */ Write in*	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
511	Lilonke, ubuwoneliseke kangakanani luhlobo lwakho lokugqibela logcwanciso- ntsapho. ? *Overall, how satisfied were you with your last birth control method?*	1….Ndoneliseke ngokugqithileyo/ *Extremely satisfied* 2.…Ndoneliseke kakhulu *Very satisfied* 3.…Ndoneliseke nje *Somewhat satisfied* 4….Ndonelisekile andonelisekanga */ Neither satisfied nor dissatisfied* 5…Andonelisekanga nje /		____
Kolu luhlu lulandelayo lwemibuzo, ndizakubuza izimvo zakho ngokunxulumene noluhlobo lokugqibela locwagciso- ntsapho ubulisebenzisa phambi kwanamhlanje. *For the next series of questions, I will ask about your opinions regarding this last method of birth control you used before today*				
512	Uthintelo nzala luyalelwe ukusetyenziswa ngama-xesha athile acwangcisiweyo. Kukulungele kangakanani okanye akukulungelanga kangakanani ukusebenzisa uthintelo nzala ngendlela oyalelwe ngayo ngqo (umz: yonke imihla, ngeveki, ngenyanqa, qho kwinyanga ezintathu)? *Birth control is prescribed to be used on a specific schedule. How convenient or*	1….Kuluge ngokugqithileyo *Extremely convenient* 2….Kulunge kakhulu */ Very convenient* 3….Kungandilungela */Somewhat convenient* 4….Kulungile kungalunganga / *Neither convenient or inconvenient* 5….Kungangandilungeli *Somewhat inconvenient* 6….Kungangandilungeli kakhulu *Very inconvenient* 7…Kungandandilung		____
513	Kukangaphi ulibala ukuthatha okanye utye ucwangcisontsapho lwakho ngendlela oyalelwe ngayo ngqo? *How often did you forget to use or take your birth control exactly as directed?*	1….Andikhe ndiluphose (ndilusebenzisa ngendlela ngalo lonke xesha) */ None of the time (use perfectly all the time)* 2….Ixeshana nje */A little of the time* *3.*…Ngamanye amaxesha*/ Some of the time* *4.*…Ixesha elininzi */ Much of the time* *5.*… Ngamaxesha amaninzi*/ Most of the time* 6…Ngawo onke amaxesha		____
514	Ikuxhalabisa kangakanani into yokumitha nangona usebenzisa ucwagciso ntsapho? *How much did you worry about getting pregnant even though you*	1….Hayi konke konke*/ Not at all* 2….Kancinci*/ A little bit* 3….Kancinci nje */Somewhat* 4…Ngaphezulwana nje */Quite* 5…Kakhulu/		____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo** */ Write in*	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
515	Ubunexhala kangakanani lokuba ungakhulelwa kwixesha elizayo emva kokuyeka uthintelo nzala lwakho? *How worried were you that*	1….Hayi konke konke*/ Not at all worried* 2….Ndixhalabile kancinci */Somewhat worried* 3….Ndixhalabe kakhulu */Very worried*		____

Abafazi abaninzi abasebenzisa ucwangciso ntsapho banamava ngeempawu . Kule mibuzo ilandelayo, nceda usazise ukuba uphawu ngalunye lukukhathaze kangakanani na kwinyanga edlulileyo. Ukuba awukhange ufumane mava ngempawu, nceda uthi "kange ndibe nalo"

Many women who use birth control experience symptoms. For these next questions, please let us know how much each of these symptoms have bothered you during the past month. If you did not experience a symptom, please say "did not have"

516 Zikhu khathaze njani naziphina kwezimpawu kwinyanga ephelileyo. *How bothered were you by any of the following symptoms in the last month*: [***FUNDA NGANYE NGANYE]*** ***[READ EACH ONE AND CIRCLE THEIR***

		Khangendi - benayo *Did not have*	**Khange indikhathazeke konke konke** *Not at all bothered*	**Indikhathaze kancinci** *A little bothered*	**Ndikhathazeke nje** *Somewhat bothered*	**Indikhathaze kakhulu** *Very bothered*	**Indikhathaze ngokugqithile yo** *Extremely*	Code
A	Ukukrala kwamabele	0	1	2	3	4	5	____
B	Ukuziva ungatyhilekanga*Feelin*	0	1	2	3	4	5	____
C	Ukucaphuka *Feeling irritated*	0	1	2	3	4	5	____
D	Amaqhakuva/ amabala / *Acne /*	0	1	2	3	4	5	____
E	Isiluma/amazantsi esisu*/Cramping/ pelvic*	0	1	2	3	4	5	____
F	Amachaphaza/ ukopha phakathi kwamathuba okuba sexesheni	0	1	2	3	4	5	____
G	Intloko ebuhlungu *Headaches*	0	1	2	3	4	5	____
H	Umoya esuswini *Bloating*	0	1	2	3	4	5	____
I	Isicaphu-caphu *Nausea*	0	1	2	3	4	5	____
J	Ukutyeba / *Weight gain*	0	1	2	3	4	5	____
K	Ukuwelwa zinwele/ inwele eziyephuyephu *Hair loss/ thinning*	0	1	2	3	4	5	____
L	Ezinye iimpawu (cacisa) *Other symptoms*	0	1	2	3	4	5	____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo** */ Write in*	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
517	Abanye abafazi baya exesheni nyanga zonke, ngelixesha abanye bengayi roqo ngenxa yocwangciso ntsapho abalusebenzisayo. Woneliseke kangakanani okanye awonelisekanga kangakanani bubungakanani bokuya kwakho exesheni? *Some women experience a period every month, while others experience it less frequently due to their method of birth*	1….Ndoneliseke ngokugqitheleyo *Extremely pleased* 2….Ndoneliseke kakhulu *Very pleased* 3….Ndingoneliseka */ Somewhat pleased* 4….Ndonelisekile ndingoneliseki *Neither pleased nor displeased* 5….Ndinokungoneliseki nje *Somewhat displeased* 6….Andonelisekanga kakhulu *Very displeased*		____
518	Ungawalinganisela kangakanani amandla ocwangciso-ntsapho lwakho lokugqibela ekwenzeni oku kulandelayo. ***[FUNDA NGANYE NGANYE]***			
A	Icutha isiluma *Reduce menstrual pain*	1…Ngokugqithisileyo */ Excellent* 2…Kakuhle kakhulu */ Very good* 3…Kakuhle */ Good* 4…Phakathi */ Fair* 5…Kakubi */ Poor*		____
B	Icwengisa igazi xa ndisexesheni*Lighten the flow of your menstrual period*	1…Ngokugqithisileyo */ Excellent* 2…Kakuhle kakhulu */ Very good* 3…Kakuhle */ Good* 4…Phakathi */ Fair* 5…Kakubi */ Poor*		____
C	Icutha inani leentsuku endiya ngazo exesheni *Reduce the number of days of your period*	1…Ngokugqithisileyo */ Excellent* 2…Kakuhle kakhulu */ Very good* 3…Kakuhle */ Good* 4…Phakathi */ Fair* 5…Kakubi */ Poor*		____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

Date:_____/_____/ __ _____

523 Bonisa izinga lokuvumelana nezintetha zilandelayo ngokurhangqa impendulo *Indicate level of agreement with the following statements by circling their response*		Ndivuma ngamandla	Ndiyavuma nje *Somewhat Agree*	Ndivuma ndingavumi	Andivumi nje *Somewhat*	Andivumi ngamandla	Ayihaphaz eli*Not Applicable*	**Ikhowudi Yempendulo** *Code*
A	Ndiziva njengesiqhelo nangona ndisebenzisa ucwangciso ntsapho *I feel like my usual self even though I am using birth control*	1	2	3	4	5	-8	____
B	Akukho miphumela (umz: ukopha kancinci, isacaphu-caphu, ukungatyhileki,) ezayanyaniswa nocwangciso ntsapho	1	2	3	4	5	-8	____
C	Imiphumela yocwangciso ntsapho iphazamisa ubom bam bemihla ngemihla *The side effects of my birth control interfere with my everyday life*	1	2	3	4	5	-8	____
D	Imiphumela yocwangciso ntsapho iphazamisa ubom bam bokwabelana ngesondo	1	2	3	4	5	-8	____
E	Ubomi bami bokwabelena ngesondo buyazenzekela koluhlobo locwangciso ntsapho ndilusebenzisayo / *My sex life has*	1	2	3	4	5	-8	____
F	Ucwangciso ntsapho buphazamisa imisebenzi yam yemhla ngemihla. *My birth control interferes with my daily activities*	1	2	3	4	5	-8	____
G	Ndonwabile nocwangciso ntsapho lwam. *I am happy with my birth control*	1	2	3	4	5	-8	____
H	Inzuzo yocwangciso ntsapho lwam zidlula izinto ezingeyiyo inzuzo kucwangciso.	1	2	3	4	5	-8	____

Place **Enrolment PTID** label here

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Date:_____/_____/ __ _____

523 Bonisa izinga lokuvumelana nezintetha zilandelayo ngokurhangqa impendulo *Indicate level of agreement with the following statements by circling their response*		Ndivuma ngamandla	Ndiyavuma nje *Somewhat Agree*	Ndivuma ndingavumi	Andivumi nje *Somewhat*	Andivumi ngamandla	Ayihaphaz eli*Not Applicable*	**Ikhowudi Yempendulo** *Code*
I	Kube lula ukufakelela olucwangciso ntsapho kubom bam bemihla ngemihla / *I have easily incorporated my birth control into my usual*	1	2	3	4	5	-8	____
J	Ucwangciso ntsapho luphazamisa amandla endlela endisebenza ngayo okanye endizonwabisa ngayo. / *My birth*	1	2	3	4	5	-8	____
K	Ucwangciso ntsapho lwam lwaziwa kuphela ngabo ndakhetha ukubaxelela okanye ukubabonisa (ndiyakwazi ukuligcina luyimfihlo ucwangcisontsapho lwam)	1	2	3	4	5	-8	____
L	Ndiziva ndizithembile ukuba ndisebenzisa ucwangciso ntsapho olundilungeleyo	1	2	3	4	5	-8	____
M	Ndiyakholwa ukuba ucwangiso-ntsapho lwam luhlobo olululungeleyo iqabane/amaqabane am kanye nam. / *I*	1	2	3	4	5	-8	____
N	Ndonelisekile kukuba kufuneka ndiluthathe roqo kangakanani ucwangciso ntsapho lwam.	1	2	3	4	5	-8	____
O	Ndiziva ndikhuselekile kukwazi ukuba ucwangciso ntsapho lwam luyasebenza	1	2	3	4	5	-8	____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: ***7***_____- ____

	523 Bonisa izinga lokuvumelana nezintetha zilandelayo ngokurhangqa impendulo *Indicate level of agreement with the following statements by circling their response*	Ndivuma ngamandla 	Ndiyavuma nje *Somewhat Agree*	Ndivuma ndingavumi 	Andivumi nje *Somewhat*	Andivumi ngamandla 	Ayihaphaz eli*Not Applicable*	**Ikhowudi Yempendulo** **Code**
P	Ndiqinisekile uku ucwangciso-ntsapho endilustebenzisayo alubeki emngciphekweni isifo sam seHIV./ *I am confident that the method I am using poses no risk*	1	2	3	4	5	-8	____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- ____

ALCOHOL AND CIGARETTE USE (AUDIT SCALE – 600s)							
Ngoku sizakubuza imibuzo ngokusebenzisa kwakho utywala. Nceda urhangqe impenduloeyiyo ngombuzo ngamnye kule ingezantsi: *We are now going to ask you some questions about your use of alcohol. Please circle the relevant answer for each question bellow:*							
	Score	0	1	2	3	4	**Code**
601	Ubusela kangakanani utywala? *How often do you have a drink containing alcohol?*	Zange *never*	Kanye ngenyanga okanye nangaphantsi *Once per month or less*	Kabini ukuya kwisine enyangeni *2-4 times a month*	Kabini ukuya kwisithathu evekini *2-3 times per week*	Kane nangaphezulu evekini *4 times or more per week*	____ If 0→ 604
602	Zingaphi iglasi zesiselo esinxilisayo oziselayo ngemini? *How many standard drinks containing alcohol do you have on a typical day when drinking?*	1 okanye 2 *1 or 2*	3 okanye 4 *3 or 4*	5 okanye 6 *5 or 6*	7 ukuya 9 *7 to 9*	10 okanye ngaphezulu *10 or more*	____
603	Kukangaphi usela iglasi ezintandathu nangaphezulu ngexesha? *How many times do you have six standard drinks or more at time?*	Zange *Never*	Ngaphantsi kwenyanya *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*	____
	Umbuzo /Question			**Impendulo / *Answer***		**Gqitha** ***Skip***	**Ikhowudi Yempendul**
604	Ukhe watshaya isigareti kwezinyanga zilishumi elinambini zidlulileyo? *Have you smoked cigarettes in the previous 12 months?*			0…. Hayi */ No* 1…. Ewe */ Yes*		0→701	____
605	Utshaya izigareti ezingaphi ngosuku okanye ngeveki? *On average, how many cigarettes do you smoke each day or week?*			___cigarettes per day or ___cigarettes per week			Day:____ Wk: ____

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: ***7***_____- _____

	MENTAL HEALTH (KESSLER-10, 700s) **Le mibuzo ilandelayo ikubuza ukuba ubuziva njani <u>kule nyanga idlulileyo</u>. Ngombuzo ngamnye yakha isangqa phants kwempendulo echaza ngokupheleleyo ubungakanani bexesha uvakalelwa njalo** *The following questions ask about how you have been feeling in the past 30 days. For each question, circle the option that best describes the amount of time that you felt that way*						
		Akukhange kubekhi xesha *None of the*	**Kubekhona ixeshana** *A little of the time*	**Abekhona amanye amaxesha** *Some of the time*	**Kubekho amaxesha amaninzi** *Most of the time*	**Ibilixesha lonke** *All of the time*	**Code**
701	Kule nyanga iphelileyo, kukangaphi uziva udiniwe ngaphandle kwesizathu? / *During the last 30 days, about how often did you feel tired out for no good reason?*	0	1	2	3	4	____
702	Kule nyanga iphelileyo, kukangaphi uziva uphakuphaku? *During the last 30 days, about how often did you feel nervous?*	0	1	2	3	4	____
703	Uphakuphaku kangangokuba kungekho nto inokukuthomalalisa? / *During the last 30 days, about how often did you feel so nervous that nothing could calm you down?*	0	1	2	3	4	____
704	Kule nyanga iphelileyo, kukangaphi uziva uphelelwa ngamathemba? / *During the last 30 days, about how often did you feel hopeless?*	0	1	2	3	4	____
705	Ungazinzanga okanye ugungqa? *During the last 30 days, about how often did you feel restless or fidgety?*	0	1	2	3	4	____
706	Ungazinzanga de ugugqagungqe xa uhleli? / *During the last 30 days, about how often did you feel so restless you could not sit still?*	0	1	2	3	4	____
707	Kule nyanga iphelileyo, kukangaphi uziva ulusizana udakumbile? *During the last 30 days, about how often did you feel depressed?*	0	1	2	3	4	____
708	Kule nyanga iphelileyo, kukangaphi uva yonke into ibiyimigudu? / *During the last 30 days, about how often did you feel that everything was an effort?*	0	1	2	3	4	____

Place **Enrolment PTID** label here

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Date:_____/_____/ __ _____

	MENTAL HEALTH (KESSLER-10, 700s) **Le mibuzo ilandelayo ikubuza ukuba ubuziva njani <u>kule nyanga idlulileyo</u>. Ngombuzo ngamnye yakha isangqa phants kwempendulo echaza ngokupheleleyo ubungakanani bexesha uvakalelwa njalo**						
		Akukhange kubekhi xesha *None of the*	**Kubekhona ixeshana** *A little of the time*	**Abekhona amanye amaxesha** *Some of the time*	**Kubekho amaxesha amaninzi** *Most of the time*	**Ibilixesha lonke** *All of the time*	**Code**
709	Udakumbile kangangokuba kungekho nanye into engakonwabisayo? /*During the last 30 days, about how often did you feel so sad that nothing could cheer you up?*	0	1	2	3	4	___
710	Kule nyanga iphelileyo, kukangaphi uziva ungena xabiso? /*During the last 30 days, about how often did you feel worthless?*	0	1	2	3	4	___

Score:_____(to be calculated by study nurse or study coordinator)

Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

Violence Against Women (WHO, 800s)

Siza kubuza imibizo yokugqibela embalwa ngokunxulumene nobundlobongela beqabane.

We are at the last section of the survey. We are going to ask you a few last questions relating to partner violence.

#	Umbuzo / Question *[Funda: To be read verbatim]*	Impendulo */Answer*	Ikhowudi Yempendul
Uhlukumezo lwengqon			
801	Iqabane lakho likhe lakuthuka okanye lakwenza awaziva kamnandi? *Has your partner insulted you or made you feel bad about yourself?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
802	Likhe lakwenze wazina umncinci phambi kwabanye abantu okanye lakwenza intlekisa phambi kwabanye abantu?? *Has he belittled or humiliated you in front of other people?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
803	Likhe lenza izinto likoyikisa okanye lakungcungcuthekisa ngabom? / *Has he done things to scare or intimidate you on purpose?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
804	Like lakugrogrisa ngokonzakalisa okanye umntu okhathalayo ngaye? *Has he threatened to hurt you or someone you care about?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
Uhlukumezo lomzimba			
805	Likhe lakuqhwaba ngempama okanye lakugibisela ngento enokukwenzakalisa? *Has he slapped you or thrown something at you that could hurt you?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
806	Likhe lakutyhala okanye lakunyola? *Has he pushed or shoved you?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
807	Likhe lakubetha ngenqindi okanye ngento enokukonzakalisa? *Has he hit you with a fist or with something else that could hurt you?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
808	Likhe likukhabe, likurhuqe okanye likubethe? *Has he kicked you, dragged you or beaten you up?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
809	Likhe likukrwitshe okanye likutshise ngabom? *Has he choked or burnt you on purpose?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
810	Likhe likugrogrise ngokusebenzisa okanye lisevenzise umpu, imesi okanye nasiphina isixhobo kuwe? *Has he threatened to use or actually used a gun, knife or other weapon against you?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
Sexual Violence			
811	Likhe likunyanzele lise ngokwebalana ngesondo wena ungafuni? *Has he physically forced you to have sexual intercourse when you didn't want to?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
812	Wakhe wabelane naye ngesondo ungafuni kuba usoyika into anokuyenza? *Did you ever have sexual intercourse when you didn't want because you were afraid of what he might do?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____

Date:_____/_____/ __ _____
Date:_____/_____/ __ _____

Place **Enrolment PTID** label here

*e.g. PTID: 8*_____-_____

ART User Baseline Questionnaire: 2IUDnCT

Violence Against Women (WHO, 800s)

#	Umbuzo / Question	Impendulo / Answer	Gqitha	Ikhowudi Yempendulo *Code*
813	Likhe likunyanzelise ngokwabelana ngesondo ngendlela ovifumanisa ithoba isidima (eveanyelisayo) okanye ekwenza intlekisa? *[To be read verbatim]* *Has he forced you to do something sexual that you found degrading or humiliating?*	(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo / *Write in*	0…. Hayi / *No* 1…. Ewe / *Yes* *Skip* -8…n/a	

Siyabulela ngokuthatha inxaxheba nokugqiba inkqubo yohluzo. Namhlanje ndiza kubuza imibuzo ngemibali yempilo, indlela ophila ngayo, kunye neembono zakho ngocwangciso ntsapho.

