

Section 4. Participant Accrual, Screening and Enrollment

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This section provides information on requirements and procedures for recruiting, screening, and enrolling participants in MTN-025.

4.1 Study Accrual Plan

All former ASPIRE participants who meet eligibility criteria will be offered enrollment in HOPE/MTN-025. Furthermore, participants who decline participation in MTN-025 but meet decliner group eligibility criteria will be offered enrollment into the decliner population (see SSP Section 2 for all procedures relating to the decliner population). For each site, accrual will begin after all applicable approvals are obtained and a site-specific study activation notice is issued by FHI 360. There are no set accrual targets for HOPE enrollment or HOPE decliner enrollment. However, site teams are expected to make every effort to complete enrollment of all eligible HOPE participants and submit a brief summary of recruitment efforts by 15 September 2017. At this point, all sites should cease formal recruitment activities and a Pre-Screening Outcome CRF should be submitted for each ASPIRE participant. Should the target date for the end of the formal recruitment period change, sites will be notified by the study management team.

In an effort to provide women with the maximum ability to access the vaginal ring by enrolling in HOPE, sites may continue to enroll women who become eligible or who are interested in HOPE participation through 25 May 2018 (i.e., as outlined in the protocol, HOPE will close to accrual 4 months ahead of the anticipated closure of the study). While it is not expected that formal recruitment efforts take place between 15 September 2017 and 25 May 2018, sites may conduct more active follow-up with participants who previously expressed interest in enrollment but had a clinical condition that prevented their enrollment during the formal accrual period (e.g. breastfeeding or other clinical conditions that may resolve, making them eligible to enroll). A shortened follow-up period will be employed for

women who enroll after the formal accrual period; Participants who are enrolled after the formal accrual period has ended (15 September 2017) and up until 25 May 2018 should be informed that their time on study will be shorter than one year, and they will exit the study around September/October 2018. At the Enrollment visit, site staff should use the visit scheduling tool available on the Study Implementation Materials page of the HOPE website to determine the target day and visit window for the Month 1 follow-up visit. However, for all participants who enroll after 15 September 2017, site staff should inform the HOPE management team, who will provide additional guidance on each participant's visit schedule and the scheduling of her PUEV.

Examples:

- *A participant who was previously ineligible due to breastfeeding anticipates she will stop nursing in December 2017, after the formal accrual period has ended (September 15th, 2017). The site takes note of this and contacts the participant around this time, and she confirms she wants to join HOPE, even though her time on-study will be shorter and will end around September/October 2018. It is acceptable to enroll this participant up until May 25th, 2018.*
- *A participant who the site has previously been unable to contact hears about HOPE through her friends. She presents to the site in February of 2018 and is interested in screening for HOPE. It is acceptable to enroll this participant up until May 25th, 2018. She should be informed prior to enrollment that her time on study will be shorter, and will end around September/October 2018.*

Screening and enrollment data will be captured on case report forms (CRFs) and submitted to the MTN Statistical and Data Management Center (SDMC). The Eligibility Criteria CRF will be completed and submitted for all participants once they are enrolled or have screened out. The Pre-Screening Outcome CRF will be completed for all former ASPIRE participants, including those who do not screen for MTN-025/HOPE (see SSP section 4.3.2, Pre-Screening/Recruitment). The SDMC will provide information on the number of participants screened and enrolled based on data received and entered into the study database. Please see Section 16 of this manual for more details on SCHARP Enrollment Reports.

Evaluations of performance will be ongoing throughout the accrual period. Discussions will be held with sites if or when there are any recommendations to modify accrual plans. Adjustments may be made after MTN Study Monitoring Committee reviews of MTN-025.

4.1.1 Accrual SOP

Study staff members are responsible for establishing study-specific participant accrual SOPs and updating these SOPs if needed to meet site-specific accrual goals. A template Accrual SOP is available on the MTN-025 Website (<http://www.mtnstopshiv.org/node/7330>). Accrual SOPs should minimally contain the following elements:

- Site-specific monthly targets for recruitment
- Recruitment methods and materials
- Pre-screening procedures
- Considerations for MTN-025 decliner population recruitment
- Methods for tracking recruitment
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures (if not specified elsewhere)

4.2 Screening and Enrollment

4.2.1 Screening and Enrollment Timeframe

All protocol-specified screening and enrollment procedures must take place within 56 days of when the potential participant provides written informed consent for screening.

