CLINICIAN

Before the scheduled enrolment visit the clinician will:

- Review all Screening part 1 and 2 laboratory results and pelvic exam findings
- All treatment requirements and repeat testing requirements will be noted on the participant's clinical information card which will be kept at the front of the participant's binder
- The last chart note before the registration chart note for enrolment will capture the clinician's entire clinical review

Enrolment clinic flow

RESEARCH ASSISTANT 1

Registration, confirm SA ID, check co-enrolment log, confirm PTID, update locator (***Co-enrolment database, participant tracking database, registration log, locator form, chart notes, tracking sheet***)

RESEARCH ASSISTANT 2

Review Screening Part I: Eligibility and Screening Part 2/Enrollment Behavioural Eligibility, collect urine
(***Non-datafax forms, laboratory specimen receipt log, chart notes, tracking sheet***)

MED TECHS.

Perform pregnancy test, perform repeat Dipstick Urinanalysis if indicated/flagged
(***Pregnancy testing log, participant clinical information card, laboratory result sheet, tracking sheet***)

NURSE

Disclose pregnancy test results
(***Chart notes, tracking sheet***)

Pregnant (participant ineligible)

Disclose Dipstick Urinanalysis results and refer if abnormal

Not pregnant Option 1
Disclose Dipstick Urinanalysis results
If unlikely to meet eligibility within scr attempt – ineligible or
Option 2 if likely to meet eligibility **c**riteria within scr attempt - pending

SITE LEADER/DESIGNEE

QC participant binder
(***Tracking sheet***)

RESEARCH ASSISTANT

Reimburse and do not rescheduled
(***Reimbursement log, chart notes, tracking sheet, update registration log, scr/enr log, participant tracking database and co-enrolment database***)

NURSE

Not pregnant (Option 3)
Disclose Dipstick Urinanalysis results, reinforce Screening IC, explain enrollment visit procedures to the participant, complete Enrolment Medical Eligibility, Baseline Family Planning, provide contraception counselling and contraception (if required) and Hep B vaccination (if required), update con-med log
(***Non datafax form, FPB, CM, chart notes, tracking sheet***)

CLINICIAN

Conduct PE (if indicated)
Provide referrals and treatment as required and reassess clinical eligibility
(***SPE, VTR, pelvic diagrams, laboratory specimen receipt log, chart notes, tracking sheet, referral letter and CM if indicated***)

↓

COUNSELLORS

Provide HIV Pre-test counselling and STI risk reduction counselling
(***Chart notes, tracking sheet***)

↓

NURSE

Blood Draw for HIV test only
(***Blood collection log, laboratory specimen receipt log, chart notes, tracking sheet***)

↓

MED TECHS.

Perform HIV Rapid tests as per HIV algorithm and SOPs
(***HIV testing logs, laboratory result sheet, SHE, tracking sheet***)

↓

COUNSELLOR

Provide HIV Post-test counselling, provide condoms
(***Chart notes, tracking sheet***)

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HIV Positive
Provide appropriate referrals
(***Chart notes, referral letter, tracking sheet***)

HIV Negative

SITE LEADER/DESIGNEE

QC participant binder
(***Tracking sheet***)

RESEARCH ASSISTANT

Reimburse and do not rescheduled
(***Reimbursement log, chart notes, tracking sheet, update registration log, scr/enr log, participant tracking database and co-enrolment database***)

CLINICIAN

*Review Screening Part 2 & Enrolment Medical Eligibility & Menstrual History and determine clinical eligibility
(***Chart notes, tracking sheet***)

SITE LEADER/DESIGNEE

Review entire binder to determine study eligibility
(***Chart notes, tracking sheet***)

RESEARCH ASSISTANT

Administer Enrolment and Specimen Storage ICs and Baseline Behaviour Assessment
(***IC, IC check list and IC comprehension checklist, BBA, chart notes, tracking sheet***)

SITE LEADER/DESIGNEE

Review ICs & complete Qu. 1 & 2 of Enrolment
(***ICs, IC checklists, ENR, chart notes, tracking sheet***)

NURSE

Blood draw for Plasma archive
(***Blood collection log, laboratory specimen receipt log, chart notes, tracking sheet***)

MED TECHS.

Process blood for archive and complete Specimen Storage/PK
(***SS-1, tracking sheet, specimen tracking log, specimen shipping log, LDMS***)

SITE LEADERS/DESIGNEE

Review participant binder to verify plasma archive collection
(***Chart notes***)

SITE LEADERS/DESIGNEE

Assign the next clinic randomisation envelope and complete the Enrolment CRF
(***Clinic randomization envelope tracking record, ENR, chart notes, tracking sheet***)

CLINICIAN

Complete the prescription
Take prescription to
Pharmacy

RESEARCH ASSISTANT

ACASI

PHARMACIST

Dispense study product to Nurse
(***Complete all accountability documents and PHR***)

NURSE

Dispense study product to participant, provide counselling and instructions on product use and adherence and observe first dose
(***Chart notes, tracking sheet***)

SITE LEADERS/DESIGNEE

QC1 of participant binder and provide a tentative date for next clinic visit
(***Tracking sheet***)

RESEARCH ASSISTANT

Schedule follow-up, remind participant to return unused product at next visit reimburse
(***Reimbursement log, chart notes, tracking sheet, update registration log, scr/enr log, participant tracking database and co-enrolment database***)

After Enrolment visit: Clinician to complete Pre-existing conditions (PRE)
QC2 to be completed before datafax