Enkosi ngexesha lakho ekuphenduleni le mibuzo. Inxaxheba yakho ibalulekile kuthi.

Thank you for taking the time to answer these questions! Your responses are very important to us.

Siza kuthetha sobabini mhlawumbi ixesha elingaphezulwana kwemizuzu engama 60. Ukuba akuwuqondi umbuzo ndicela undazise, sikwazi ukuxoxa ngawo.

Thank you for participating and completing the screening process. Today, I am going to ask you some questions about your health history, current activities, pregnancies, and about family planning. We will probably talk together for a little over an hour. If you don't

To be completed by study nurse or study coordinator:

Tick all to show completed:

- ☐ **ALCOHOL USE: Check questions 602 and 603, if question 602 has been coded as 2, 3 or 4, or 603 has been coded as 3 or 4, refer for alcohol counselling.**
- ☐ **MENTAL HEALTH: Tally the score for 701-710 and record below. Refer for counselling if score is greater than or equal to 25**

  Mental Health Score: _____
- ☐ **VIOLENCE: Check questions 803-813. If participant answered YES to ANY question, provide referral for partner violence services.**

Signature of study nurse or study coordinator: _____

Signature date: _____

Demographic Information (200s)

201	*Umhla wakho wokuzalwa?* *What is your date of birth?*	DOB: |_|_| / |_|_|_| / |_|_|_|_| *(dd/mmm/yyyy)* Mingaphi iminyaka yakho? *What is your age?* |_|_| Iminyaka / *years*		
202	Lulophi ulwimi olu phambili olisebenzisayo ekhaya? *What is the primary language you use at home?*	1…..IsiXhosa / *Xhosa* 2…..IsiZulu / *Zulu* 3…..IsiBhulu / *Afrikaans* 4…..Isingesi / *English*		_____
203	Sithini isimo sakho sobudlelwane neqabane? *What is your current partnership status?*	1….Andinamntu / *Single/ no steady partner/boyfriend* 2….Sitshatile sihlala kunye / *Married and live together* 3….Sitshatile asihlali kunye *Married, live apart* 4….Sihlala kunye asitshatamga *Live together, not married* 6 …Ndineqabane lwisisigxina, asihlali kunye/ *Steady*		_____
204	Uya sebenza ngoku? *Are you currently employed?*	0…. Hayi / *No* 1…. Ewe, manqaphanqapha / *Yes, part-time* 2…. Ewe, isigxina / *Yes, full time*		_____
205	Hlobo luni lwendlu ohlala kuyo? *What type of house do you live in?*	1…..Imbacu / ityotyombe *Informal dwelling / hokkie* 2…. ndihlala endlini / *Live in a home* 3….Ifleti / indlu kamasipala *Flat / municipal housing* 4…. Enye (chaza) / *Other (specify):* _____		_____

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____- _____

Date:_____/_____/ __ _____

#	Umbuzo /Question *[To be read verbatim]*	Impendulo / *Answer* (Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo / *Write in*	Gqitha *Skip*	Ikhowudi Yempendulo *Code*
206	Bangaphi abatwana nabantu abadla abablala endlini yakho? *How many adults and children live in your house?*	|_|_| abadala (kuquka nawe) *adults (including yourself))* |_|_| abantwana / *children*		_____ _____
207	Liliphi elona banga eliphezulu oligqibileyo eskolweni? *What is the highest level of school you have completed?*	Grade (1-12): |___|		_____
		or Standard (1-10): |___|		_____
		or Imfundo ephakamileyo (cacisa) *Post secondary (explain)* _____		
208	Ingaba ungumfundi ngoku? *Are you currently a student?*	0…. Hayi / *No* 1…. Ewe, manqaphanqapha / *Yes, part-time*		_____
209	Unawo amanzi ahamba ngopipe endlini yakho?	0…. Hayi / *No* 1…. Ewe / *Yes*		_____
210	Unayo indlu yangasese egungxulwayo?	0…. Hayi / *No* 1…. Ewe / *Yes*		_____
211	Unawo na umbane endlini yakho? *Do you have electricity in your house?*	0…. Hayi / *No* 1…. Ewe, owam okanye igenerator / *Yes, my own or a generator* 2…. Ewe owam osuka kummelwane /		_____
212	Unaye umabona-kude osebenzayo endlini yakho?	0…. Hayi / *No* 1…. Ewe / *Yes*		_____
213	Unayo ifowuni ohamba uyiphethe esebenzayo?	0…. Hayi / *No* 1…. Ewe / *Yes*		_____
Menstrual, pregnancy and fertility history (300s) ***Uqhuba kakuhle.Siza kubuza ngoku ngamava akho ngokuya exesheni.***				
301	Wawuneminyaka emingaphi ukuqala kwakho ukuya exesheni? *How old were you when you started your menses?*	|_|_| iminyaka /years		_____
302	Kwinyanga ezintathu			

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____ - _____

Date: _____/_____/ __ _____

#	**Umbuzo /Question** ***[To be read verbatim]***	**Impendulo** ***/ Answer*** **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo** ***/ Write in***	**Gqitha** ***Skip***	**Ikhowudi Yempendulo** ***Code***
	ezidlulileyo, zingaphi intsuku phakathi kosuku lokuqala lokuya exesheni nosuku lokuqala phambi kokuya exesheni kwinyanga elandeleyo? *In the last three months, about how many days were there between the first day of your menstrual cycle and the first day of your next*	|_|_| iintsuku /days 999…. Andiyi exesheni /ukuya exesheni manqaphanqapha kuhlobo locwangciso ntsapho endilidebenzisayo (BCM) / *Amenorrheic / not menstruating /* *irregular menses on current BCM* ***[Show participant calendar to***	999→306	_____
303	Kwezinyanga zi-3 zidlulileyo uqhele ukopha intsuku ezingaphi xa usiya exesheni? *In the last 3 months, for how many*	|_|_| iintsuku /days		_____
304	Ungayichaza njani imini owopha kakhulu ngayo (khetha eyona mpendulo)? *How would you describe a "heavy bleeding" day?* ***[Do not read responses, circle those that are mentioned by the respondent]***	1… Ngamaxa enditshintsha ngawo iiphedi *By the number of times I change my*		_____
		2….Xa ndibona amahlwili *By whether I see blood clots*		_____
		3….Xa ndinentlungu okanye ezinye ingqaqambo *By whether I have cramping or other pain*		_____
		4….Xa ndiphumela kwiphedi nokuba ndiyitshintshe amaxa amaninzi		_____
		5… Ezinye cacisa / *Other (specify):* _____		_____
305	Ngosuku owophe ngalo, uyitshintsha kangaphi ipadi? *On one of these heavy days, about*	|_|_| inani lamaxesha / *times*		_____

Place **Enrolment PTID** label here

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#	Umbuzo /Question *[To be read verbatim]*	Impendulo */ Answer* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo */ Write in**	Gqitha *Skip*	Ikhowudi Yempendulo *Code*
306	Ungakuchaza njani ukuya kwakho exesheni kwezinyanga zi-3 zidlulileyo? *In the last 3 months, how would you describe your bleeding pattern overall?* ***[Read each of these options and have them select <u>one</u> best answer]***	1…. Ukuya exesheni ngokwesiqhelo iintsuku ezi 3 ukuya kwezi 7 kungekho kopha phakathi kwalamaxesha *Regular menstruation of 3-7 days with no bleeding in between these times* 2…. Manqapha nqapha (nganeno kwamatyeli amabini kweli xesha)*Infrequent (less than 2 bleeding events in this time)* 3…. Ukopha qho, amatyeli angaphezulu kwesiqhelo okuya exesheni (ngaphezu kwamatyeli amane >=ngaphezu kwentsuku ezimbini kwinyanga ezintathu ezidlulileyo) / *Frequent bleeding events tha are more frequent than menstruation (more than 4 events (>=2 days) in last 3 months)* 4…. Ukopha ngokutsalileyo (mhlawumbi ityeli elinye litsale iintsuku ezilishumi nangaphezulu); kungenzeka ngokongezelelekileyo kunokuya exesheni ngokwesiqhelo / *Prolonged bleeding (at least one event lasting >=10 days); may occur in addition to regular menstruation*	6→308	_____
307	Kwinyanga ezintathu ezidlulileyo, ingaba oku kulandelayo kuye kwenzeka na kuwe? **(funda nganye)**			
A1	Amantsi esisu anxulumene nokutya, ukuchama nokuyangasese. Lower abdominal pain related to eating/urination/having	0…. Hayi / *No* 1…. Ewe / *Yes*		
B	Ukopha kakhulu / amahlwili xa usexesheni *Heavy bleeding or clots during menses*	0…. Hayi / *No* 1…. Ewe / *Yes*		_____

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____ - _____

Date: _____/_____/ __ _____

#	**Umbuzo /Question** ***[To be read verbatim]***	**Impendulo** ***/ Answer*** **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo** ***/ Write in***	**Gqitha** ***Skip***	**Ikhowudi Yempendulo** ***Code***
C	Ukopha manqaphanqapha (ukungayi exesheni nyanga zonke) *Irregular bleeding (not having menses every month; menses less than 1/month*))	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
C1	Ukopha okungaqhelekanga (ukuya exesheni nangaphezulu enyangeni enye) *Irregular bleeding (having menses*	0…. Hayi */ No* 1…. Ewe */ Yes*		
D	Ukopha phakathi kwentsuku zakho zokuya exesheni okanye amachaphaza egazi (ukopha kwenzeke ngaphezu kwentshuku ezimbini phambi kokuya exesheni nasemva kokuya exesheni kwaye kungeyonxalenye yokuya kwakho exesheni. *Bleeding in between your menstrual*	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
E	Ezinye chaza Other, explain _____	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
308	Uyathanda ukuya exesheni? *Do you like having periods?*	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
309	Ukuba ungakhetha, ungathanda ukuya kangaphi exesheni? *If you could choose, how often would you like to have a period?*	0…Andifuni */ Never* 1….Ngenyanga*/ Monthly* 2… Emva kwenyanga ezintatu *At least every 3 months* _____ 3….Ezinye chaza */ Other (specify):*		_____
310	Wawukhe wasebenzisa ucwangciso ntsapho olwamisa ukuya kwakho exesheni?	0…. Hayi */ No* 1…. Ewe */ Yes*		_____

Place **Enrolment PTID** label here

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Ngoku ndizakubuza imibuzo malunga nolwazi lwakho ngokhulelo? ***Now I am going to ask you some questions about your experiences with pregnancies.***				
311	Wakhe wakhululelwa? *Have you ever been pregnant?*	0…. Hayi / No 1… Ewe	0→ skip to 316	_____

Previous Pregnancy History

312 **(Ukuba Ewe)Kumitho ngalunye uqale ngolokugqibela, nceda cacisa oku kulandelayo**: ***[If Yes] for each pregnancy starting with the most recent please specify the following:***

	A. **Unyaka [isiphumo]** *Year [of outcome]*	B. **Isiphumo?** *Outcome?* 1= Ukuzala usana oluphilayo */live birth* 2= Ukukhutswa kwesisu ngenjongo /*induced abortion* 3= Ukuphuma kwesisu/ozelwe engaphili */miscarriage- still birth*	C. **Isini?** *Sex?* 1 = inkwenkwe *male* 2= Intombi *femal e*	D. **Isimo sentsholongwane sosana ngexesha ezalwa?** *HIV status of child at birth?* 0 = alikho ichaphaza /*negative* 1 = likhona ichaphaza */ positive* 99 = Andazi, aluka vavanywa usana *unknown: child untested*	E. **Luyaphila ngoku**? *Currently alive?* 0= Hayi */no* 1= Ewe */yes* ***Ukuba 1, gqithela kumitho olulandelayo. Ukuba alukho olunye, yiya ku 313***	F. **Ubudala ngelixa esweleka?** *Age at death?* _____ ***Cacisa iinyanga okanye iminyaka*** ***[indicate in months or years]*** ***Gqithela kumitho olulandelayo. Ukuba alukho lolunye, yiya ku 313*** ***[Go to next pregnancy. If no other pregnancy go to 313]***
1						
2						
3						
4						
5						
6						

Place **Enrolment PTID** label here

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
313	Kukhulelo lwakho lwangaphambili, wawukhe wadibana nezinye zezingxaki zilandelayo? [Funda ngezantsi uphedulo] *During your previous pregnancy or pregnancies did you ever experience any of the following? [Read list to participant]*			
A	Ukopha kakhulu de uthiwe igazi	0…. Hayi */ No*		_____
B	Uqhaqho lokubeleka *Need for Cesarean section*	0…. Hayi */ No*		_____
C	Ukunyukelwa yi Highblood/ elumithweni /	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
D	Ukuxhuzula kwilixa lokusondela ukubeleka / *Seizures around time of birth /*	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
E	Ulwasuleleko ngelixesha ubelekayo okanye emva	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
F	Ukrazuko ebufazini okwenze ukuchama,ukuzithuma,okanye ukwabelana ngesondo	0…. Hayi */ No* 1…. Ewe */ Yes*		_____
314	Ukuya kwakho exesheni kuye kwatshintsha enyakeni emva nje kokukhulelwa? *Did your menses change within the year*	0…. Hayi */ No* 1…. Ewe */ Yes* 99… Andazi */ I don't know*	0→ 316 99→ 316	_____
315	Ukuba ngu Ewe, njani? If yes, in what way?	1….Ukuya exesheni kunqabile *Menses became less regular* 2….Ukuya exesheni kubenje ngesiqhelo */ Menses became more regular* 3….Ukuya exesheni akujiyanga / akuthathanga xesha elide */ Menses became lighter or didn't last as long* 4….Ukuya exesheni kakhulu / kwathatha ixesha elide /		_____
316	Wakhe wacetyiswa ukuba ungabinabantwana ngenxa yezizathu zempilo yakho? *Have you ever been advised for*	0…. Hayi */ No* 1…. Ewe */ Yes* 99… Andazi */ I don't know*		_____

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____- _____

Date:_____/_____/ __ _____

#	**Umbuzo** */ Question* ***[Funda ngohlobo ebhalwe ngalo*** */To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
Olu luhlu lulandelayo lwemibuzo lungeengcinga zakho ngoku nokuba uziva njani ngokuba nabantwana kwixesha elizayo. Ukuba umbuzo ukwenza ungakhululeki, nceda ndixelele sixoxe ngawo. Unako ukusala ukuphendula loo mbuzo. *The next set of questions is about your CURRENT thoughts and feelings*				
317	Ungathanda ukuba nomntwana/abantwana, okanye ukheta ukungabi nabantwana konke konke? *Would you like to have (a/another) child, or would you prefer not to have*	0….Andifuni konke konke *No more / none* 1….Ndiyamfuna omnye umntwana *Have a/nother child* 99…Andazi / andiqinisekanga *Undecided/don't know*	0→ 320 99→ 320	_____
318	Ungathanda ukulinda ixesha elingakanani ukususela ngoku phambi kokuba ubenomnye umntwana/ubenabanye abantwana? *How long would you like to wait from now before the birth of a/nother child?*	|___|___| iminyaka */ years* *or* |___|___| iinyanga*/ months*	**Ukuba ngaphantsi kweminyak a emi 2, yazisa umphathi wovavany**	Yrs: _____ Mos: _____
319	Bangaphi abantwana (abongezelelekileyo) onqwenela ukuba nabo kwixesha elizayo?	|___|___| Bantwana */ children*		_____
320	Likhe waxoxa ngomnqweno wakho wokufuna ukuba nabanye abantwana okanye umnqweno wakho wokungafuni ukuba nabantwana neqabane lakho lokugqibela obunalo/onalo? *Have you discussed your desire to*	0…. Hayi / *No* 1…. Ewe /*Yes*		_____
321	Ingaba ukuba nesifo seHIV sakutshintsla kwizigqibo zakho zokuba nomntwana/okanye ukungabi namntwana? *Did*	0…. Hayi / *No* 1…. Ewe /*Yes*		____

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____- _____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
322	Ingaba IHIV ithe yabangela ukuba utshintshe izigqibo zokuba uzakumfumana nini na umntwana/omnye umntwana? *Did HIV diagnosis change your decision about WHEN to have (a)nother child?*	0…. Hayi / *No* 1…. Ewe indenze ndafuna ukuba naye ngokukhawuleza. /*Yes, made me want to have one sooner* 2…. Ewe indenze ndafuna ukulinda ixesha elide *Yes, made me want to wait longer* -8…Andifuni abanye abantwana		____
323	Ingaba ukuqala amachiza okuthomalalisa iHIV kusitshintshile na isigqibo sakho ngokuba nomntana okanye omnye umntwana *?*	0…. Hayi / *No* 1…. Ewe /*Yes*		____
324	Ingaba ukuqalisa amachiza okuthomalalisa iHIV kusitshintshile isigqibo sakho sokuba umfuna nini na umntwana okanye omnye umntwana. *Did starting ART change your decision about WHEN to have*	0…. Hayi / *No* 1…. Ewe indenze ndafuna ukuba naye ngokukhawuleza. /*Yes, made me want to have one sooner* 2…. Ewe indenze ndafuna ukulinda ixesha elide *Yes, made me want to wait longer* -8…Andifuni abanye abantwana		____

Sexual Health and HIV (400s)

Olu luhlu lulandelayo lwemibuzo luzakubuza ngempilo yakho yesondo namava esondo, ngamava akho ngezesondo kwanesimo sakho seHIV. Ukuba ufuna ixesha elongezelelweyo ukuphendula lemibuzo okanye uziva ungakhulelekanga, nceda undixelele. *The next section of questions will ask about your sexual*

401	Wawuneminyaka emingaphi ukuqala kwakho ukwabelana ngesondo? *How*	|___|___| iminyaka */ years*		____
402	Mangaphi amaqabane akho esondo owakhe wanawo ebomini? *How many sexual partners have you had in your lifetime?*	|___|___| inani labantu *persons* ***[If they cannot give an exact number, ask them to estimate]***		____
403	Mangaphi amaqabane akho esondo okhe wanawo kulo nyaka uphelileyo? *How many sexual partners have you had in the last year?*	|___|___| inani labantu *Persons* ***[If none enter 00]***	00→ 410	____