If all screening and enrollment procedures are not completed within 56 days of obtaining written informed consent for screening, the participant must repeat the entire screening process except for PTID assignment, beginning with the screening informed consent process. A new participant identification number (PTID) is not assigned when a participant repeats the screening process (see Section 4.3.5 below). The term “screening attempt” is used to describe each time a participant screens for the study (i.e., each time she provides written informed consent for screening). There is no limit to the number of screening attempts for HOPE. Participants may or may not be rescreened per the discretion of study staff.

4.2.2 Screening and Enrollment Logs

The DAIDS policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* requires study sites to document screening and enrollment activity on screening and enrollment logs. These logs may be maintained electronically but must be 21 CFR Part 11 compliant if the log is considered a source document. Screening and enrollment logs should be updated in real time and completed once a participant provides informed consent for screening. Participants who are approached, but do not provide informed consent for screening should not be included on this log. A sample screening and enrollment log suitable for use in MTN-025 is available on the MTN-025/HOPE website under *Study Implementation Materials*. Study sites are encouraged to reference the eligibility criteria item numbers in protocol Sections 5.2 and 5.3 when recording the reason for screening failure/discontinuation on the screening and enrollment logs; these item numbers are also shown on the Eligibility Checklist (available on MTN-025 website under *Study Implementation Materials*). As mentioned above, reasons for screen failure will also be recorded within the Eligibility Criteria CRF, and reasons for not contacting ASPIRE participants will be recorded on the Pre-Screening Outcome CRF, and submitted to the SDMC. If a participant is rescreened, a new Eligibility Criteria CRF should not be completed for the second screening attempt (see Section 14). Instead, the Eligibility Criteria CRF from the first screening attempt should be updated and submitted to SCHARP.

4.3 Screening

4.3.1 Definition of Screening

The term “screening” refers to all procedures performed to determine whether a potential participant is eligible to take part in MTN-025. The study eligibility criteria are listed in protocol Sections 5.2 and 5.3. Required screening procedures are listed in protocol Section 7.2. All eligibility criteria are initially assessed at the Screening Visit, and some are reconfirmed on the day of Enrollment. The Eligibility Checklist provides further operational guidance on the timing of assessment and source documentation for each eligibility criterion (<http://www.mtnstopshiv.org/node/7330>).

4.3.2 Pre-Screening/Recruitment Procedures

Sites are encouraged to implement pre-screening procedures for MTN-025 as part of their outreach and recruitment strategy. Like all outreach and recruitment strategies, pre-screening approaches and materials used during pre-screening must be IRB approved. During pre-screening, staff may explain MTN-025 to potential study participants and ascertain elements of presumptive eligibility, to be confirmed at an on-site screening visit. Process information (e.g., number of potential participants contacted, number presumptively eligible) may be recorded and stored at the study site in the absence of written informed consent from potential participants, provided the information is collected in such a manner that it cannot be linked to potential participant identifiers.

A PTID listing of all former enrolled ASPIRE participants will be provided by SDMC to help sites track recruitment activities. These listings will be site-specific and will include all participants, including transfers (listed under her original ASPIRE site) and participants from the Umkomaas site (on the Isipingo listing). Each site must develop a system to track all recruitment contact(s) and outcomes (e.g., a log, recruitment contact sheets) that is outlined in the accrual SOP. Outcomes of recruitment contacts should include:

- Scheduled for MTN-025 screening visit
- Scheduled for a MTN-025 decliner screening/enrollment visit
- Reason for not contacting the participant to screen/enroll in either cohort (e.g., unable to contact, ineligible based upon ASPIRE information (seroconverted, permanently discontinued from product, deceased), participant did not provide permission to contact for future studies, etc.)