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____ - _____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
404	Unalo iqabane elisisigxina lokwabelana	0…. Hayi / *No* 1…. Ewe / *Yes*	0→ 406	____
405	Kukangaphi wena neqabane lakho elisisigxina nisebenzisa ikhondom kwezi nyanga zi 3 zigqithileyo? *How often did you use condoms with your steady partner in the last 3 months?*	1….Rhoqo */ always* 2….Phantse onke amaxesha*(>75%)* *almost all the time (>75%)* 3….Maxesha onke (50% - 75%) *most of the time* (50% - 75%) 4….Ngamanye amaxesha (25%		____
406	Ingaba unawo amanye amaqabane obelana ngawo ngesondo? *Do you currently have any (other) sexual partners?*	0…. Hayi */ No* 1…. Ewe */Yes*	0→ 408	____
407	Ukuba ewe, kukangaphi usebenzisa ikhondom neliqabane kwezinyanga zintathu zidlulileyo? *If yes, how often did you use condoms with this partner/these partners in the last 3 months?*	1….Rhoqo */ always* 2….Phantse onke amaxesha*(>75%)* *almost all the time (>75%)* 3….Maxesha onke(50% - 75%) *most of the time* (50% - 75%) 4…. Ngamanye amaxesha(25%		____
408	Xa usebenzisa iikhondom, zeziphi ezona zizathu zibalulekileyo zokuba usebenzise ikhondom? *When you use condoms, what are the most important reasons you use condoms?* ***Sukufunda okubhaliweyo, qwalasela okuphuma kumthathi nxaxeba*** ***[Do not read responses, note all the responses that are stated by the participants]***	0…Andisebenzisi ikhondom*/ I don't use condoms*		____
		1 …Ukuthintela ukumitha/andifuni mntwana *Protecting against pregnancy/ don't*		____
		2….Isimo sentsholongwane seqabane asaziwa */ Partner's HIV status unknown*		____
		3….Iqabane alinachaphaza lentsholongwane */ Partner HIV negative*		____
		4….Iqabane liphila nentsholongwane; ukukhusela ulwasuleleko olubhindeneyo /		____
		5….Ukhuselo kwizifo ezifumaneka ngokwabelana ngesondo/intsholongwane		____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
		6….Iqabane liyagxininisa ukusebenzisa ikhondom / *Partner insists to use them*		____
		7….Ixhala lokuba ucwangcisontsapho aluthembekanga ngokupheleleyo/alusebenzi ngokupheleleyo / *Concerned birth control method is unreliable/ not*		____
		8….Andifuni iqabane lazi ukuba ndisebenzisa olunye uhlobo locwangcisontsapho / *Don't*		____
		9….Okunye(bhala) / *Other (write in)*: _____		____
409	Xa uqikelela wabelana kangaphi ngesondo kwezinyanga zintathu zidlulileyo? *In the last 3 months, about how often did you have sexual intercourse?*	0….Khange, ndabelane ngesondo kwezi nyanga zi 3 zigqithileyo *Not sexually active in the last 3 months* 1….Ngaphantsi kwenyanga *<1 per month* 2….Kanye – kathathu ngenyanga *1-3 times per month* 3….Kanye ngeveki / *1 per week* 4….Kabini ukuya kathathu evekini		____
409a	Zingaphi iintsuku ogqibele ngazo ukwabelana ngesondo? *How many days ago did you last have sexual intercourse?*	_____days (Enter 99 if participant does not remember)		
409b	Ingaba iqabane lakho lisebenzise ikhondom yotata okanye wena usebenzise eyotata okugqibela kwakho ukwabelana ngesondo? *Did your partner use a male condom or*	0….Hayi */ No* 1….Ewe */Yes* 99…Andikhumbuli/andazi *.I don't know/ recall*		
	Ngoku, ndingakubuza imibuzo malunga netsholongwane kagawulayo nokhathalelo. *Now I would like to ask you some questions about your HIV diagnosis and care*			

Place **Enrolment PTID** label here

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
412	Uzaze nini ukuba uphila neHIV? *When were you diagnosed with HIV?*	|___|___|___|month |___|___|___|___|year ***[If participant unsure, please show them calendar and ask them to estimate. If they really***		Mo_____ Yr _____
413	Uqale ukuzazi ukuba uneHIV ngexesha ubukhulelwe?	0….Hayi */ No* 1….Ewe */Yes*		____
414	Uye watshintsha indlela yocwangisontsapho ngenxa yokuphila nentsholongwane? *Did you change your birth control method due to your HIV diagnosis?*	0….Hayi */ No* 1….Ewe */Yes*	0→ 416	____
415	Ukuba Ewe, ngoba? *If yes, why?*	_____ _____		____
416	Ukuya kwakho exesheni kuye kwatshintsha wakuzazi ukuba uphila neHIV?	0…. Hayi */ No* 1…. Ewe */ Yes*	0→ 418	____
417	Ukuba ngu ewe, njani? *[If yes], how?*	1….Ukuya exesheni kunqabile *Menses became less regular* 2….Ukuya exesheni kubenje ngesiqhelo */ Menses became more regular* 3….Ukuya exesheni akujiyanga/ akuthathanga xesha elide */ Menses became lighter or didn't last as long* 4….Ukuya exesheni kakhulu / kwathatha ixesha elide */ Menses became heavier/ lasted*		____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
418	Kwinyanga ezi 6 ezidlulileyo, kukangaphi ubonana nomnikezi wezempilo kule kliniki ngokhathalelo lwakho lweHIV? In the last 6 months, how many	|___|___| kangaphi/*times*		____
419	Usichazile isimo sakho sentsholongwane kwaba...? *Have you disclosed your HIV status to…?*			
A	Abantwana */ your children*	0…. Hayi / No 1…. Ewe /Yes		____
B	Mama */ mother*	0…. Hayi / No 1…. Ewe /Yes		____
C	Tata */ father*	0…. Hayi / No 1…. Ewe /Yes		____
D	Utatomkhulu/makhulu */grandparents*	0…. Hayi / No 1…. Ewe /Yes		____
E	Umnakwenu/dadewenu */ Brothers or sisters*	0…. Hayi */ No* 1…. Ewe */ Yes*		____
F	Iqabane llokugqibela okanye langokul lokwabelana ngesondo *Current/most recent sexual partner*	0…. Hayi */ No* 1…. Ewe */ Yes* 8…. Not applicable		____
420	Uyasazi isimo sentsholongwane kagawulayo seqabane lakho langoku okanye lokugqibela ubunalo?	0…. Hayi / No 1…. Ewe /Yes		____
421	Ingaba iqabana lakho langoku liyazi ukuba uthatha amachiza okuthomalalisa iHIV? *Does your current/most recent sexual partner know you are*	0…. Hayi / No 1…. Ewe /Yes		
422	Uqale nini ukuthatha amachiza okuthomalisa itsholongwane kagawulayo? *When did you start taking ART medicines?*	|___|___|___|month |___|___|___|___|year ***[If participant unsure, please show them calendar and ask them to estimate. If they really do not know the month, enter***		

Place **Enrolment PTID** label here

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
423	Kwakutheni ukuze uqale ukuthatha amachiza okuthomalisa itsholongwane kagawulayo? *Why did you start taking ART?* (If participant has had history of stopping then resuming ART, please list the most recent reason for starting ART)	1...Low CD4 count	0…. Hayi / *No* 1…. Ewe /*Yes*	____
		2... Pregnancy	0…. Hayi / *No* 1…. Ewe /*Yes*	____
		3... Tuberculosis	0…. Hayi / *No* 1…. Ewe /*Yes*	____
		4... Other infection due to HIV	0…. Hayi / *No* 1…. Ewe /*Yes*	____
		5... Cervical cancer	0…. Hayi / *No* 1…. Ewe /*Yes*	____
		6... Other (specify): _____	0…. Hayi / *No* 1…. Ewe /*Yes*	____
424	Ingaba ulitshintshile uhlobo lwakho locwangciso emva kokuba uqale amachiza okuthomalalisa iHIV (ART)?	0….Hayi */ No* 1….Ewe */Yes*	0→ 426	____
425	Ukuba ngu-ewe,ngoba? *If yes, why?*	_____ _____		
426	Ingaba ukuya kwakho exesheni kutshintshile uhlobo emva kokuba uqale amachiza okuthomalalisa iHIV? *Did your menses change after you started ART medicines?*	0…. Hayi */ No* 1…. Ewe */ Yes* -8. .. akungqamenanga ngenxa yokuya exesheni ngohlobo locwangciso endilusebenzisayo	0→ 428	____
427	Ukuba ngu-ewe, njani? [*If yes], how?*	1….Ukuya exesheni kunqabile *Menses became less regular* 2….Ukuya exesheni kubenje ngesiqhelo */ Menses became more regular* 3….Ukuya exesheni akujiyanga/ akuthathanga xesha elide */ Menses became lighter or didn't last as long* 4….Ukuya exesheni kakhulu / kwathatha ixesha elide */ Menses became heavier/ lasted*		____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
428	Ukusebenzisa ikhondom nalo naliphi iqabane kutshintshile ukusukela oko waqala amachiza okuthomalalisa iHIV? *Has using condoms with any sexual partner changed since you started*	0...No 1...Ewe, sisebenzisa ngakumbi ngoku *Yes, we use them more often* 2...Ewe, sisebenzisa nganeno kwesiqhelo *Yes, we use them less often* 3... Ewe, siyekile		
	Contraceptive History (500s) **Ngoku ndizakubuza imibuzo eyongeziweyo malunga namava akho ngocwanciso-ntsapho.**			
501	Ngaphambi kokungenela oluphando, wakhe weva nge IUD okanye iloop? *Prior to joining this study, had you ever heard of the IUD or loop?*	0…. Hayi */ No* 1…. Ewe */ Yes*		____
502	Wakhe weva ngolunye uhlobo locwangciso-ntsapho olufakelwayo olubizwa ngokuba yi-implant?	0…. Hayi */ No* 1…. Ewe */ Yes*		____
503	**Wena okanye iqabane lakho nakhe nazisebenzisa na i…./** Have you or your partner ever **used**….. . **[fund ingohlobo ngamva]**			
A	Ipilisi / eziselwayo *Pill or Oral Contraceptive*	0….Hayi */ No* 1….Ewe */ Yes*		____
B	Net-en / naliti (istofu senyanga ezi 2) *Net-en/2 monthly injectable*	0….Hayi */ No* 1….Ewe */ Yes*		____
C	Idepo naliti (istofu senyanga ezi 3) *DepoProvera/3 monthly Injectable*	0….Hayi */ No* 1….Ewe */ Yes*		____
D	Isivalo-mlomo sesibeleko (loop) *IUD (Loop)*	0….Hayi */ No* 1….Ewe */ Yes*		____
E	Ikhondom yamadoda *Male condom*	0….Hayi */ No* 1….Ewe */ Yes*		____
F	Ikhondom yabafazi *Female condom*	0….Hayi */ No* 1….Ewe */ Yes*		____
G	Isivalo nzala samadoda *Male sterilization*	0….Hayi */ No* 1….Ewe */ Yes*		____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
H	Ukurhoxisa ubudoda phambi kokuchama imbewu yobudoda	0….Hayi */ No* 1….Ewe */ Yes*		____
I	Okunye (chaza) / *other method (explain)* _____	0….Hayi */ No* 1….Ewe */ Yes* 99...Adiqinisekanga / *Not sure*		____
504	Uye watshintsha uhlobo locwangciso ntsapho kwezi nyanga zi 12 zidlulileyo?	0…. Hayi */ No* 1…. Ewe */ Yes*	0→ 506	____
505	Ukuba ewe, kutheni / If Yes, why? ***[Ungazifundeli ngaphandle iiopshini Rhangqa konke umthathi nxaxheba akuxelela kona]*** **[*DO NOT READ OPTIONS. CIRCLE ALL THAT THE PARTICIPANT IS TELLING YOU HERSELF]***	1….Ndifuna ukukhulelwa		____
		2….Andabelani ngesondo *Not sexually active*		____
		3….Ndohlukene neqabane *Broke up with partner*		____
		4….Ukopha kakhulu/ mangaphangap		____
		5….Ndandingayi exesheni rhoqo		____
		6….Ukuba nentlungu nengqaqambo xa ndiseyexeni /		____
		7….Luyandityebisa */ Gained weight*		____
		8….Luyandibhityisa */ Lost weight*		____
		9….Iqabane alifuni sisebenzise ucwangciso ntsapho lwangaphambili */ Partner did not*		____
		10...Andazi ukuba uhlobo locwangciso ntsapho luza kusichaphazela njani isifo sam seHIV / Did not know how the		____
		11… Ndixhalabile lulosuleleko */ Worried abour risk of infections*		____
		12….Ezinye, cacisa */ Other, specify:* _____		____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
506	Ugqibele nini ukusebenzisa ucwangciso ntsapho ngaphambi kwanamhlanje? *When was the last time you used a contraceptive method before today?* UMYALEZO KUMSEBENZI: ikhondom lolunye uhlobo locwangciso ntsapho. Ukuba ibisisitofu (DMPA okanye NET-	|___|___| iinyanga */months ago* **00 = Ukuba ngeneno kwenyanga enye ukuza kuthi ga namhlanje, xa ubuza kubuyela istofu esilandelayo** ***00 = if less than 1 month ago***		____
507	Loluphi uhlobo locwangciso- ntsapho obulusebenzisa ngaphambi kwanamhlanje? *What is the last contraceptive method you used before today?* ***Khetha ibenye. Ukuba usebenzise ikhondom nolunye uhlobo locwangciso, khetha olunye uhlobo]*** ***[STAFF NOTE: Select only one. If they used a condom plus another method, choose the non-condom method]***	1….Ipilisi / eziselwayo */ Pill or Oral Contraceptive* 2….Net-en inaliti yenyanga ezimbini *Net-en 2 monthly injectable* 3….Idepo inaliti yenyanga ezintathu *DepoProvera 3 monthly Injectable* 4….Isivalo-mlomo sesibeleko (loop) *IUD (Loop)* 5….Isiciko somlomo wesibeleko *Diaphragm* 6….Ikhondom yamadoda */ Male condom* 7….Ikhondom yabafazi */ Female condom* 8….Isivalo nzala samadoda *Male sterilization* _____ 9….Ukurhoxisa ubudoda phambi		____
508	Ngeloxesha, iqabane lakho belisazi ukuba usebenzisa olu hlobo? *At that time, did your*	0…..Hayi */ No* 1…..Ewe */ Yes* 99…Andazi */ I don't*		____
509	Ungaluncoma uhlobo lwakho lokugqibela locwangciso- ntsapho kwisihlobo okanye kwilungu losapho lwakho? *Would you recommend your last method of birth control to a friend or family member*?	1….Ewe, ngokuqinisekileyo *Yes, I would definitely recommend it* 2….Ewe, ndingazama *Yes, I would probably recommend it* 3….Andiqinisekanga */ I am unsure* 4….Hayi, andinako		____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
510	Ukuba olu phandobelungaqhu beki ubuzakuba nomdla kangakanani wokuqhubekeka usebenzisa uhlobo lwakho lokugqibela lo wangciso-	1….Ukuba nomdla kakhulu kakhulu ndingaqhubeka / *Extremely willing* 2…Ukubanomdla kakhulu / *Very willing* 3….Ukubanomdla nje / *Somewhat willing* 4…Ukungabinamdla tu / *Not at all*		____
511	Lilonke, ubuwoneliseke kangakanani luhlobo lwakho lokugqibela logcwanciso- ntsapho. ? *Overall, how satisfied were you with your last birth control method?*	1….Ndoneliseke ngokugqithileyo/ *Extremely satisfied* 2.…Ndoneliseke kakhulu *Very satisfied* 3.…Ndoneliseke nje *Somewhat satisfied* 4….Ndonelisekile andonelisekanga */ Neither satisfied nor dissatisfied* 5….Andonelisekanga nje / *Somewhat dissatisfied*		____
Kolu luhlu lulandelayo lwemibuzo, ndizakubuza izimvo zakho ngokunxulumene noluhlobo lokugqibela locwagciso- ntsapho ubulisebenzisa phambi kwanamhlanje. *For the next series of questions, I will ask about your opinions regarding this last method of birth control you used before today*				
512	Uthintelo nzala luyalelwe ukusetyenziswa ngama-xesha athile acwangcisiweyo. Kukulungele kangakanani okanye akukulungelanga kangakanani ukusebenzisa uthintelo nzala ngendlela oyalelwe ngayo ngqo (umz: yonke imihla, ngeveki, ngenyanqa, qho kwinyanga ezintathu)?? *Birth control is prescribed to be used on a specific schedule. How convenient or*	1….Kuluge ngokugqithileyo *Extremely convenient* 2….Kulunge kakhulu */ Very convenient* 3….Kungandilungela */Somewhat convenient* 4….Kulungile kungalunganga / *Neither convenient or inconvenient* 5….Kungangandilungeli *Somewhat inconvenient* 6….Kungangandilungeli kakhulu *Very inconvenient*		____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*	**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** *Skip*	**Ikhowudi Yempendulo**
513	Kukangaphi ulibala ukuthatha okanye utye ucwangcisontsapho lwakho ngendlela oyalelwe ngayo ngqo? *How often did you forget to use or take your birth control exactly as directed?*	1….Andikhe ndiluphose (ndilusebenzisa ngendlela ngalo lonke xesha) */ None of the time (use perfectly all the time)* 2….Ixeshana nje */A little of the time* *3.*…Ngamanye amaxesha*/ Some of the time* *4.*…Ixesha elininzi */ Much of the time* *5.*… Ngamaxesha amaninzi*/ Most of the time* 6…Ngawo onke amaxesha		____
514	Ikuxhalabisa kangakanani into yokumitha nangona usebenzisa ucwagciso ntsapho? *How much did you worry about getting pregnant even though a bit*	1….Hayi konke konke*/ Not at all* 2….Kancinci*/ A little bit* 3….Kancinci nje */Somewhat* 4…Ngaphezulwana nje */Quite* 5…Kakhulu */A great deal*		____
515	Ubunexhala kangakanani lokuba ungakhulelwa kwixesha elizayo emva kokuyeka uthintelo nzala lwakho? *How worried were you that you would not be able to get*	1….Hayi konke konke*/ Not at all worried* 2….Ndixhalabile kancinci */Somewhat worried* 3….Ndixhalabe kakhulu */Very worried*		____

Abafazi abaninzi abasebenzisa ucwangciso ntsapho banamava ngeempawu . Kule mibuzo ilandelayo, nceda usazise ukuba uphawu ngalunye lukukhathaze kangakanani na kwinyanga edlulileyo. Ukuba awukhange ufumane mava ngempawu, nceda uthi "kange ndibe nalo"

Many women who use birth control experience symptoms. For these next questions, please let us know how much each of these symptoms have bothered you during the past month. If you did not experience a symptom, please say "did not have"

516 Zikhu khathaze njani naziphina kwezimpawu kwinyanga ephelileyo. *How bothered were you by any of the following symptoms in the last month*: [***FUNDA NGANYE NGANYE]*** ***[READ EACH ONE AND CIRCLE THEIR***