Each ASPIRE participant will be assigned an MTN-025/HOPE Pre-Screening Number. The Pre-Screening Number will be generated in the Medidata Rave database, and site staff will transcribe each ASPIRE participant's Pre-Screening Number in the designated space next to her ASPIRE PTID on the SDMC list provided. In the event that a participant wishes to screen for HOPE at a CRS that is different than the site where she started or ended participation for ASPIRE, the ASPIRE site should get verbal approval from the participant to relay this information to the potential HOPE site so they can reach out to her. On the recruitment list of the former ASPIRE site, it should be noted that 'participant intends to screen at X CRS for HOPE.' The site *where the participant intends to screen* for HOPE should assign the pre-screening ID and complete the Pre-Screening Outcome CRF for this participant. The pre-screening site should add a new row to their recruitment list with all applicable information (ASPIRE PTID, HOPE Pre-screening ID, and outcome of recruitment contact). It is important that each former ASPIRE participant only be assigned a single pre-screening ID and a single pre-screening outcome CRF be submitted, as such, sites should communicate closely in these instances. Note that no ASPIRE records need to be transferred in these cases.

It is recommended that prescreening primarily focus on education and messages about choice rather than detailed discussion of inclusion/exclusion criteria or evaluation of presumptive eligibility. Staff carrying out pre-screening activities can maintain awareness of behavioral and basic demographic eligibility criteria, but should err on the side of referring all potentially eligible participants who express interest in HOPE to the clinic for a screening visit. For example, a prescreening session may include education about HOPE and choice, followed by asking participants if they are interested in screening, and if a participant declines, asking if she is interested in coming for just one visit to answer questions about why she does not want to participate (i.e. the decliner cohort). This approach will maximize access to MTN-025 for participants who want to join, and also help to identify the decliner cohort more clearly.

Participants may also be provided the screening informed consent or other IC materials for review prior to their screening visit as part of the pre-screening procedures. Should participants decline screening or show general disinterest in joining MTN-025 at the point of pre-screening, sites should offer enrollment into the decliner population as appropriate (see SSP section 2).

The pre-screening outcome for all ASPIRE participants will be recorded on the Pre-Screening Outcome CRF. This form will capture whether each ASPIRE participant has been contacted and has conducted a HOPE Screening Visit, or reasons why not contacted. The Pre-Screening Outcome CRF will be the only CRF that is completed for ASPIRE participants who do not complete a Screening Visit for HOPE. Should the pre-screening status of a participant change, the Pre-Screening Outcome CRF should be updated as appropriate (e.g. if contact is made with a participant who was previously uncontactable, or a participant who previously completed decliner screening changes her mind and screens for the main HOPE study).

4.3.3 Eligibility SOP

It is the responsibility of the site Investigator of Record (IoR) and other designated staff to ensure that only participants who meet the study eligibility criteria are enrolled in the study. Note that documentation should support verification of clinical eligibility by qualified staff (i.e. the medical officer), so it is recommended that the MO be one of the individuals providing sign-off on the eligibility criteria checklist. Alternatively, clinical eligibility would need to be clearly verified in the source (e.g. by the MO signing off the clinically-related eligibility criteria on the checklist or otherwise documenting in the chart notes verification that the participant is clinically eligible) which is then reviewed and signed off by designated staff. Each study site must establish a standard operating procedure (SOP) that describes how study staff will fulfill this responsibility. A template eligibility SOP is available on the MTN-025 Website (<http://www.mtnstopshiv.org/node/7330>). This SOP minimally should contain the following elements:

- Eligibility determination procedures, including:
 - Eligibility assessment procedures for MTN-025 and MTN-025 Decliner population
 - Documentation of each eligibility criteria
 - Final confirmation and sign-off procedures prior to enrollment
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures (if not specified elsewhere)

Should study staff identify that an ineligible participant has inadvertently been enrolled in the study, the IoR or designee should contact the MTN-025 study management team immediately, using the following email address: mtn025mgmt@mtnstopshiv.org.

4.3.4 Screening Procedures

Study screening procedures are specified in the MTN-025 protocol section 7.2 and reflected in the visit checklists available on the MTN-025 website under *Study Implementation Materials*.

Per protocol, informed consent for screening must be obtained prior to conduct of any screening procedures. After consenting, participants will be eligible for MTN-025 PTID assignment and undergo a series of behavioral assessments, clinical evaluations, and laboratory tests.

As part of the screening/eligibility procedures, sites will need to confirm a participant's former ASPIRE PTID. It is recommended that a certified copy of the ASPIRE PTID Name Link Log be made and filed with HOPE essential documents for this purpose. Sites should maintain the same security of this certified copy as with other study essential documents (i.e. double lock system). In order to streamline ASPIRE PTID confirmation, sites can consider a number of strategies including but not limited to: highlighting enrolled ASPIRE participants (to reduce number of participant names to search), marking PTIDs off as they screen for HOPE (thus reducing the size of the list as accrual progresses), and/or using the date of ASPIRE screening/enrollment to narrow the scope of search (if available from co-enrollment database, for example).

Locator information will be collected initially during the screening visit, and updated at visits throughout the study. Staff should confirm adequate locator information is provided prior to enrollment as defined in their site-specific SOP for retention.

Eligibility criteria which are based on self-report will be evaluated by administration of the Screening Behavioral Eligibility Worksheet (available on the MTN-025 Website: <http://www.mtnstopshiv.org/node/7330>). It is suggested that staff administer this worksheet early in the screening visit, so that more time-consuming clinical and laboratory evaluations can be avoided if the participant is determined ineligible due to behavioral criteria (unless sites decide to administer clinical and laboratory evaluations regardless of eligibility as a service to the participant). To maintain consistency across sites and participants, questions on this form will be translated into local-languages so that they are asked verbatim.

Note that given the nature of HOPE as an OLE, with the primary goal of offering access to the ring to former ASPIRE participants, it is at the discretion of the site IoR how the study area is defined under exclusion criteria 2a (plans to relocate away from the study site during study participation) and 2b (plans to travel away from the study site for more than three consecutive months during study participation) and whether a participant who has relocated since the end of ASPIRE is eligible for participation. If the participant has relocated and there is a different HOPE site closer to her, sites should discuss her willingness to screen at this alternative site (see SSP section 4.3.2). If the participant has relocated to an area without a HOPE site, but is willing to travel the distance to the clinic for study visits, and, during eligibility assessment, does not have plans to move so far away as to make attendance to visits impossible, the participant can be considered eligible at the discretion of the IoR. Any reimbursement for travel above the amount specified in the study informed consents should be approved by the site IRB. Clarification about the intention of the relocation eligibility criteria were made to the protocol in clarification memo #02.

Clinical screening visit procedures are described in detail in Section 10 of this manual, briefly:

- Clinical procedures include collection of medical, menstrual, pregnancy, and contraceptive history, concomitant medications, contraceptive medications, physical exam, and pelvic exam.
- Participants will be evaluated for use of prohibited medications, STI/RTI/UTIs, genital signs/symptoms, drug/alcohol use and overall general health.
- Participants will also receive contraceptive counseling, urine pregnancy testing, and discussion of pregnancy/breastfeeding history and future pregnancy intentions.
- Participants should receive all available test results and treatment or referrals for UTI/RTI/STIs.

Details regarding laboratory tests and sample collection at screening are provided in Section 13 of this manual. In summary:

- Participants receive testing for STIs (Gonorrhea, Chlamydia, Syphilis, Trichomonas and HIV), pregnancy testing, serum chemistries, and CBC with platelets.
 - NOTE: Chart notes should document decisions and rationale behind the retesting of abnormal, exclusionary results.
- If required for eligibility or clinically-indicated, a Pap smear specimen will be collected.
- If indicated, participants may be tested for any other conditions per clinical discretion to evaluate a participant's overall health

Note that during MTN-025 screening, sites will collect samples for local lab testing which are tested in real time, possibly maintained for a short period of time as part of standard clinical lab practices, then destroyed. No MTN-025 samples collected during screening will be placed in LDMS for storage for future testing.

The HIV testing algorithm for screening and testing consideration can be found in SSP Section 13. Participants will receive HIV pre- and post-test counseling as well as risk reduction counseling, including provision of condoms in conjunction with HIV testing during screening. Counseling considerations are described in detail in SSP Section 12.

If the participant meets eligibility criteria at the end of the screening visit, she should be scheduled for her enrollment visit, making sure the enrollment visit takes place within the allowable 56-day time frame. Participants should be provided any study informational material (i.e., factsheets and/or enrollment informed consent for review), clinic contact information, and instructions to contact the clinic with any questions as needed prior to their scheduled enrollment visit.

Between screening and enrollment, appropriately delegated site staff should review lab results and other eligibility criteria as outlined in the site-specific Eligibility SOP. Paper versions of the Screening Visit CRFs should be completed as participants are assessed for study eligibility and only data entered into Medidata Rave together with the Enrollment Visit CRFs should a participant enroll into MTN-025. Should a participant be ineligible for enrollment, the Eligibility Criteria CRF should be completed and submitted and the screening file should be retained on site per the site's Data Management SOP (see also Section 4.3.6).