		Khangendi - benayo *Did not have*	**Khange indikhathazeke konke konke** *Not at all bothered*	**Indikhathaze kancinci** *A little bothered*	**Ndikhathazeke nje** *Somewhat bothered*	**Indikhathaze kakhulu** *Very bothered*	**Indikhathaze ngokugqithile yo** *Extremely*	Code
A	Ukukrala kwamabele	0	1	2	3	4	5	____
B	Ukuziva ungatyhilekanga*Feeli*	0	1	2	3	4	5	____
C	Ukucaphuka *Feeling irritated*	0	1	2	3	4	5	____
D	Rhashalala / amabala / *Acne /*	0	1	2	3	4	5	____
E	Isiluma/amazantsi	0	1	2	3	4	5	____

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#	**Umbuzo** */ Question* *[Funda ngohlobo ebhalwe ngalo /To be read*		**Impendulo** */ Answer Key* **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**			**Gqitha** *Skip*		**Ikhowudi Yempendulo**
F	Amachaphaza/ ukopha phakathi kwamathuba okuba sexesheni	0	1	2	3	4	5	____
G	Intloko ebuhlungu *Headaches*	0	1	2	3	4	5	____
H	Umoya esuswini *Bloating*	0	1	2	3	4	5	____
I	Isicaphu-caphu *Nausea*	0	1	2	3	4	5	____
J	Ukutyeba / *Weight gain*	0	1	2	3	4	5	____
K	Ukuwelwa zinwele/ inwele eziyephuyephu *Hair loss/ thinning*	0	1	2	3	4	5	____
L	Ezinye iimpawu (cacisa) *Other symptoms*	0	1	2	3	4	5	____
517	Abanye abafazi baya exesheni nyanga zonke, ngelixesha abanye bengayi roqo ngenxa yocwangciso ntsapho abalusebenzisayo. Woneliseke kangakanani okanye awonelisekanga kangakanani bubungakanani bokuya kwakho exesheni? *Some women experience a period every month, while others experience it less frequently due to their method of*		1….Ndoneliseke ngokugqitheleyo *Extremely pleased* 2….Ndoneliseke kakhulu *Very pleased* 3….Ndingoneliseka */ Somewhat pleased* 4….Ndonelisekile ndingoneliseki *Neither pleased nor displeased* 5….Ndinokungoneliseki nje *Somewhat displeased* 6….Andonelisekanga kakhulu *Very displeased*					____

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#	**Umbuzo /Question** ***[To be read verbatim]***	**Impendulo / *Answer*** **(Bhala ngaphandle kokuba uyalelwe ngolunye uhlobo /**	**Gqitha** ***Skip***	**Ikhowudi Yempendulo**
518	Ungawalinganisela kangakanani amandla ocwangciso-ntsapho lwakho lokugqibela ekwenzeni oku kulandelayo. ***[FUNDA NGANYE NGANYE]***			
A	Icutha isiluma *Reduce menstrual pain*	1…Ngokugqithisileyo */ Excellent* 2…Kakuhle kakhulu */ Very good* 3…Kakuhle */ Good* 4…Phakathi */ Fair* 5…Kakubi */ Poor*		____
B	Icwengisa igazi xa ndisexesheni*Lighten the flow of your menstrual period*	1…Ngokugqithisileyo */ Excellent* 2…Kakuhle kakhulu */ Very good* 3…Kakuhle */ Good* 4…Phakathi */ Fair* 5…Kakubi */ Poor*		____
C	Icutha inani leentsuku endiya ngazo exesheni *Reduce the number of days of your period*	1…Ngokugqithisileyo */ Excellent* 2…Kakuhle kakhulu */ Very good* 3…Kakuhle */ Good* 4…Phakathi */ Fair* 5…Kakubi */ Poor*		____

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523 Bonisa izinga lokuvumelana nezintetha zilandelayo ngokurhangqa impendulo *Indicate level of agreement with the following statements by circling their response :*		Ndivuma ngamandla	Ndiyavuma nje *Somewhat Agree*	Ndivuma ndingavumi	Andivumi nje *Somewhat*	Andivumi ngamandla	Ayihaphaz eli*Not Applicable*	**Ikhowudi Yempendulo** *Code*
A	Ndiziva njengesiqhelo nangona ndisebenzisa ucwangciso ntsapho *I feel like my usual self even though I am using birth control*	1	2	3	4	5	-8	____
B	Akukho miphumela (umz: ukopha kancinci, isacaphu-caphu, ukungatyhileki,) ezayanyaniswa nocwangciso ntsapho *The unwanted effects of my birth control*	1	2	3	4	5	-8	____
C	Imiphumela yocwangciso ntsapho iphazamisa ubom bam bemihla ngemihla *The side effects of my birth control interfere with my everyday life*	1	2	3	4	5	-8	____
D	Imiphumela yocwangciso ntsapho iphazamisa ubom bam bokwabelana ngesondo *The side effects of my birth control interfere with my sex life*	1	2	3	4	5	-8	____
E	Ubomi bami bokwabelena ngesondo buyazenzekela koluhlobo locwangciso ntsapho ndilusebenzisayo / *My sex life has become more spontaneous with my current birth control*	1	2	3	4	5	-8	____
F	Ucwangciso ntsapho buphazamisa imisebenzi yam yemhla ngemihla. *My birth control interferes with my daily activities*	1	2	3	4	5	-8	____
G	Ndonwabile nocwangciso ntsapho lwam. *I am happy with my birth control*	1	2	3	4	5	-8	____
H	Inzuzo yocwangciso ntsapho lwam zidlula izinto ezingeyiyo inzuzo kucwangciso. *The advantages of my birth control outweigh*	1	2	3	4	5	-8	____
I	Kube lula ukufakelela olucwangciso ntsapho kubom bam bemihla ngemihla / *I have easily incorporated my birth control into my usual*	1	2	3	4	5	-8	____

Place **Enrolment PTID**

label here

e.g. PTID: ***8*** _____- _____

Date:_____/_____/ __ _____

523 Bonisa izinga lokuvumelana nezintetha zilandelayo ngokurhangqa impendulo *Indicate level of agreement with the following statements by circling their response :*		Ndivuma ngamandla a	Ndiyavuma nje *Somewhat Agree*	Ndivuma ndingavumi	Andivumi nje *Somewhat*	Andivumi ngamandla a	Ayihaphaz eli*Not Applicable*	**Ikhowudi Yempendulo** *Code*
J	Ucwangciso ntsapho luphazamisa amandla endlela endisebenza ngayo okanye endizonwabisa ngayo. / *My birth control interferes with my ability to perform sexual as I*	1	2	3	4	5	-8	____
K	Ucwangciso ntsapho lwam lwaziwa kuphela ngabo ndakhetha ukubaxelela okanye ukubabonisa (ndiyakwazi ukuligcina luyimfihlo ucwangcisontsapho lwam)	1	2	3	4	5	-8	____
L	Ndiziva ndizithembile ukuba ndisebenzisa ucwangciso ntsapho olundilungeleyo	1	2	3	4	5	-8	____
M	Ndiyakholwa ukuba ucwangiso-ntsapho lwam luhlobo olululungeleyo iqabane/amaqabane am kanye nam. / *I believe that my birth control is the right method for me*	1	2	3	4	5	-8	____
N	Ndonelisekile kukuba kufuneka ndiluthathe roqo kangakanani ucwangciso ntsapho lwam. *I am pleased with how often I need to use birth*	1	2	3	4	5	-8	____
O	Ndiziva ndikhuselekile kukwazi ukuba ucwangciso ntsapho lwam luyasebenza	1	2	3	4	5	-8	____
P	Ndiqinisekile uku ucwangciso-ntsapho endilustebenzisayo alubeki emngciphekweni isifo sam seHIV./ *I am confident that the method I am using poses no risk*	1	2	3	4	5	-8	____

Place **Enrolment PTID**

label here

e.g. PTID: ***8*** _____- _____

Date:_____/_____/ __ _____

523 Bonisa izinga lokuvumelana nezintetha zilandelayo ngokurhangqa impendulo *Indicate level of agreement with the following statements by circling their response :*		Ndivuma ngamandla	Ndiyavuma nje *Somewhat Agree*	Ndivuma ndingavumi	Andivumi nje *Somewhat*	Andivumi ngamandla	Ayihaphaz eli*Not Applicable*	**Ikhowudi Yempendulo** *Code*
Q	Ndiqinisekile ukuba uhlobo endilusebenzisayo aluzuyitshintsha ifuthe lamachiza okuthomalalisa iHIV *I am confident that the method I am using will not change the effect of my ART medicines*	1	2	3	4	5	-8	____
R	Ndiqinisekile ukuba ifuthe lohlobo locwangciso endilusebenzisayo ukukhusela ukukhulelwa aluzukuncitshiswa ngamachiza okuthomalalisa iHIV	1	2	3	4	5	-8	____

Place **Enrolment PTID**

label here

e.g. PTID: ***8***_____- _____

Date:_____/_____/ __ _____

ALCOHOL AND CIGARETTE USE (AUDIT SCALE – 600s)							
Ngoku sizakubuza imibuzo ngokusebenzisa kwakho utywala. Nceda urhangqe impenduloeyiyo ngombuzo ngamnye kule ingezantsi: *We are now going to ask you some questions about your use of alcohol. Please circle the relevant answer for each question bellow:*							
	Score	0	1	2	3	4	**Code**
601	Ubusela kangakanani utywala? *How often do you have a drink containing alcohol?*	Zange *never*	Kanye ngenyanga nangaphantsi *Once per month or less*	Kabini ukuya kwisine enyangeni *2-4 times a month*	Kabini ukuya kwisithathu evekini *2-3 times per week*	Kane nangaphezulu evekini *4 times or more per week*	____ If 0→ 604
602	Zingaphi iglasi zesiselo esinxilisayo oziselayo ngemini? *How many standard drinks containing alcohol do you have on a typical day when drinking?*	1 okanye 2 *1 or 2*	3 okanye 4 *3 or 4*	5 okanye 6 *5 or 6*	7 ukuya 9 *7 to 9*	10 okanye ngaphezulu *10 or more*	____
603	Kukangaphi usela iglasi ezintandathu nangaphezulu ngexesha? *How many times do you have six standard drinks or more at time?*	Zange *Never*	Ngaphantsi kwenyanya *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*	____
	Umbuzo /Question			**Impendulo / *Answer***		**Gqitha** ***Skip***	**Ikhowudi Yempendul**
604	Ukhe watshaya isigareti kwezinyanga zilishumi elinambini zidlulileyo? *Have you smoked cigarettes in the previous 12 months?*			0…. Hayi */ No* 1…. Ewe */ Yes*		0→701	____
605	Utshaya izigareti ezingaphi ngosuku okanye ngeveki? *On average, how many cigarettes do you smoke each day or week?*			___cigarettes per day or ___cigarettes per week			Day:____ Wk: ____

Place **Enrolment PTID**

label here

e.g. PTID: ***8***_____- _____

Date:_____/_____/ __ _____

	MENTAL HEALTH (KESSLER-10, 700s) **Le mibuzo ilandelayo ikubuza ukuba ubuziva njani <u>kule nyanga idlulileyo</u>. Ngombuzo ngamnye yakha isangqa phants kwempendulo echaza ngokupheleleyo ubungakanani bexesha uvakalelwa njalo**						
		Akukhange kubekhi xesha *None of the*	**Kubekhona ixeshana** *A little of the time*	**Abekhona amanye amaxesha** *Some of the time*	**Kubekho amaxesha amaninzi** *Most of the time*	**Ibilixesha lonke** *All of the time*	**Code**
701	Kule nyanga iphelileyo, kukangaphi uziva udiniwe ngaphandle kwesizathu? / *During the last 30 days, about how often did you feel tired out for no good reason?*	0	1	2	3	4	____
702	Kule nyanga iphelileyo, kukangaphi uziva uphakuphaku? *During the last 30 days, about how often did you feel nervous?*	0	1	2	3	4	____
703	Uphakuphaku kangangokuba kungekho nto inokukuthomalalisa? / *During the last 30 days, about how often did you feel so nervous that nothing could calm you down?*	0	1	2	3	4	____
704	Kule nyanga iphelileyo, kukangaphi uziva uphelelwa ngamathemba? / *During the last 30 days, about how often did you feel hopeless?*	0	1	2	3	4	____
705	Ungazinzanga okanye ugungqa? *During the last 30 days, about how often did you feel restless or fidgety?*	0	1	2	3	4	____
706	Ungazinzanga de ugugqagungqe xa uhleli? / *During the last 30 days, about how often did you feel so restless you could not sit still?*	0	1	2	3	4	____
707	Kule nyanga iphelileyo, kukangaphi uziva ulusizana udakumbile? *During the last 30 days, about how often did you feel depressed?*	0	1	2	3	4	____
708	Kule nyanga iphelileyo, kukangaphi uva yonke into ibiyimigudu? / *During the last 30 days, about how often did you feel that everything was an effort?*	0	1	2	3	4	____
709	Udakumbile kangangokuba kungekho nanye into engakonwabisayo? /*During the last 30 days, about how often did you feel so sad that nothing could cheer you up?*	0	1	2	3	4	____

Place **Enrolment PTID**

label here

e.g. PTID: ***8*** _____- _____

Date:_____/_____/ __ _____

	MENTAL HEALTH (KESSLER-10, 700s) **Le mibuzo ilandelayo ikubuza ukuba ubuziva njani kule nyanga idlulileyo. Ngombuzo ngamnye yakha isangqa phants kwempendulo echaza ngokupheleleyo ubungakanani bexesha uvakalelwa njalo**						
		Akukhange kubekhi xesha *None of the*	**Kubekhona ixeshana** *A little of the time*	**Abekhona amanye amaxesha** *Some of the time*	**Kubekho amaxesha amaninzi** *Most of the time*	**Ibilixesha lonke** *All of the time*	**Code**
710	Kule nyanga iphelileyo, kukangaphi uziva ungena xabiso? /*During the last 30 days, about how often did you feel worthless?*	0	1	2	3	4	___

Score:_____(to be calculated by study nurse or study coordinator)

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____- _____

Date:_____/_____/ __ _____

Violence Against Women (WHO, 800s)

Siza kubuza imibizo yokugqibela embalwa ngokunxulumene nobundlobongela beqabane.

We are at the last section of the survey. We are going to ask you a few last questions relating to partner violence.

#	Umbuzo / Question *[Funda: To be read verbatim]*	Impendulo /Answer	Ikhowudi Yempendul
Uhlukumezo lwengqon			
801	Iqabane lakho likhe lakuthuka okanye lakwenza awaziva kamnandi? *Has your partner insulted you or made you feel bad about yourself?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
802	Likhe lakwenze wazina umncinci phambi kwabanye abantu okanye lakwenza intlekisa phambi kwabanye abantu?? *Has he belittled or humiliated you in front of other people?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
803	Likhe lenza izinto likoyikisa okanye lakungcungcuthekisa ngabom? / *Has he done things to scare or intimidate you on purpose?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
804	Like lakugrogrisa ngokonzakalisa okanye umntu okhathalayo ngaye? *Has he threatened to hurt you or someone you care about?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
Uhlukumezo lomzimba			
805	Likhe lakuqhwaba ngempama okanye lakugibisela ngento enokukwenzakalisa? *Has he slapped you or thrown something at you that could hurt you?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
806	Likhe lakutyhala okanye lakunyola? *Has he pushed or shoved you?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
807	Likhe lakubetha ngenqindi okanye ngento enokukonzakalisa? *Has he hit you with a fist or with something else that could hurt you?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
808	Likhe likukhabe, likurhuqe okanye likubethe? *Has he kicked you, dragged you or beaten you up?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
809	Likhe likukrwitshe okanye likutshise ngabom? *Has he choked or burnt you on purpose?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
810	Likhe likugrogrise ngokusebenzisa okanye lisevenzise umpu, imesi okanye nasiphina isixhobo kuwe? *Has he threatened to use or actually used a gun, knife or other weapon against you?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
Sexual Violence			
811	Likhe likunyanzele lise ngokwebalana ngesondo wena ungafuni? *Has he physically forced you to have sexual intercourse when you didn't want to?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____
812	Wakhe wabelane naye ngesondo ungafuni kuba usoyika into anokuyenza? *Did you ever have sexual intercourse when you didn't want because you were afraid of what he might do?*	0…. Hayi */ No* 1…. Ewe */ Yes*	____

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____ - _____

Date:_____/_____/ __ _____

813	Likhe likunyanzelise ngokwabelana ngesondo ngendlela oyifumanisa ithoba isidima (eyeanyelisayo) okanye ekwenza intlekisa? *Has he forced you to do something sexual that you found degrading or humiliating?*	0…. Hayi */ No* 1…. Ewe */ Yes* -8…n/a	____

Enkosi ngexesha lakho ekuphenduleni le mibuzo. Inxaxheba yakho ibalulekile kuthi.
Thank you for taking the time to answer these questions! Your responses are very important to us.

To be completed by study nurse or study coordinator:

Tick all to show completed.

- ☐ **ALCOHOL USE: Check questions 602 and 603, if question 602 has been coded as 2, 3 or 4, or 603 has been coded as 3 or 4, refer for alcohol counselling.**

- ☐ **MENTAL HEALTH: Tally the score for 701-710 and record below. Refer for counselling if score is greater than or equal to 25**

  Mental Health Score: _____

- ☐ **VIOLENCE: Check questions 803-813. If participant answered YES to ANY question, provide referral for partner violence services.**

Signature of study nurse or study coordinator: _____

Signature date: _____

Place **Screening PTID**

label here

e.g. PTID: ***5*** _____- _____

Date:_____/_____/ __ _____

SCREENING ELIGIBILITY CHECKLIST PRE-ART: 2IUDnCT

Interviewer Instructions:

- **Mark ☒ or a number in the response boxes |___| unless otherwise indicated.**
- **Proceed to next study procedure only if the volunteer passes the Screening Eligibility Checklist**

BASIC ELIGIBILITY CRITERIA—to be completed by Counsellor

1.	What is your age? |___|___| *If 18-40, tick "Yes."* *If under the age of 18 or over the age of 40, tick "No."*	Yes ☐	No ☐
2.	What is your date of birth? |___|___| / |___|___|___| / |___|___|___|___| (dd/mmm/yyyy) *Confirm that DOB matches age.*		
3.	What is your home language? 1☐**English** 2☐**IsiXhosa** 4☐**Other** *If English or isiXhosa, tick Yes and skip to question 4. If Other, ask 3b.*	Yes ☐	
3b.	If Other, are you fluent in English or isiXhosa?	Yes ☐	No ☐
4.	Are you currently pregnant?	Yes ☐	No ☐
5.	Do you plan/wish to become pregnant in the next 2 years?	Yes ☐	No ☐
6.	Are you willing to be randomized to use either a C-IUD or LNG-IUD as a family planning method?	Yes ☐	No ☐
7.	Do you plan to live in the same place or in the Cape Town area for the next 30 months?	Yes ☐	No ☐
8.	Have you had a tubal ligation/sterilization or do you have infertility?	Yes ☐	No ☐
9.	Have you been diagnosed with HIV infection?	Yes ☐	No ☐
	a) When were you diagnosed? |___|___| / |___|___|___| / |___|___|___|___| (dd/mmm/yyyy)		
10.	Have you ever taken antiretroviral medicines (ART)? ***If no → 14.***	Yes ☐	No ☐
11.	If yes, why did you start?		