4.3.5 Assignment of Participant ID Numbers

HOPE participant identification number (PTID) assignment is defined as completion of an entry on the MTN-025 PTID-Name Linkage Log for a given participant. The PTID name link log should not be completed until the participant signs the screening informed consent. Participants will not be assigned new identification numbers for their HOPE PTID. Rather, each participant will retain her Pre-screening Number, which will be considered and referred to as her HOPE PTID going forward (i.e., as of the time it is assigned).

The MTN SDMC (SCHARP) will provide each study site with a site-specific MTN-025 PTID-Name Linkage Log for sites to record each participant's HOPE PTID and name (see Figure 4-1). Note that a single PTID Name Linkage Log will be used for HOPE enrolled and decliner populations. Information regarding the storage and completion of the PTID-Name Link Log can be found in the site's Data Management SOP. Additional information on the structure and use of PTIDs can be found in the Data Collection section of this manual. Participants who complete multiple screening attempts or who have previously enrolled in the Decliner Group will retain the same HOPE PTID.

Note that MTN-025 PTIDs are not sequential, and therefore sites may need to consider implementation of shadow systems for the purposes of file organization/filing (e.g. utilizing the sequential row numbers on the PTID-name link log 1, 2, 3, etc. for filing purposes). It is acceptable to print PTID stickers to use on any paper-based study documentation within the participant file.

Figure 4-1

Sample Site-Specific PTID-Name Linkage Log (PTID List) for MTN-025

	Participant ID	Participant Name	Clinic Staff Initials	Date (dd-MMM-yy)
1				
2				
3				
4				
5				
6				
7				
8				

4.3.6 Participants Found to be Ineligible (Screen Failures)

Screening should be discontinued if the woman is determined to be ineligible. If the participant is found to be ineligible at the beginning of the screening visit, sites may choose to continue with clinical and laboratory evaluations as a service to the participant, per their site SOPs. If a participant screens out due to a clinical condition requiring follow-up, appropriate referrals should be provided to ensure well-being of the participant. Documentation of all referrals should be included in the participant chart. All lab results should be provided and explained to participants within a reasonable timeframe, regardless of eligibility determination. For all screened out participants, the following documentation should be in place:

- Completed Screening ICF
- Specific, per protocol, reason(s) for ineligibility, with date of determination, as per the completed Eligibility Checklist. Documentation in chart notes, by designated staff, can be substituted if preferred.
- Completed Pre-Screening Outcome CRF
- Completed Eligibility Criteria CRF, updated with screen failure reason(s) and submitted to SCHARP
- Necessary referrals on file (as appropriate) and documentation that any clinically significant abnormalities (labs, etc.) were communicated to the participant (even if referral is not necessary)
- All source documentation complete up until the time that ineligibility was determined
- Chart notes complete up until the time ineligibility was determined
- Indication of what visit procedures were conducted (on visit checklists)

In addition, the Screening and Enrollment Log should be updated with date of discontinuation of screening and reason for screen failure (list item number as appropriate from the Eligibility Checklist).

Note that some participants who screen out may later become eligible to join the study (e.g. after pregnancy outcome or breastfeeding cessation). In these cases, sites should discuss a plan for following up with screened out participants at a later date to assess eligibility and interest in joining the study, if applicable.

Note that being found ineligible (screen failure) does not equate to declining participation in the study. Only participants who actively decline study participation (i.e., express disinterest in enrollment) should be considered for decliner group enrollment. For example, if a

participant was ineligible due to positive HIV or pregnancy testing she should not be considered for decliner population enrollment.

4.4 Enrollment

4.4.1 Definition of Enrollment

Enrollment is defined as once a participant has provided written informed consent for enrollment and it has been determined she is eligible for the study (based on completion and final sign off of the Eligibility Checklist by designated staff).

4.4.2 Enrollment Procedures

Study enrollment procedures are specified in protocol section 7.3 and reflected in the visit checklists available on the MTN-025 website under *Study Implementation Materials*.