Place **Screening PTID** label here

e.g. PTID: ***5*** _____- _____

Date:_____/_____/ __ _____

	1 ☐ Pregnancy/breastfeeding 2 ☐ Low CD4 count 3 ☐ Diagnosed with TB or other OI 4 ☐ Other reason : specify :_____		
12.	Are you currently taking antiretroviral medicines (ART)?	Yes ☐	No ☐
13.	If no longer taking ART, how long ago did you stop? **Date stopped: |____|____| / |____|____|____| / |____|____|____|____|** (dd/mmm/yyyy) **Number of months since stopped taking ARVs |____|____|** **[Enter '24" if 2 or more years ago]** *If number of months is >6, tick Yes. If number of months is <6, tick No*	Yes ☐	No ☐
14.	Do you agree to follow all procedures for the study?	Yes ☐	No ☐
15.	Do you agree to participate in this research study for up to 24 months?	Yes ☐	No ☐
16.	Do you agree to provide the study staff with an address, phone number, and times you can be reached? (Addresses and phone numbers are confidential.)	Yes ☐	No ☐
17.	Do you agree to allow the study staff to review your clinical records to check laboratory information and confirm HIV diagnosis?	Yes ☐	No ☐
18.	If you enter this trial, do you agree not to participate in any other HIV trial requiring medications until this study ends?	Yes ☐	No ☐
19.	Have you had a termination of pregnancy or miscarriage in the last four weeks?	Yes ☐	No ☐
20.	Based on the responses to question 1-19 is the person eligible to continue? *If all responses are in shaded boxes tick yes.* *If any of the responses are not shaded tick no, she is not eligible and should be asked to complete a Decliner/Ineligible Questionnaire.*	Yes ☐ Continue to Q 21.	No ☐ NOT ELIGIBLE- End interview

Counsellor signature:_____**Date**_____

Medical Eligibility Questionnaire—to be completed by study nurse

21.	Have you had PID or an infection in the uterus in the last 3 months? *If no, skip to question 23.*	Yes ☐	No ☐
22.	If you have had PID or an infection in the uterus in the last 3 months, did you	Yes ☐	No ☐

	complete treatment?		
23.	Have you ever had or been diagnosed with any of the following conditions:		
	a) Wilson's Disease	Yes ☐	No ☐
	b) Hormonally-dependent tumor	Yes ☐	No ☐
	c) Abnormal uterine shape/septum	Yes ☐	No ☐
	d) Liver disease or tumor	Yes ☐	No ☐
	e) Sensitivity to plastic polymer or copper	Yes ☐	No ☐
	f) Tuberculosis (TB) *If no →23g*	Yes ☐	No ☐
	f1 When were you diagnosed with TB? |___|___| / |___|___|___| / |___|___|___|___| (dd/mmm/yyyy) *Is this date prior to HIV diagnosis or not concurrent with HIV diagnosis? (#9a)*	Yes ☐	No ☐
	g) Recurrent pneumonia (more than three episodes in the last three months)	Yes ☐	No ☐
	h) Cervical cancer	Yes ☐	No ☐
	i) Ectopic pregnancy	Yes ☐	No ☐
	j) Oesophageal candidiasis *If no → 24*	Yes ☐	No ☐
	j1 When were you diagnosed with oesophageal candidiasis? |___|___| / |___|___|___| / |___|___|___|___| (dd/mmm/yyyy) *Is this date more than three years prior to HIV diagnosis? (#9a)*	Yes ☐	No ☐

INTERVIEW—to be completed by Study Nurse

Ask the patient to answer the following.

24. Has the participant had a pap smear within the last three years?

☐ Yes

☐ No or don't know →**27**. Perform pap smear at this visit.

25. Date last Pap smear: |____|___\| / |____|____|____| / |____|____|____|____| (dd/mmm/yyyy)

26. Pap Result: 0☐NEGATIVE 1☐ASCUS 2☐LSIL 3☐HSIL 99☐ Unknown

Place **Screening PTID**

label here

e.g. PTID: ***5*** _____- _____

Date:_____/_____/ __ _____

OR:

☐ Participant has never had or doesn't know if she had a CD4 count test → **29**

28. CD4 Count Result: _____

29. Injectable contraceptive use:

☐ Net-en/2 monthly; Date of last injection: |___|___| / |___|___|___| / |___|___|___|___|

Date next injection due: |___|___| / |___|___|__ _|/ |___|___|___|___|

☐ Depo Provera/3 monthly ; Date of last injection: |___|___| / |___|___|___| / |___|___|___|___|

Date next injection due: |___|___| / |___|___|__ _|/ |___|___|___|___|

☐ Oral contraceptive pill :Date of last menses|___|___| / |___|___|___| / |___|___|___|___|

Date of last active pill |___|___| / |___|___|___| / |___|___|___|___|

☐ None

Nurse Signature:_____Date: _____

Stop here and review results with study coordinator or second nurse

CONFIRMATION OF ELIGIBILITY—to be completed by Study Coordinator

30. Does the volunteer pass the eligibility criteria to be considered for enrolment in this research study and agree to continue with screening?

0☐ **NO** 1☐ **YES**

If YES:

- Sign below and proceed with study procedures.
- If the volunteer is eligible but requires delayed enrolment, reschedule her for re-screening

If NO:

- Inform participant they may not enter into the research study at this time or support them in their decision to decline enrolment;
- Complete the SCREENING AND ENROLMENT LOG and ask participant to complete the the decliner/ineligible questionnaire.

_____ Date_____

If study coordinator unavailable, one nurse may sign to verify eligibility in her absence. The study coordinator must initial this form prior to enrolment

_____ Date_____

_____Study coordinator initials

CHART REVIEW—TO BE SIGNED OFF BY STUDY COORDINATOR OR STUDY NURSE PRIOR TO ENROLMENT

Place **Screening PTID**

label here

e.g. PTID: ***5*** _____- _____

Date:_____/_____/ __ _____

VERIFICATION OF DOCUMENTED HIV STATUS

31. Has documented HIV status been filed at the study site?

0☐ No, participant is unable to provide documented HIV status and declines rapid HIV testing.**f** participant is present, ask her to complete the Decliner/Ineligible Questionnaire. –> End form

1☐ Yes Date filed: _____

32. How was documented HIV status obtained?

1☐ Confirmation via NHLS database

2☐ Confirmation via GCHC Folder

3☐Other, specify:_____

33. What is the participant's documented HIV status?

1☐ HIV positive → continue with study procedures

2☐ HIV negative →ask to complete Decliner/Ineligible questionnaire

Staff initials_____Date _____

VERIFICATION OF PAP SMEAR IN THE LAST THREE YEARS

34. Has documentation of pap smear result in the last three years been filed at the study site?

0☐ No → **37**. Perform pap smear prior to IUD insertion

1☐ Yes Date filed: _____

35. How was pap smear result obtained?

1☐ Confirmation via NHLS database

2☐ Confirmation via GCHC Folder

☐ Other, specify: _____

36. What is the pap smear result?

0☐**NORMAL**

1☐**ASCUS**

2☐**LSIL**

3☐**HSIL →Notify study coordinator immediately**

99☐Not yet available

Staff initials_____Date _____

VERIFICATION OF DATE OF BIRTH

Place **Screening PTID**

label here

e.g. PTID: ***5*** _____- _____

Date:_____/_____/ __ _____

37. Has documentation of date of birth has been filed at the study site?

0 ☐ No. Participant is unable to provide documentation of date of birth, ask participant to complete Decliner/Ineligible Questionnaire

1 ☐ Yes Date filed: _____

38. How was date of birth verified?

1 ☐ Confirmation via NHLS database 2 ☐

Confirmation via GCHC Folder 3 ☐
Presentation of ID book

4 ☐ Other, specify: _____

39. Is the participant 18-40 years old (inclusive) based on her documented date of birth?

0 ☐ No → ask participant to complete Decliner/Ineligible Questionnaire

1 ☐ Yes → continue with study procedures

Staff initials_____Date _____

STUDY COORDINATOR SIGN-OFF

40. Has chart review been completed and eligibility to proceed with enrolment visit confirmed?

0 ☐ **NO** 1 ☐ **YES**

Signature of study coordinator verifying eligibility

_____ Date_____

Place **Screening PTID** label here

*e.g. PTID: **6**_____- ____*

Date:_____/_____/ __ _____

ART USER SCREENING ELIGIBILITY CHECKLIST: 2IUDnCT

Interviewer Instructions:

- **Mark ☒ or a number in the response boxes |___| unless otherwise indicated.**
- **Proceed to next study procedure only if the volunteer passes the Screening Eligibility Checklist**

BASIC ELIGIBILITY CRITERIA—to be completed by Counsellor

1.	What is your age? |___|___| *If 18-40, tick "Yes."* *If under the age of 18 or over the age of 40, tick "No."*	Yes ☐	No ☐
2.	What is your date of birth? |___|___| / |___|___|___| / |___|___|___|___| (dd/mmm/yyyy) *Confirm that DOB matches age.*		
3.	What is your home language? 1☐**English** 2☐**IsiXhosa** 4☐**Other** *If English or isiXhosa, tick Yes and skip to question 4. If Other, ask 3b.*	Yes ☐	
3b.	If Other, are you fluent in English or isiXhosa?	Yes ☐	No ☐
4.	Are you currently pregnant?	Yes ☐	No ☐
5.	Do you plan/wish to become pregnant in the next 30 months?	Yes ☐	No ☐
6.	Are you willing to be randomized to use either a C-IUD or LNG-IUD as a family planning method?	Yes ☐	No ☐
7.	Do you plan to live in the same place or in the Cape Town area for the next 30 months?	Yes ☐	No ☐
8.	Have you had a tubal ligation/sterilization or do you have infertility?	Yes ☐	No ☐
9.	Have you been diagnosed with HIV infection?	Yes ☐	No ☐
	a) When were you diagnosed? |___|___| / |___|___|___| / |___|___|___|___| (dd/mmm/yyyy)		
10.	Have you ever taken antiretroviral medicines (ART)?	Yes ☐	No ☐
11.	If yes, why did you start?		

Place **Screening PTID**

label here

e.g. PTID: ***6*** _____- _____

Date:_____/_____/ __ _____

	1 ☐ Pregnancy/breastfeeding 2 ☐ Low CD4 count 3 ☐ Diagnosed with TB or other OI 4 ☐ Other reason : specify :_____		
12.	Are you currently taking antiretroviral medicines (ART)? ***If no*** → **Stop. Assess if participant is eligible for screening as pre-ART participant (if patient has stopped ART with pregnancy >6 months ago).** **If stopped taking ART by choice, alert study coordinator**	Yes ☐	No ☐
14.	Do you agree to follow all procedures for the study?	Yes ☐	No ☐
15.	Do you agree to participate in this research study for up to 24 months?	Yes ☐	No ☐
16.	Do you agree to provide the study staff with an address, phone number, and times you can be reached? (Addresses and phone numbers are confidential.)	Yes ☐	No ☐
17.	Do you agree to allow the study staff to review your clinical records to check laboratory information and confirm HIV diagnosis, possibly including a blood test for HIV?	Yes ☐	No ☐
18.	If you enter this trial, do you agree not to participate in any other HIV trial of medications or other biomedical interventions until this study ends?	Yes ☐	No ☐
19.	Have you had a termination of pregnancy or miscarriage in the last four weeks?	Yes ☐	No ☐
20.	Based on the responses to question 1-19 is the person eligible to continue? *If all responses are in shaded boxes tick yes.* *If any of the responses are not shaded tick no, she is not eligible and should be asked to complete a Decliner/Ineligible Questionnaire.*	Yes ☐ Continue to Q 21.	No ☐ NOT ELIGIBLE- End interview

Counsellor signature:_____**Date**_____

Medical Eligibility Questionnaire—to be completed by study nurse

21.	Have you had PID or an infection in the uterus in the last 3 months? *If no, skip to question 23.*	Yes ☐	No ☐
22.	If you have had PID or an infection in the uterus in the last 3 months, did you	Yes ☐	No ☐

	complete treatment?		
23.	Have you ever had or been diagnosed with any of the following conditions:		
	a) Wilson's Disease	Yes ☐	No ☐
	b) Hormonally-dependent tumor	Yes ☐	No ☐
	c) Abnormal uterine shape/septum	Yes ☐	No ☐
	d) Liver disease or tumor	Yes ☐	No ☐
	e) Sensitivity to plastic polymer or copper	Yes ☐	No ☐
	f) Tuberculosis (TB) *If no →23g*	Yes ☐	No ☐
	f1 When were you diagnosed with TB? |___|___| / |___|___|___| / |___|___|___|___| (dd/mmm/yyyy)		
	g) Recurrent pneumonia (more than three episodes in the last three months)	Yes ☐	No ☐
	h) Cervical cancer	Yes ☐	No ☐
	i) Ectopic pregnancy	Yes ☐	No ☐
	j) Oesophageal candidiasis *If no → 24*	Yes ☐	No ☐
	j1 When were you diagnosed with oesophageal candidiasis? |___|___| / |___|___|___| / |___|___|___|___| (dd/mmm/yyyy) *Is this date prior to HIV diagnosis? (#9a)*	Yes ☐	No ☐

INTERVIEW—to be completed by Study Nurse

Ask the patient to answer the following:

24. Has the participant had a pap smear within the last three years?

☐ Yes

☐ No or don't know →**27**. Perform pap smear at this visit.

25. Date last Pap smear: |____|___\| / |____|____|____| / |____|____|____|____| (dd/mmm/yyyy)

26. Pap Result: 0☐NEGATIVE 1☐ASCUS 2☐LSIL3☐HSIL 99☐ Unknown

27a. Date Last Plasma Viral load count: |____|___\| / |____|____|____| / |____|____|____|____|

Place **Screening PTID**

label here

e.g. PTID: ***6*** _____- _____

Date:_____/_____/ __ _____

(If no documented plasma viral load, please inform the study coordinator; eligibility cannot be determined at this time)

28a. Plasma viral Load

0☐ **≥1000 copies/mL**

1☐ **<1000 copies/mL or undetectable**

(If ≥1000 copies/mL , please inform study coordinator)

2☐ **Do not know**

29. Injectable contraceptive use:

☐ Net-en/2 monthly; Date of last injection: |___|___| / |___|___|___| / |___|___|___|___|

Date next injection due: |___|___| / |___|___|__ _|/ |___|___|___|___|

☐ Depo Provera/3 monthly ; Date of last injection: |___|___| / |___|___|___| /|___|___|___|_ |

Date next injection due: |___|___| / |___|___|___|/ |___|___|___|___|

☐ Oral contraceptive pill :Date of last menses|___|___| / |___|___|___| / |___|___|___|___|

Date of last active pill |___|___| / |___|___|___| / |___|___|___|___|

☐ None

Nurse Signature:_____Date: _____

CONFIRMATION OF ELIGIBILITY—to be completed by Study Coordinator

30. Does the volunteer pass the eligibility criteria to be considered for enrolment in this research study and agree to continue with screening?

0☐ **NO If** 1☐ **YES**

YES:

- Sign below and proceed with study procedures.
- If the volunteer is eligible but requires delayed enrolment, reschedule her for re-screening

If NO:

- Inform participant they may not enter into the research study at this time or support them in their decision to decline enrolment;
- Complete the SCREENING AND ENROLMENT LOG and ask participant to complete the the decliner/ineligible questionnaire.

Signature of study coordinator verifying eligibility

_____ Date_____

If study coordinator unavailable, one nurse may sign to verify eligibility in her absence. The study coordinator must initial this form prior to enrolment.

Place **Screening PTID**

label here

e.g. PTID: ***6*** _____- _____

Date:_____/_____/ __ _____

_____ Date_____

_____Study coordinator initials

CHART REVIEW—TO BE SIGNED OFF BY STUDY COORDINATOR OR STUDY NURSE PRIOR TO ENROLMENT

VERIFICATION OF DOCUMENTED HIV STATUS

31. Has documented HIV status been filed at the study site?

0☐ No, participant is unable to provide documented HIV status and declines rapid HIV testing.**f** participant is present, ask her to complete the Decliner/Ineligible Questionnaire. –> End form

1☐ Yes Date filed: _____

32. How was documented HIV status obtained?

1☐ Confirmation via NHLS database

2☐ Confirmation via GCHC Folder

3☐Other, specify:_____

33. What is the participant's documented HIV status?

1☐ HIV positive → continue with study procedures

2☐ HIV negative →ask to complete Decliner/Ineligible questionnaire

Staff initials_____Date _____

VERIFICATION OF ART USE AND NON-DETECTABLE PLASMA VIRAL LOAD

34. Has documentation of plasma viral load in the last 6 months been filed at the study site?

0☐No. Participant is unable to provide documentation of most recent plasma viral load. Ask participant to either obtain documentation from her home clinic or get an updated plasma VL test if she desires enrolment. Patient is ineligible at this point.

1☐Yes Date filed: _____

35. How was documentation of most recent plasma viral load verified?

1☐ Confirmation via NHLS database

2☐ Confirmation via GCHC Folder

3☐ Other, specify: _____

36. Was the participant's most recent viral load suppressed (<1000 copies/mL)?

Place **Screening PTID**

label here

e.g. PTID: ***6*** _____- _____

Date:_____/_____/ __ _____

1☐ No, participant is on ART but viral load not suppressed → ask to complete Decliner/Ineligible questionnaire and advise return to clinic for provider consultation.

2☐ Yes, participant is on ART and the most recent viral load is <1000 copies/mL. → continue with study procedures.

Staff initials_____Date _____

VERIFICATION OF PAP SMEAR IN THE LAST THREE YEARS

37. Has documentation of pap smear result in the last three years been filed at the study site?

0☐ No → **37**. Perform pap smear prior to IUD insertion

1☐ Yes Date filed: _____

38. How was pap smear result obtained?

1☐ Confirmation via NHLS database

2☐ Confirmation via GCHC Folder

3☐ Other, specify: _____

39. What is the pap smear result?

0☐**NORMAL**

1☐**ASCUS**

2☐**LSIL**

3☐**HSIL →Notify study coordinator immediately**

99☐Not yet available

Staff initials_____Date _____

VERIFICATION OF DATE OF BIRTH

Place **Screening PTID**

label here

*e.g. PTID: **6**_____- _____*

Date:_____/_____/ __ _____

40. Has documentation of date of birth been filed at the study site?

0☐No. Participant is unable to provide documentation of date of birth, ask participant to complete Decliner/Ineligible Questionnaire

1☐Yes Date filed: _____

41. How was date of birth verified?

1☐ Confirmation via NHLS database 2☐

Confirmation via GCHC Folder 3☐
Presentation of ID book

4☐ Other, specify: _____

42. Is the participant 18-40 years old (inclusive) based on her documented date of birth?

0☐No → ask participant to complete Decliner/Ineligible Questionnaire

1☐Yes → continue with study procedures

Staff initials_____Date _____

STUDY COORDINATOR SIGN-OFF

43. Has chart review been completed and eligibility to proceed with enrolment visit confirmed?

0 ☐ **NO** 1 ☐ **YES**

Signature of study coordinator verifying eligibility

_____ Date_____

Place **Screening PTID**

label here

e.g. PTID: ***5***_____- _____

Date:_____/_____/ __ _____

Clinical CRF for Screening Pre-ART : 2IUDnCT

Pregnancy and Medical History

0. U- alegic kwi latex / Are you allergic to latex?

   1☐ Yes → **Use nitrile gloves**

   0☐ No

1.

2. Weight: |_____|_____| kg

3. hCG Pregnancy Test:

   1☐ Positive → **Stop form and inform study coordinator**

   0☐ Negative

4. Wakhe wakhulelwa embhabheni/ etyhubhini / Have you ever had an ectopic pregnancy?

   1☐ Yes → **Stop form and inform study coordinator**

5. 0☐ No

   1☐ Yes→Describe and confirm with PI before scheduling enrolment: _____

   _____

   0☐ No

6. Wakhe Wawathatha amachiza okuthomalalisa intsholongwane kagawulayo?

   Have you taken any medication(s)/treatment(s) for your HIV infection?

   1☐ Yes

   0☐ No → **7**

   a. Yayingamachiza okuthomalalisa intsholongwane na?

   1☐ Yes

   0☐ No →

Place **Screening PTID**

label here

e.g. PTID: ***5***_____- _____

Date:_____/_____/ __ _____

b. Ukuba ewe, uyawathatha ngoku lamayeza okanye ubuwathatha kwinyanga ezintandathu ezidlulileyo?

1☐ Yes → **Stop form and inform study coordinator**

0☐ No

7. Ungaba uyopha kangangokuba usebenzisa ipad/ liner namhlanje?
Do you have vaginal bleeding such that you need to use a liner/pad today?

1☐ Yes → **Stop form and reschedule participant**

0☐ No

8. Ubunini umhla wakho oqale ngawo ukuya exesheni kweli lixa lokugqibela lokuhlamba? When was the first day of your last menstrual period?

Date: |____|____| / |____|____|____| / |____|____|____| (dd/mmm/yyyy)
_____|

OR

a. ☐ Not menstruating on current contraceptive method →**6_1**

Kuthatha iintsuku ezingaphi oko kuya exesheni /

How many days did that period last?

|____|____| *number of days*

Place **Screening PTID** label here

e.g. PTID: ***5***_____-_____

Date:_____/_____/ __ _____

9. Ingaba oku kulandelayo kuyezeka na kuwe ? Are you currently experiencing any of the following symptoms: **Read list.**

Symptom	**Yes/No**	**If yes, duration**
a. Izilonda okanye inyebethu kwilungu langasese Genital sores or ulcers	1☐ Yes 0☐ No	_____days
b. Ukurhawuzelela kwilungu langasese	1☐ Yes 0☐ No	_____days
c. Ukutshisa kwilungu langasese	1☐ Yes 0☐ No	_____days
d. Ezinye iintlungu kwilungu langasese	1☐ Yes 0☐ No	_____days
e. Iintlungu xa uchama	1☐ Yes 0☐ No	_____days
f. Ukuchama okongezelelekileyo rhoqo	1☐ Yes 0☐ No	_____days
g. Ukopha okungaqhelekanga ebufazini(ingekuko ukuya exesheni) Abnormal vaginal bleeding	1☐ Yes 0☐ No	_____days
h. Ukoma okungaqhelekanga ebufazini(ungasebenzisi zomiso Abnormal vaginal dryness (without using any drying agents)	1☐ Yes 0☐ No	_____days
i. Iintlungu xa usabelana ngesondo Pain during sex	1☐ Yes 0☐ No -8☐ No sex	_____days
j. Iintlungu emazantsi esisu Lower abdominal pain	1☐ Yes 0☐ No	_____days
k. Iintlungu emazantsi omqolo Lower back pain	1☐ Yes 0☐ No	_____days
l. Ubumanzi apha ebufazini obungaqhelekanga Abnormal vaginal discharge	1☐ Yes 0☐ No	_____days
m. Ukujikelezelwa yintloko Dizziness	1☐ Yes 0☐ No	_____days
n. Isicafu cafu Nausea	1☐ Yes 0☐ No	_____days
o. Ukugabha Vomiting	1☐ Yes 0☐ No	_____days
p. Ukudinwa Fatigue	1☐ Yes 0☐ No	_____days
q. Umkhuhlane ongachazekiyo Unexplained fever	1☐ Yes 0☐ No	_____days

Place **Screening PTID** label here

e.g. PTID: ***5***_____- _____

Date:_____/_____/ __ _____

Symptom	Yes/No	If yes, duration
r. Ukubila ebusuku	1☐ Yes 0☐ No	_____days
s. Ukungabinamdla wokutya nokuya kuncipha	1☐ Yes 0☐ No	_____days
t. Ukumimitheka	1☐ Yes 0☐ No	_____days
u. Ukuhambisa okumandla (>kwentsuku ezi7)	1☐ Yes 0☐ No	_____days
v. Ulosuleleko emlonyeni	1☐ Yes 0☐ No	_____days
w. Ukudumba kwamadlala la asemqaleni ngasezindlebeni	1☐ Yes 0☐ No	_____days
x. Intloko ebuhlungu ngokugqithisileyo Severe headaches	1☐ Yes 0☐ No	_____days

**If any "Yes" answers provided, follow up on pelvic exam for genital complaints or refer for evaluation of other symptoms.*

10. Were there any palpable inguinal lymph

0☐ None 1☐ Unilateral left 2☐ Unilateral right 3☐ Bilateral

11. Were any abnormalities detected on the external genitalia by <u>naked eye</u>

0☐ No

1☐ Yes → **If yes, record below:**

1☐ Warts

2☐ Painful ulcer

3☐ Non-painful Vesicle(s)

4☐ Tearing/ bruising at vaginal

5☐ Cyst

6☐ Enlarged Bartholin's gland

Other (specify): _____

Place **Screening PTID**

label here

e.g. PTID: ***5***_____- _____

Date:_____/_____/ __ _____

12. On speculum examination, was vaginal discharge present?

1 ☐ Yes

0 ☐ No → **13**

-8 ☐ Not assessed/evident bleeding. **IF BLEEDING→Stop form and inform study coordinator**

a. If yes, record colour of discharge:

1 ☐ Clear

2 ☐ White

3 ☐ Yellow/green

4 ☐ Bloody/brown

6 ☐ Cream-colored/gray

c. If yes, consistency of discharge:

1 ☐ Non-homogenous, normal

2 ☐ Non-homogenous, curd-like

3 ☐ Homogenous, smooth

4 ☐ Homogenous, frothy

b. Is an abnormal odour present? 1 ☐ Yes 0 ☐ No

13. What was the quantity of cervical mucus?

1 ☐ No mucus visible at os → **15.**

2 ☐ Mild-moderate mucus visible at

3 ☐ Abundant mucus flowing from

14. Colour of cervical mucus:

1 ☐ Clear

2 ☐ Whit

3 ☐ Yellow/gree

4 ☐ Bloody/brow

6 ☐ Cream-

Mixed. Specify:_____

15. Was there any contact bleeding when swabs were taken for STI testing?

1 ☐ Yes 0 ☐ No

15a. Was there any visible abnormality/lesion suspicious for neoplasia on the

Place **Screening PTID**

label here

e.g. PTID: ***5***_____- _____

Date:_____/_____/ __ _____

1☐ Yes 0☐ No

16. Was there any pain on bimanual examination?

1☐ Yes 0☐ No → 17

a. If YES, how would you rate this pain?

1☐ Mild (reported by woman, no change in facial expression or muscle

2☐ Moderate (change in facial expression/muscle tone, but woman tolerates

3☐ Severe (woman cannot tolerate exam without body movement)

17. Was there any cervical motion tenderness?

1☐ Yes 0☐ No → 18

a. If YES, how would you rate this tenderness?

1☐ Mild (reported by woman, no change in facial expression or muscle

2☐ Moderate (change in facial expression/muscle tone, but woman tolerates

3☐ Severe (woman cannot tolerate exam without body movement)

18. Were there any adnexal mass(es)?

1☐ Yes (**Specify location(s)**: ☐ Left ☐ Right)

0☐ No

-8☐ Could not palpate adnexae

19. Was the uterus enlarged?

1☐ Yes, **describe**:_____

Place **Screening PTID**

label here

e.g. PTID: ***5***_____- _____

Date:_____/_____/ __ _____

20. Perform rapid tests now and record results and lot numbers on **Screening Lab CRF**

	Rapid Test	Test done and results recorded	Kit info
a	Pregnancy	1☐ Yes 0☐ No	kit # : _____ Expiry date: |__|__| /|__|__|.| / |__|__|__|__|
b	OSOM Trich	1☐ Yes 0☐ No	kit # : _____ Expiry date: |__|__| /|__|__|.| / |__|__|__|__|
c	OSOM BV	1☐ Yes 0☐ No	kit # : _____ Expiry date: |__|__| /|__|__|.| / |__|__|__|__|
d	Syphilis	1☐ Yes 0☐ No	kit # : _____ Expiry date: |__|__| /|__|__|.| / |__|__|__|__|

Clinical Summary

23. Were any diagnoses made at today's visit?

1☐ Yes → **Specify:** _____

_____

0☐ No

24. Were any referrals made at today's visit?

1☐ Yes → **Specify:** _____

_____

0☐ No

25. Were any medications prescribed at today's

1☐ Yes → specify:_____

Check for allergies; record on Concomitant Medications Log.

0☐ No → **Comments**

Remember: Record all medications on the Concomitant Medications Log, including anything she is currently taking or was prescribed at this visit.

Place **Screening PTID**

label here

e.g. PTID: ***5***_____- _____

Date:_____/_____/ __ _____

Nurse signature:_____**Date:** _____

Stamp for Data Entry:_____**Stamp for Quality Control:** _____

Place **Screening PTID**

label here

e.g. PTID: ***6***_____- _____

Date:_____/_____/ __ _____

Clinical CRF for Screening ART-User: 2IUDnCT

Pregnancy and Medical History

0. U- alegic kwi latex /Are you allergic to latex?

   1☐ Yes → **Use nitrile gloves**

1. 0☐ No

2. Weight: |_____|_____| kg

3. hCG Pregnancy Test:

   1☐ Positive → **Stop form and inform study coordinator**

   0☐ Negative

4. Wakhe wakhulelwa embhabheni/ etyhubhini / Have you ever had an ectopic pregnancy?

   1☐ Yes → **Stop form and inform study coordinator**

5. 0☐ No

   Wakhe wenziwa utyando lomlomo sibeleko /Have you had previous cervical surgery?

   0☐ No

6. Wakhe Wawathatha amachiza okuthomalalisa intsholongwane kagawulayo?

   Have you taken any medication(s)/treatment(s) for your HIV infection?

   1☐ Yes

   0☐ No → **Stop form and inform study coordinator**

   a. Yayingamachiza okuthomalalisa intsholongwane na?

   Were these medications antiretrovirals (e.g. odimune, tenofovir/tdf, efavirenz, lamivudine/3tc, combivir, viramune, AZT/zidovudine)?

   b. Ukuba ewe, uyawathatha ngoku lamayeza? If yes, are you currently taking these medications months?

   1☐ Yes

   0☐ No → **Stop form and inform study coordinator**

Place **Screening PTID**

label here

e.g. PTID: ***6***_____- _____

Date:_____/_____/ __ _____

.

c. iAR uzithatha kangaphi ngemini/ How many times a day do you take your ART pills?
|____|____|

d. Zingaphi ipilisi ozityayo ngexesha /How many pills do you take each time you take your ART medicines?

Morning (am) |____|
_____|

e. Ingama layeza e ART ozityayo ngokui /What is/are the names of the ART medicine(s) you are taking right now?

1 ☐ Tribus
2 ☐ Odimune
3 ☐ Combivir
☐ Tenofovir/t
5 ☐ Lamivudime
6 ☐ Efavirenz
7 ☐ Viramune
8 ☐ Other, specify: _____
9 ☐ Atroiza10
☐ 3TC
11 ☐ Nevirapine
12 ☐ Aluvia
13 ☐ Zidovudine

[Note: please use picture chart to assist participant in identifying the correct pill.]

f. Igama leklinic lofuma khona kunanakelwa kwentsholongwane ngawulayo kanye nama chiza akho ART? What is the name of the clinic where you receive your ART medicines and HIV care?

1 ☐ Hannan Crusade
2 ☐ Nyanga clinic
3 ☐ New Crossroad Clinic
☐ Vuyani
5 ☐ Old Crossroad Clinic
6 ☐ NY1 clinic
7 ☐ Mzamonhl
other; specify: _____

7. Ungaba uyopha kangangokuba usebenzisa ipad/ liner namhlanje? Do you have vaginal bleeding such that you need to use a liner/pad today?

1 ☐ Yes → **Stop form and reschedule the participant**

0 ☐ No

Place **Screening PTID**

label here

e.g. PTID: ***6***_____- _____

Date:_____/_____/ __ _____

8. Ubunini umhla wakho oqale ngawo ukuya exesheni kweli lixa lokugqibela lokuhlamba

Date: |____|____| / |____|____|____| / |____|____|____|____| (dd/mmm/yyyy)

OR

☐ Not menstruating on current contraceptive method **→9_a**

a. Inani leentsuku How many days did that period last? |____|____| *number of days*

9. Ingaba oku kulandelayo kuyezeka na kuwe ? Are you currently experiencing any of the following symptoms: **Read list.**

Symptom	**Yes/No**	**If yes, duration**
a. Izilonda okanye inyebethu kwilungu langasese Genital sores or ulcers	1☐ Yes 0☐ No	_____days
b. Ukurhawuzelela kwilungu langasese	1☐ Yes 0☐ No	_____days
c. Ukutshisa kwilungu langasese	1☐ Yes 0☐ No	_____days
d. Ezinye iintlungu kwilungu langasese	1☐ Yes 0☐ No	_____days
e. Iintlungu xa uchama	1☐ Yes 0☐ No	_____days
f. Ukuchama okongezelelekileyo rhoqo	1☐ Yes 0☐ No	_____days
g. Ukopha okungaqhelekanga ebufazini(ingekuko ukuya exesheni) Abnormal vaginal bleeding	1☐ Yes 0☐ No	_____days
h. Ukoma okungaqhelekanga ebufazini(ungasebenzisi zomiso Abnormal vaginal dryness (without using any drying agents)	1☐ Yes 0☐ No	_____days
i. Iintlungu xa usabelana ngesondo	1☐ Yes 0☐ No -8☐ No sex	_____days
j. Iintlungu emazantsi esisu	1☐ Yes 0☐ No	_____days
k. Iintlungu emazantsi omqolo	1☐ Yes 0☐ No	_____days

Place **Screening PTID** label here

*e.g. PTID: **6**_____- _____*

Date:_____/_____/ __ _____

Symptom	Yes/No	If yes, duration
l. Ubumanzi apha ebufazini obungaqhelekanga Abnormal vaginal discharge	1☐ Yes 0☐ No	_____days
m. Ukujikelezelwa yintloko Dizziness	1☐ Yes 0☐ No	_____days
n. Isicafu cafu Nausea	1☐ Yes 0☐ No	_____days
o. Ukugabha Vomiting	1☐ Yes 0☐ No	_____days
p. Ukudinwa Fatigue	1☐ Yes 0☐ No	_____days
q. Umkhuhlane ongachazekiyo Unexplained fever	1☐ Yes 0☐ No	_____days
r. Ukubila ebusuku Night sweats	1☐ Yes 0☐ No	_____days
s. Ukungabinamdla wokutya nokuya kuncipha Loss of appetite and/or weight	1☐ Yes 0☐ No	_____days
t. Ukumimitheka Weight gain	1☐ Yes 0☐ No	_____days
u. Ukuhambisa okumandla (>kwentsuku ezi7) Chronic diarrhea (>7 days)	1☐ Yes 0☐ No	_____days
v. Ulosuleleko emlonyeni Yeast infection in mouth	1☐ Yes 0☐ No	_____days
w. Ukudumba kwamadlala la asemqaleni ngasezindlebeni Swollen lymph nodes (glands)	1☐ Yes 0☐ No	_____days
x. Intloko ebuhlungu ngokugqithisileyo Severe headache	1☐ Yes 0☐ No	_____days

**If any "Yes" answers provided, follow up on pelvic exam for genital complaints or refer for evaluation of other symptoms.*

Place **Screening PTID**

label here

e.g. PTID: ***6***_____- _____

Date:_____/_____/ __ _____

Pelvic Exam

10. Were there any palpable inguinal lymph

0☐ None 1☐ Unilateral left 2☐ Unilateral right 3☐ Bilateral

11. Were any abnormalities detected on the external genitalia by naked eye

0☐ No

1☐ Yes → **If yes, record below:**

1☐ Warts

2☐ Painful ulcer

3☐ Non-painful Vesicle(s)

4☐ Tearing/ bruising at vaginal

5☐ Cyst

6☐ Enlarged Bartholin's gland

Other (specify): _____

12. On speculum examination, was vaginal discharge present?

1☐ Yes

0☐ No → **13**

☐ Not assessed/evident bleeding. **IF BLEEDING→Stop form and inform study coordinator**

a. If yes, record colour of discharge:

1☐ Clear

2☐ White

3☐ Yellow/green

4☐ Bloody/brown

6☐ Cream-colored/gray

5☐ Mixed (specify): _____

b. Is an abnormal odour present? 1☐ Yes 0☐ No

c. If yes, consistency of discharge:

1☐ Non-homogenous, normal

2☐ Non-homogenous, curd-like

3☐ Homogenous, smooth

4☐ Homogenous, frothy

Place **Screening PTID**

label here

e.g. PTID: ***6***_____- _____

Date:_____/_____/ __ _____

13. What was the quantity of cervical

1☐ No mucus visible at os → **15.**

2☐ Mild-moderate mucus visible at

☐ Abundant mucus flowing from

14. Colour of cervical mucus:

1☐ Clear

2☐ Whit

3☐ Yellow/gree

Bloody/brow

4☐ Cream-

6☐ Mixed. Specify:_____

15. Was there any contact bleeding when swabs were taken for STI testing?

1☐ Yes 0☐ No

15a. Was there any visible abnormality/lesion suspicious for neoplasia on the

1☐ Yes 0☐ No

16. Was there any pain on bimanual examination?

1☐ Yes 0☐ No → **17**

a. If YES, how would you rate this pain?