The following procedures will be completed as part of eligibility confirmation and prior to potential study product provision on the day of enrollment:

- Obtain informed consent for enrollment (must be conducted before any other procedures on the day of enrollment).
- Confirm 56-day screening window has not been exceeded
- Update and confirm adequacy of locator information
- Confirm behavioral eligibility criteria through administration of the Enrollment Behavioral Eligibility Worksheet
- Update medical/menstrual history since screening visit. Evaluate use of prohibited medications, STI/RTI/UTIs, genital signs/symptoms, drug/alcohol use and overall general health.
- Provide contraceptive counseling and discussion of pregnancy/breastfeeding history and future pregnancy intentions.
- Perform pregnancy testing, HIV testing, and collection of blood for plasma archive (**Note for sites not conducting finger stick HIV rapids:** to reduce participant burden, sites should consider collecting plasma archive and HIV samples as part of a single blood draw, prior to study product provision)
- In conjunction with HIV testing, participants will receive HIV pre- and post-test counseling, including offer of condoms.
- Self-collection of swab for vaginal fluid
- If indicated, conduct a physical exam
- If indicated, conduct a pelvic exam
- If indicated, participants may be tested for any other conditions per clinical discretion to evaluate a participants overall health
- Participants should receive all available test results and treatment or referrals for UTI/RTI/STIs.
- Complete the following behavioral assessments: Baseline Behavior Assessment and Baseline Vaginal Practices CRFs and the Baseline ACASI questionnaire
- Protocol counseling to include HIV risk reduction counseling and vaginal ring (VR) adherence counseling, referred hereafter as “HIV Prevention Options Counseling”
 - NOTE: Participants will be offered the ring for use, and messages will be tailored based on whether or not the participant chooses to accept study product or alternative HIV prevention options. See counseling SSP section 12.

Designated staff will document the status of each eligibility criteria by checking “Yes” or “No” on the MTN-025 Eligibility Checklist (available on the MTN-025 Website):

<http://www.mtnstopshiv.org/node/7330>). If the participant is confirmed to be eligible based on procedures listed above, the IoR or designee should complete final sign-off of eligibility on the Eligibility Checklist, have this verified by a second staff member who will also sign-off on the Eligibility Checklist. **At this point the participant is considered enrolled in the study.** All staff members who are responsible for signing off on the Eligibility Checklist should be clearly delegated per the Delegation of Authorities Log and listed as sub-investigators on the FDA Form 1572. Only staff delegated the responsibility of primary eligibility determination per site DoA may complete the first signature line; only staff delegated the responsibility of secondary/verification of eligibility may complete the second signature line. Further details regarding study product provision procedures, as indicated, can be found in SSP Section 9.

The following procedures must occur after final determination of eligibility:

- If the participant has chosen to accept the ring: provide study VR instructions and one study VR for self-insertion
- If indicated, digital exam to check for correct ring placement
- Reimbursement
- Schedule next visit

Detailed instructions on VR use including insertion/removal procedures and first product use, as well as VR adherence counseling is provided in Section 12 of this manual.

To ensure an accurate assessment of baseline conditions is documented and eligibility is confirmed on the day of potential initial study product provision, the enrollment visit should ideally not be conducted as a split visit. If, for some reason, the participant starts the enrollment visit, but cannot complete it (e.g. participant has to leave early due to an emergency or there was an abnormal finding on the day of enrollment requiring additional follow-up prior to enrollment), all procedures related to the confirmation of eligibility and collection of baseline samples for storage will need to be repeated when the participant returns to complete the enrollment visit. The only procedures that do NOT need to be repeated in these cases are the enrollment informed consent and the behavioral assessments (including the Baseline Behavior Assessment CRF, Baseline Vaginal Practices CRF, and the Baseline ACASI questionnaire). If the Options counseling was completed during the initial visit, it is up to the site's discretion whether this needs to be repeated (e.g. taking into consideration how many days it has been since she was counseled and whether her situation has changed during this time in such a way that would impact her ring choice). In the case that any baseline samples for storage (plasma, self-collected vaginal swab) were collected during the incomplete enrollment visit, these samples will need to be recollected on the date the participant enrolls in the study. In these cases, destroy the original plasma and/or swab sample, update LDMS, and document the new collection date for plasma storage and/or self-collected vaginal fluid swab on the Specimen Storage CRF within Rave. In the case that an enrollment visit is completed, but some required procedures are missed, contact the MTN-025 management team for guidance.