1☐ Mild (reported by woman, no change in facial expression or muscle

2☐ Moderate (change in facial expression/muscle tone, but woman tolerates

☐ Severe (woman cannot tolerate exam without body

17. Was there any cervical motion tenderness?

1☐ Yes 0☐ No → **18**

a. If YES, how would you rate this tenderness?

1☐ Mild (reported by woman, no change in facial expression or muscle

2☐ Moderate (change in facial expression/muscle tone, but woman tolerates

☐ Severe (woman cannot tolerate exam without body

Place **Screening PTID** label here *e.g. PTID:* ***6***_____- _____

Date:_____/_____/ __ _____

18. Were there any adnexal mass(es)?

1 ☐ Yes (**Specify location(s)**: ☐ Left ☐ Right)

0 ☐ No

-8 ☐ Could not palpate adnexae

19. Was the uterus enlarged?

1 ☐ Yes, **describe**:_____

0 ☐ No

	Rapid Test	Test done and results recorded	Kit info
a	Pregnancy	1 ☐ Yes 0 ☐ No	kit # : _____ Expiry date: |__|__| /|__|__|.| / |__|__|__|__|
b	OSOM Trich	1 ☐ Yes 0 ☐ No	kit # : _____ Expiry date: |__|__| /|__|__|.| / |__|__|__|__|
c	OSOM BV	1 ☐ Yes 0 ☐ No	kit # : _____ Expiry date: |__|__| /|__|__|.| / |__|__|__|__|
d	Syphilis	1 ☐ Yes 0 ☐ No	kit # : _____ Expiry date: |__|__| /|__|__|.| / |__|__|__|__|

Clinical Summary

23. Were any diagnoses made at today's visit?

1 ☐ Yes → **Specify:** _____

_____

0 ☐ No

24. Were any referrals made at today's visit?

1 ☐ Yes → **Specify:** _____

_____

0 ☐ No

Place **Screening PTID**

label here

e.g. PTID: ***6***_____- _____

Date:_____/_____/ __ _____

25. Were any medications prescribed at today's

1☐ Yes → specify:_____

Check for allergies; record on Concomitant Medications Log.

0☐ No → **Comments**

Remember: Record all medications on the Concomitant Medications Log, including anything she is currently taking or was prescribed at this visit.

Nurse signature:_____**Date:** _____

Stamp for Data Entry:_____**Stamp for Quality Control:** _____

Place **Enrolment PTID**

label here

*e.g. PTID: 7*_____- _____

Date:_____/_____/ __ _____

Clinical CRF for Enrolment Pre-ART: 2IUDnCT

Pregnancy and Medical History

0. Are you allergic to latex?

1☐ Yes → **Use nitrile gloves**

1. 0☐ No

2. hCG Pregnancy Test:

1☐ Positive → **Stop form and inform study coordinator**

3. 0☐ Negative

Wakhe Wawathatha amachiza okuthomalalisa intsholongwane kagawulayo /Have you taken any medication(s)/treatment(s) for your HIV infection?

1☐ Yes

0☐ No → **4**

a. Yayingamachiza okuthomalalisa intsholongwane na ? Were these antiretroviral medications (e.g. odimune, tenofovir/tdf, efavirenz, lamivudine/3tc, combivir, viramune, AZT/zidovudine)?

1☐ Yes → **Stop form and inform study coordinator**

0☐ No

b. Ukuba ewe, uyawathatha ngoku lamayeza? If yes, are you currently taking these medications ?

4. 1☐ Yes

0☐ No → **update con med log**

b. Ukhe wazityura okanye wahlambisisa imiphakatho yakho izolo, namhlanje okanye izolo elinye? Did you *douche or wash inside* your vagina yesterday, today, or the day before?

1☐ Yes → **Stop form and re-schedule pt. Remind participant to not insert anything in the vagina for 3 days prior to a scheduled study visit**

0☐ No

c. Ukhe wabelana ngesondo kwintsuku ezintathu ezidlulileyo? Did you have sexual intercourse in the last 3 days?

1☐ Yes → **Stop form and re-schedule pt. Remind participant to not insert anything in the vagina for 3 days prior to a scheduled study visit**

0☐ No

Place **Enrolment PTID**

label here

*e.g. PTID: 7*_____- _____

Date:_____/_____/ __ _____

5. Ubunini umhla wakho oqale ngawo ukuya exesheni kweli lixa lokugqibela lokuhlamba

Date: |____|____| / |____|____|____| / |____|____|____|____| (dd/mmm/yyyy)

OR

⌋ Not menstruating on current contraceptive method **→6_1**

a. Inani leentsuku *How many days did that period last?* |____|____| *number of days*

6_1. Ngaphambi kokuba ungenele oluphando, ukhe waxelelwa ngugqirha okanye unesi ngokukulandelayo / *Prior to joining this study, have you ever been told you have one of the following by a doctor or nurse?*

Condition	**Yes/No/Don't know**	**If YES, in the past year?**
a. Idischarge engaqhelekanga ephuma ebufazini /*Abnormal vaginal discharge*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No
b. Amazantsi esisu adumbileyo *Pelvic Inflammatory Disease*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No
c. Inyebethu yangaphantsi (Izilonda) *Genital ulcer disease*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No
d. Intsumpa zangaphantsi *Genital warts*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No
e. Igcushuwa *Syphilis*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No

6_2. Ukhe waxelelwa ngu nesi okanye ugqirha ukuba unezinye zezizifo zilandelayo?
Have you ever been told by a doctor or nurse that you have one of the following conditions?

Condition	**Yes/No/Don't know**
a. isifo sesibindi *Hepatitis*	1☐ Yes 0☐ No 99☐ Don't know
b. Isifo sentliziyo *Heart disease*	1☐ Yes 0☐ No 99☐ Don't know
c. Iswekile *Diabetes*	1☐ Yes 0☐ No 99☐ Don't know
d. Isifuba esiminxanayo *Asthma/Breathing Problems*	1☐ Yes 0☐ No 99☐ Don't know
e. Ukuba ngqindilili kwegazi *Problems with your blood clotting*	1☐ Yes 0☐ No 99☐ Don't know
f. Isifo senzintso *Kidney disease*	1☐ Yes 0☐ No 99☐ Don't know
g. Igazi elincinci emzimbeni *Anemia*	1☐ Yes 0☐ No 99☐ Don't know

If they reported having had syphilis in question 6_1 or any of the conditions in question 6_2, note these conditions on the Pre-existing conditions CRF

Place **Enrolment PTID** label here

*e.g. PTID: 7*_____- _____

Date:_____/_____/ __ _____

6. Ingaba oku kulandelayo kuyezeka na kuwe **sukela kutyelelo lwakho lokuggibela**? Have you experienced any of the following symptoms **since your last study visit? Read list.**

Symptom	Yes/No	If yes, duration
a. Izilonda okanye inyebethu kwilungu langasese Genital sores or ulcers	1☐ Yes 0☐ No	_____days
b. Ukurhawuzelela kwilungu langasese	1☐ Yes 0☐ No	_____days
c. Ukutshisa kwilungu langasese	1☐ Yes 0☐ No	_____days
d. Ezinye iintlungu kwilungu langasese	1☐ Yes 0☐ No	_____days
e. Iintlungu xa uchama	1☐ Yes 0☐ No	_____days
f. Ukuchama okongezelelekileyo rhoqo	1☐ Yes 0☐ No	_____days
g. Ukopha okungaqhelekanga ebufazini(ingekuko ukuya exesheni) Abnormal vaginal bleeding	1☐ Yes 0☐ No	_____days
h. Ukoma okungaqhelekanga ebufazini(ungasebenzisi zomiso Abnormal vaginal dryness (without using any drying agents)	1☐ Yes 0☐ No	_____days
i. Iintlungu xa usabelana ngesondo Pain during sex	1☐ Yes 0☐ No -8☐ No sex	_____days
j. Iintlungu emazantsi esisu Lower abdominal pain	1☐ Yes 0☐ No	_____days
k. Iintlungu emazantsi omqolo Lower back pain	1☐ Yes 0☐ No	_____days
l. Ubumanzi apha ebufazini obungaqhelekanga Abnormal vaginal discharge	1☐ Yes 0☐ No	_____days
m. Ukujikelezelwa yintloko Dizziness	1☐ Yes 0☐ No	_____days
n. Isicafu cafu Nausea	1☐ Yes 0☐ No	_____days
o. Ukugabha Vomiting	1☐ Yes 0☐ No	_____days
p. Ukudinwa Fatigue	1☐ Yes 0☐ No	_____days
q. Umkhuhlane ongachazekiyo Unexplained fever	1☐ Yes 0☐ No	_____days
r. Ukubila ebusuku Night sweats	1☐ Yes 0☐ No	_____days

Place **Enrolment PTID** label here

*e.g. PTID: 7*_____- _____

Date:_____/_____/ __ _____

Symptom	Yes/No	If yes, duration
s. Ukungabinamdla wokutya nokuya kuncipha	1☐ Yes 0☐ No	_____days
t. Ukumimitheka	1☐ Yes 0☐ No	_____days
u. Ukuhambisa okumandla (>kwentsuku ezi7)	1☐ Yes 0☐ No	_____days
v. Ulosuleleko emlonyeni	1☐ Yes 0☐ No	_____days
w. Ukudumba kwamadlala la asemqaleni ngasezindlebeni Swollen lymph nodes (glands)	1☐ Yes 0☐ No	_____days
x. Intloko ebuhlungu ngokugqithisileyo	1☐ Yes 0☐ No	_____days

**If any "Yes" answers provided, follow up on pelvic exam for genital complaints or refer for evaluation of other symptoms.*

7. Ubukhe walala esibhedlela sukela kutyelelo lwakho lokugqibela? Have you been hospitalized since your last visit?

1☐ Yes → **AE log and SAE form (following exam) and inform study coordinator.**

0☐ No

Place **Enrolment PTID** label here

e.g. PTID: 7_____- _____

Date:_____/_____/ __ _____

Pelvic exam

Note: The pelvic exam should be performed following collection of genital tract specimens.

8. Were there any palpable inguinal lymph

1☐ None 2☐ Unilateral left 3☐ Unilateral right 4☐ Bilateral

9. Were any abnormalities detected on the external genitalia by naked eye exam?

0☐ No

1☐ Yes → **If yes, record below:**

1☐ Warts

2☐ Painful ulcer

3☐ Non-painful ulcer

4☐ Vesicle(s)

5☐ Tearing/ bruising at vaginal introitus

6☐ Cyst

10. On speculum examination, was vaginal discharge present?

1☐ Yes

0☐ No → **11**

a. If yes, record colour of discharge:

1☐ Clear

2☐ White

3☐ Yellow/green

4☐ Bloody/brown

6☐ Cream-colored/gray

5☐ Mixed (specify): _____

c. If yes, consistency of discharge:

1☐ Non-homogenous, normal

2☐ Non-homogenous, curd-like

3☐ Homogenous, smooth

4☐ Homogenous, frothy

Yes 0☐ No

Place **Enrolment PTID**

label here

*e.g. PTID: 7*_____- _____

Date:_____/_____/ __ _____

11. What was the quantity of cervical mucus?

1☐ No mucus visible at os → **13**

2☐ Mild-moderate mucus visible at os

3☐ Abundant mucus flowing from os

12. Colour of cervical mucus:

1☐ Clear

2☐ White

3☐ Yellow/green

4☐ Bloody/brown

6☐ Cream-colored/gray

5☐ Mixed (specify): _____

1☐ Yes 0☐ No

14. Was there any pain on bimanual examination?

1☐ Yes 0☐ No → **15**

a. If YES, how would you rate this pain?

1☐ Mild (reported by woman, no change in facial expression or muscle

2☐ Moderate (change in facial expression/muscle tone, but woman tolerates

☐ Severe (woman cannot tolerate exam without body

15. Was there any cervical motion tenderness?

1☐ Yes 0☐ No → **16**

a. If YES, how would you rate this tenderness?

1☐ Mild (reported by woman, no change in facial expression or muscle

2☐ Moderate (change in facial expression/muscle tone, but woman tolerates

☐ Severe (woman cannot tolerate exam without body

Place **Enrolment PTID**

label here

*e.g. PTID: 7*_____- _____

Date:_____/_____/ __ _____

16. Were there any adnexal mass(es)?

1 ☐ Yes (**Specify location(s)**: ☐ Left ☐ Right)

0 ☐ No

-8 ☐ Could not palpate adnexae

1 ☐ Yes, **describe**:_____

0 ☐ No

Clinical Summary

18. Were any diagnoses made at today's visit?

_____

0 ☐ No → **Comments.**

19. Were any referrals made at today's visit? **(Please be sure to check questionnaire for alcohol, mental health and violence responses for additional need for referrals)**

☐ [illegible]

_____

0 ☐ No

If evidence of infection or pregnant, notify study coordinator immediately and DO NOT proceed with randomisation and IUD insertion.

Place **Enrolment PTID**

label here

*e.g. PTID: 7*_____- _____

Date:_____/_____/ __ _____

Randomisation

20. Injectable status:
Date of last injection: |_____|____| / |___|____|____| / |___|____|____|____| (dd/mmm/yyyy)

1☐ Yes, she has had recent (in the last 120 days) exposure to injectable contraceptive

0☐ No exposure to injectable contraceptives in the last 120 days

21. Age group:

1☐ 18-23 years

2☐ 24-31 years

3☐ 32-40 years

22. Group assignment:

1☐ Group 1 = No recent exposure to injectable, 18-23 years

2☐ Group 2 = No recent exposure to injectable, 24-31 years

3☐ Group 3 = No recent exposure to injectable, 32-40 years

Group 4 = Recent exposure to injectable, 18-23 years old

4☐ Group 5 = Recent exposure to injectable, 24-31 years old

6☐ Group 6 = Recent exposure to injectable, 32-40 years old

23. Randomisation number: ☐☐☐☐

24. Arm assignment:

1☐ Arm A

2☐ Arm B

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____-_____

Date:_____/_____/ __ _____

Clinical CRF for ~~Enrolment~~ IUD Insertion ART User: 2IUDnCT

~~Pregnancy and Medical History~~

0. Are you allergic to latex?

1 ☐ Yes

1 ☐ Yes → **Use nitrile gloves**
0 ☐ No → **explain**: _____

1. What was the uterine depth during sounding?_____cm
2. hCG Pregnancy Test:

1 ☐ Yes

1 ☐ Positive → **Stop form and inform study coordinator**

0 ☐ No → **explain:** _____

0 ☐ Negative

3. Wakhe Wawathatha amachiza okuthomalalisa intsholongwane kagawulayo /Have you taken any medication(s)/treatment(s) for your HIV infection?

1 ☐ Yes → **describe:** _____

0 ☐ No
1 ☐ Yes

4. Was the participant stable following the procedure?

0 ☐ No → **Stop form and inform study coordinator**
1 ☐ Yes

a. Yayingamachiza okuthomalalisa intsholongwane na ? Were these antiretroviral medications (e.g. odimune, tenofovir/tdf, efavirenz, lamivudine/3tc, combivir, viramune, AZT/zidovudine)?

1 ☐ Yes → **specify**: _____

Check for allergies; record on Concomitant Medications Log.

0 ☐ No → **Stop form and inform study coordinator**

b. Ukuba ewe, uyawathatha ngoku lamayeza? If yes, are you currently taking these medications ?

1 ☐ Yes

0 ☐ No → **Stop form and inform study coordinator**

Remember: Record all medications on the Concomitant Medications Log, including ibuprofen given during this visit, anything she is currently taking or was prescribed at this visit. Record all pre-existing conditions on the Pre-existing Conditions CRF

Nurse signature:_____Date: _____

a. Ungaba uyopha kangangokuba usebenzisa ipad/ liner namhlanje? Do you have vaginal bleeding such that you need to use a liner/pad today?

1 ☐ Yes → **Stop form and re-schedule pt. Remind participant to not insert anything in the vagina for 3 days prior to a scheduled study visit**

0 ☐ No

Did you *douche or wash inside* your vagina yesterday, today, or the day before?

Stamp for Data Entry:_____ **Stamp for Quality Control:** _____

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

c. Ukhe wabelana ngesondo kwintsuku ezintathu ezidlulileyo? Did you have sexual intercourse in the last 3 days?

1☐ Yes → **Stop form and re-schedule pt. Remind participant to not insert anything in the vagina for 3 days prior to a scheduled study visit**

0☐ No

5. Ubunini umhla wakho oqale ngawo ukuya exesheni kweli lixa lokugqibela lokuhlamba

Date: |____|____| / |____|____|____| / |____|____|____|____| (dd/mmm/yyyy)

OR

☐ Not menstruating on current contraceptive method →**6_1**

a. Inani leentsuku How many days did that period last? |____|____| *number of days*

b. iAR uzithatha kangaphi ngemini How many times a day do you take your ART pills?

|____|____|

c. Zingaphi ipilisi ozityayo ngexesha How many pills do you take each time you take your ART medicines?

Morning (am) |____|____|

Afternoon (pm) |____|____|

d. Ingama layeza e ART ozityayo ngoku ? What is/are the names of the ART medicine(s) you are taking right now?

1☐ Tribus

2☐ Odimune

3☐ Combivir Tenofovir/t

4☐ Lamivudime

6☐ Efavirenz

7☐ Viramune

8☐ Other, specify: _____

9☐ Atroiza

10☐ 3TC

11☐ Nevirapine

12☐ Aluvia

13☐ Zidovudine

[Note: please use picture chart to assist participant in identifying the correct pill.]

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

e. Igama leklinic lofuma khona kunanakelwa kwentsholongwane ngawulayo kanye nama chiza akho ART? What is the name of the clinic where you receive your ART medicines and HIV care?

1 ☐ Hannan Crusade

2 ☐ Nyanga clinic

3 ☐ New Crossroad Clinic Vuyani

5 ☐ Old Crossroad Clinic

6 ☐ NY1 clinic Mzamonhl

7 ☐ other; specify: _____

f) Kwintsuku ezi-30 ezidlulileyo, zimini ezinfaphi okhe walibala ukutya amchiza akho entsholongwana Kanye nje?
In the last 30 days, on how many days did you miss at least one dose of your HIV medication?

| | | # days

g) Kwezi ntsuku zi-30 zidlulileyo, uwatye kakuhle kanjani amachiza akho entsolongwane njengohlobo omele ukuwatya ngalo?
In the last 30 days, how good a job did you do at taking your HIV medicines in the way that you were supposed to?

1 ☐ kabi kakhulu / Very poor

2 ☐ Kakubi /Poor

3 ☐ Ndiphakathi /Fair kakuhle /Good

4 ☐ Kakuhle kakhulu / Very good

5 ☐ kakhuhle okugqithisileyo /Excellent

h) Kwezi ntsuku zi-30 zidlulileyo, kukangaphi usitya amachiza akho entsholongwane ngendlela omele kuwatay ngayo? In the last 30 days, how often did you take your HIV medicines in the way that you were supposed to?

1 ☐ Zange / Never

2 ☐ Nqqbile/Rarely

3 ☐ Ngamanye amaxesha /Sometimes Ngesiqhelo /Usually

4 ☐ Malunga lonke ixesha /Almost always

5 ☐ Lonke ixesha/ Always

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

6_1. Ngaphambi kokuba ungenele oluphando, ukhe waxelelwa ngugqirha okanye unesi ngokukulandelayo / *Prior to joining this study, have you ever been told you have one of the following by a doctor or nurse?*

Condition	**Yes/No/Don't know**	**If YES, in the past year?**
a. Idischarge engaqhelekanga ephuma ebufazini /*Abnormal vaginal discharge*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No
b. Amazantsi esisu adumbileyo *Pelvic Inflammatory Disease*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No
c. Inyebethu yangaphantsi (Izilonda) *Genital ulcers or herpes*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No
d. Intsumpa zangaphantsi *Genital warts*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No
e. Igcushuwa *Syphilis*	1☐ Yes 0☐ No 99☐ Don't know	1☐ Yes 0☐ No

6_2. Ukhe waxelelwa ngu nesi okanye ugqirha ukuba unezinye zezizifo zilandelayo?
Have you ever been told by a doctor or nurse that you have one of the following conditions?

Condition	**Yes/No/Don't know**
a. isifo sesibindi *Hepatitis*	1☐ Yes 0☐ No 99☐ Don't know
b. Isifo sentliziyo *Heart disease*	1☐ Yes 0☐ No 99☐ Don't know
c. Iswekile *Diabetes*	1☐ Yes 0☐ No 99☐ Don't know
d. Isifuba esiminxanayo *Asthma/Breathing Problems*	1☐ Yes 0☐ No 99☐ Don't know
e. Ukuba ngqindilili kwegazi *Problems with blood clotting*	1☐ Yes 0☐ No 99☐ Don't know
f. Isifo senzintso *Kidney disease*	1☐ Yes 0☐ No 99☐ Don't know
g. Igazi elincinci emzimbeni *Anemia*	1☐ Yes 0☐ No 99☐ Don't know

If they reported having had syphilis in question 6_1 or any of the conditions in question 6_2, note these conditions on the Pre-existing conditions CRF

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

6. Ingaba oku kulandelayo kuyezeka na kuwe sukela kutyelelo lwakho lokugqibela? Have you experienced any of the following symptoms **since your last study visit? Read list.**

Symptom	Yes/No	If yes, duration
a. Izilonda okanye inyebethu kwilungu langasese Genital sores or ulcers	1☐ Yes 0☐ No	_____days
b. Ukurhawuzelela kwilungu langasese	1☐ Yes 0☐ No	_____days
c. Ukutshisa kwilungu langasese	1☐ Yes 0☐ No	_____days
d. Ezinye iintlungu kwilungu langasese	1☐ Yes 0☐ No	_____days
e. Iintlungu xa uchama	1☐ Yes 0☐ No	_____days
f. Ukuchama okongezelelekileyo rhoqo	1☐ Yes 0☐ No	_____days
g. Ukopha okungaqhelekanga ebufazini(ingekuko ukuya exesheni) Abnormal vaginal bleeding	1☐ Yes 0☐ No	_____days
h. Ukoma okungaqhelekanga ebufazini(ungasebenzisi zomiso Abnormal vaginal dryness (without using any drying agents)	1☐ Yes 0☐ No	_____days
i. Iintlungu xa usabelana ngesondo Pain during sex	1☐ Yes 0☐ No -8☐ No sex	_____days
j. Iintlungu emazantsi esisu Lower abdominal pain	1☐ Yes 0☐ No	_____days
k. Iintlungu emazantsi omqolo Lower back pain	1☐ Yes 0☐ No	_____days
l. Ubumanzi apha ebufazini obungaqhelekanga Abnormal vaginal discharge	1☐ Yes 0☐ No	_____days
m. Ukujikelezelwa yintloko Dizziness	1☐ Yes 0☐ No	_____days
n. Isicafu cafu Nausea	1☐ Yes 0☐ No	_____days
o. Ukugabha Vomiting	1☐ Yes 0☐ No	_____days
p. Ukudinwa Fatigue	1☐ Yes 0☐ No	_____days
q. Umkhuhlane ongachazekiyo Unexplained fever	1☐ Yes 0☐ No	_____days
r. Ukubila ebusuku Night sweats	1☐ Yes 0☐ No	_____days

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

Symptom	Yes/No	If yes, duration
s. Ukungabinamdla wokutya nokuya kuncipha	1☐ Yes 0☐ No	_____days
t. Ukumimitheka	1☐ Yes 0☐ No	_____days
u. Ukuhambisa okumandla (>kwentsuku ezi7)	1☐ Yes 0☐ No	_____days
v. Ulosuleleko emlonyeni	1☐ Yes 0☐ No	_____days
w. Ukudumba kwamadlala la asemqaleni ngasezindlebeni Swollen lymph nodes (glands)	1☐ Yes 0☐ No	_____days
x. Intloko ebuhlungu ngokugqithisileyo	1☐ Yes 0☐ No	_____days

**If any "Yes" answers provided, follow up on pelvic exam for genital complaints or refer for evaluation of other symptoms.*

7. Ubukhe walala esibhedlela sukela kutyelelo lwakho lokugqibela? Have you been hospitalized since your last visit?

1☐ Yes → **AE log and SAE form (following exam) and inform study coordinator.**

0☐ No

Place **Enrolment PTID** label here

e.g. PTID: 8_____- _____

Date:_____/_____/ __ _____

Pelvic exam

Note: The pelvic exam should be performed following collection of genital tract specimens.

8. Were there any palpable inguinal lymph

1☐ None 2☐ Unilateral left 3☐ Unilateral right 4☐ Bilateral

9. Were any abnormalities detected on the external genitalia by naked eye exam?

0☐ No

1☐ Yes → **If yes, record below:**

1☐ Warts

2☐ Painful ulcer

3☐ Non-painful ulcer

4☐ Vesicle(s)

5☐ Tearing/ bruising at vaginal introitus

6☐ Cyst

10. On speculum examination, was vaginal discharge present?

1☐ Yes

0☐ No → **11**

a. If yes, record colour of discharge:

1☐ Clear

2☐ White

3☐ Yellow/green

4☐ Bloody/brown

6☐ Cream-colored/gray

c. If yes, consistency of discharge:

1☐ Non-homogenous, normal

2☐ Non-homogenous, curd-like

3☐ Homogenous, smooth

4☐ Homogenous, frothy

b. Is an abnormal odour present? 1☐ Yes 0☐ No

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

11. What was the quantity of cervical mucus?

1☐ No mucus visible at os → **13**

2☐ Mild-moderate mucus visible at os

3☐ Abundant mucus flowing from os

12. Colour of cervical mucus:

1☐ Clear

2☐ White

3☐ Yellow/green

4☐ Bloody/brown

5☐ Mixed (specify): _____

13. Was there any contact bleeding when swabs were taken for genital tract

1☐ Yes 0☐ No

14. Was there any pain on bimanual examination?

1☐ Yes 0☐ No → **15**

a. If YES, how would you rate this pain?

1☐ Mild (reported by woman, no change in facial expression or muscle

2☐ Moderate (change in facial expression/muscle tone, but woman tolerates

☐ Severe (woman cannot tolerate exam without body

15. Was there any cervical motion tenderness?

1☐ Yes 0☐ No → **16**

a. If YES, how would you rate this tenderness?

1☐ Mild (reported by woman, no change in facial expression or muscle

2☐ Moderate (change in facial expression/muscle tone, but woman tolerates

☐ Severe (woman cannot tolerate exam without body

16. Were there any adnexal mass(es)?

1☐ Yes (**Specify location(s)**: ☐ Left ☐ Right)

0☐ No

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

17. Was the uterus enlarged?

1☐ Yes, **describe**:_____

0☐ No

Clinical Summary

18. Were any diagnoses made at today's visit?

_____

0☐ No → **Comments.**

19. Were any referrals made at today's visit? **(Please be sure to check questionnaire for alcohol, mental health and violence responses for additional need for referrals)**

☐ [illegible]

_____

0☐ No

If evidence of infection or pregnant, notify study coordinator immediately and DO NOT proceed with randomisation and IUD insertion.

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

Randomisation

20. Injectable status:

Date of last injection: |_____|____| / |____|____|____| / |____|____|____|
_____|(dd/mmm/yyyy)

1☐ Yes, she has had recent (in the last 120 days) exposure to injectable contraceptive

☐ [illegible]

21. Age group:

1☐ 18-23 years

2☐ 24-31 years

3☐ 32-40 years

22. Group assignment:

1☐ Group 1 = No recent exposure to injectable, 18-23 years

2☐ Group 2 = No recent exposure to injectable, 24-31 years

3☐ Group 3 = No recent exposure to injectable, 32-40 years

Group 4 = Recent exposure to injectable, 18-23 years old

4☐ Group 5 = Recent exposure to injectable, 24-31 years old

5☐ Group 6 = Recent exposure to injectable, 32-40 years old

23. Randomisation number: ☐☐☐

(ART will be given randomization envelopes sequentially from the last envelope (100th) moving backward numerically)

24. Armassignment:

1☐ Arm A

☐ Arm B

Place **Enrolment PTID**

label here

*e.g. PTID: 8*_____- _____

Date:_____/_____/ __ _____

IUD Insertion

25. Was ibuprofen provided at least 40 minutes prior to insertion?

    1☐ Yes

    0☐ No → **explain**: _____

26.

27. Was the IUD inserted?

    1☐ Yes

    0☐ No → **explain:** _____

28. Was there anything difficult about the IUD insertion?

    1☐ Yes → **describe:** _____

    0☐ No

29. Was the participant stable following the procedure?

    1☐ Yes

30.

    1☐ Yes → **specify**: _____

    Check for allergies; record on Concomitant Medications Log

    0☐ No

Notes:

_____

_____

Remember: Record all medications on the Concomitant Medications Log, including ibuprofen given during this visit, anything she is currently taking or was prescribed at this visit. Record all pre-existing conditions on the Pre-existing Conditions CRF

Nurse signature:
Date:

Stamp for Data Entry:_____**Stamp for Quality Control:** _____

Place **Screening PTID**

label here

e.g. PTID: 5_____- ____

Screening Laboratory Results CRF Pre-ART: 2IUDnCT

Instructions: Staff should initial on the day results are available/received.

Screening Lab Results		Date of collection	Test result	Date received results	Staff Initials
1.	Pregnancy test	____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Not done		
2.	OSOM Trich rapid test	____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Not done		
3.	OSOM BV blue rapid test	____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Not done		
4.	Determine Syphilis rapid test	____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Not done Determine test negative →6 If rpr done at previous visit and within 3months →6		
5.	(If POSITIVE rapid syphilis test): RPR titre	____/_____/ _____	0☐ non-reactive 2☐1:2 16☐1:16 4☐1:4 32☐1:32 8☐1:8 64☐1:64 or higher -8☐Not done, but rapid test positive → If repeating	____/_____/ _____ **1:4 or higher → notify coordinator**	
6.	Chlamydia	____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Invalid or not done → If repeating specimen, please complete a separate CRF	____/_____/ _____ **Positive→ notify coordinator**	

Place **Screening PTID**

label here

e.g. PTID: 5_____- ____

Screening Laboratory Results CRF Pre-ART: 2IUDnCT

Screening Lab Results		Date of collection	Test result	Date received results	Staff Initials
7.	Gonorrhoea	____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Invalid or not done → If repeating specimen, please complete a separate CRF	____/_____/ _____ **Positive→ notify coordinator**	
8.	Screening CD4 count	____/_____/ _____	_____cells/mm3 If indeterminate or not done, enter -8 → If repeating specimen, please complete a separate	____/_____/ _____	
9.	Pap result	____/_____/ _____	0☐ Normal 1☐ ASCUS 2☐ LSIL 3☐ HSIL → **notify PI** _____ 4☐ Other, specify:	____/_____/_____ (If pap smear results were obtained from DISA, record day results were retrieved)	

Notes: _____

_____

Stamp for Data Entry:_____**Stamp for Quality Control:** _____

Place **Screening PTID**

label here

e.g. PTID: 6_____- ____

Screening Laboratory Results CRF ART-User: 2IUDnCT

Instructions: Staff should initial on the day results are available/received.

Screening Lab Results		Date of collection	Test result	Date received results	Staff Initials
1.	Pregnancy test	____/_____/ _____	0☐ Negative 1☐ Positive -8☐Not done		
2.	OSOM Trich rapid test	____/_____/ _____	0☐ Negative 1☐ Positive -8☐Not done		
3.	OSOM BV blue rapid test	____/_____/ _____	0☐ Negative 1☐ Positive -8☐Not done		
4.	Determine Syphilis rapid test	____/_____/ _____	0☐ Negative 1☐ Positive -8☐Not done Determine test negative →6 If rpr done at previous visit and within 3 months →6		
5.	(If POSITIVE rapid syphilis test): RPR titre	____/_____/ _____	0☐ non-reactive 2☐1:2 16☐1:16 4☐1:4 32☐1:32 8☐1:8 64☐1:64 or higher -8☐Not done, but rapid test positive → If repeating	____/_____/ _____ **1:4 or higher → notify coordinator**	
6.	Chlamydia	____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Invalid or not done → If repeating specimen, please complete a separate CRF	____/_____/ _____ **Positive→ notify coordinator**	

Place **Screening PTID**

label here

e.g. PTID: 6_____- ____

Screening Laboratory Results CRF ART-User: 2IUDnCT

Screening Lab Results		Date of collection	Test result	Date received results	Staff Initials
7.	Gonorrhoea	____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Invalid or not done → If repeating specimen, please complete a separate CRF	____/_____/ _____ **Positive→ notify coordinator**	
9	Pap result	____/_____/ _____	0☐ Normal 1☐ ASCUS 2☐ LSIL 3☐ HSIL → **notify PI** _____ 4☐ Other, specify:	____/_____/_____ (If pap smear results were obtained from DISA, record day results were retrieved)	
10	Plasma Viral load	____/_____/_____ Source of information: 1☐ DISA 2☐ Printed records from	a. Detectable? 0☐No 1☐Yes 2☐NQ (<40 copies/ml) b. If detectable, _____copies/ mL	____/_____/ _____	

Stamp for Data Entry: _____ **Stamp for Quality Control:** _____

Enrolment Laboratory Results CRF Pre-ART: 2IUDnCT

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- _____

Instructions: Staff should initial on the day results are

Enrolment Lab Results	Date of collection	Test result	Date received results	Staff Initials
1. Plasma viral load ("blood" result from NHLS)	_____/_____/ _____	a. Detectable? 0☐ No 1☐ Yes 2☐ NQ (<20 copies/ml) b. If detectable, _____copies/ mL -8☐ Invalid or not done → If repeating	_____/_____/ _____	
2. Full blood count	_____/_____/ _____	a. HGB :_____g/dl b. HCT :_____l/l c. MCV :_____fl -8☐ Invalid or not done → If repeating specimen, please complete a separate CRF	_____/_____/ _____ **IF Hgb<10.0,** **prescribe FeSO4** **If less than 8.0 prescribe FeSO4 and inform**	
3. Pregnancy test	_____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Not done		

Enrolment Laboratory Results CRF Pre-ART: 2IUDnCT

Place **Enrolment PTID** label here

e.g. PTID: **7**_____- ____

Enrolment Lab Results	Date of collection	Test result	Date received results	Staff Initials
4. Genital tract viral load (MC specimen)	____/_____/ _____	a. Detectable? 0☐ No 1☐ Yes 2☐ NQ (<20 copies/ml) b. If detectable, _____copies/ mL -8☐ Invalid or not done → If repeating specimen, please complete a separate CRF	____/_____/ _____	

Notes:

_____

_____

Stamp for Data Entry:_____ **Stamp for Quality Control:** _____

Enrolment Laboratory Results CRF ART-User: 2IUDnCT

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____ - _____

Instructions: Staff should initial on the day results are

Enrolment Lab Results	Date of collection	Test result	Date received results	Staff Initials
1. Plasma viral load ("blood" result from NHLS)	_ ___/_____/ _____	a. Detectable? 0☐ No 1☐ Yes 2☐ NQ (<20 copies/ml) b. If detectable, _____copies/ mL -8☐ Invalid or not done → If repeating	_____/_____/ _____	
2. Full blood count	_____/_____/ _____	a. HGB :_____g/dl b. HCT :_____l/l c. MCV :_____fl -8☐ Invalid or not done → If repeating specimen, please complete a separate CRF	_____/_____/ _____ **IF Hgb<10.0,** **prescribe $FeSO_4$** **If less than 8.0 prescribe $FeSO_4$ and inform**	
3. Pregnancy test	_____/_____/ _____	0☐ Negative 1☐ Positive -8☐ Not done		

Enrolment Laboratory Results CRF ART-User: 2IUDnCT

Place **Enrolment PTID** label here

e.g. PTID: ***8*** _____ - _____

Enrolment Lab Results	Date of collection	Test result	Date received results	Staff Initials
4. Genital tract viral load (MC specimen)	_____/_____/ _____	a. Detectable? 0☐ No 1☐ Yes 2☐ NQ (<20 copies/ml) b. If detectable, _____copies/ mL -8☐ Invalid or not done → If repeating specimen, please complete a separate CRF	_____/_____/ _____	

Notes:

_____

_____

Stamp for Data Entry:_____ **Stamp for Quality Control:** _____

Appendix IV – Supplementary Table

Supplementary Table 1

Table 1a Association of ART status and plasma HIV-1 viral load at baseline

	ART- Naïve	ART- Using
Plasma HIV VL (0-49 copies / ml)	2 (4.2%)	45 (80.4%)
Plasma HIV VL (50-999 copies / ml)	6 (12.5%)	6 (10.7%)
Plasma HIV VL (1000-9999 copies / ml)	22 (45.8%)	3 (5.4%)
Plasma HIV VL (≥10000 copies / ml)	18 (37.5%)	2 (3.6%)
Total	48 (100%)	56

Table 1b Association of ART status and plasma HIV-1 viral load at 3 Months followed up visit

	ART- Naïve	ART- Using
Plasma HIV VL (0-49 copies / ml)	2 (4.4%)	39 (78.0%)
Plasma HIV VL (50-999 copies / ml)	10 (22.2%)	6 (12.0%)
Plasma HIV VL (1000-9999 copies / ml)	14 (31.1%)	2 (4.0%)
Plasma HIV VL (≥10000 copies / ml)	19 (42.2%)	3 (6.0%)
Total	45 (100%)	50 (100%)

Table 1c Association of ART status and plasma HIV-1 viral load at 6 Months followed up visit

	ART- Naïve	ART- Using
Plasma HIV VL (0-49 copies / ml)	1 (2%)	37 (75.5%)
Plasma HIV VL (50-999 copies / ml)	6 (12.8%)	6 (12.2%)
Plasma HIV VL (1000-9999 copies / ml)	27 (57.5%)	1 (2.0%)
Plasma HIV VL (≥10000 copies / ml)	13 (27.7%)	5 (1.2%)
Total	47 (100%)	49 (100%)