

## Section 4. Participant Accrual

---

This section covers general guidelines for accrual and recruitment methods at the site. Additional information regarding participant accrual can be found in the MTN 002 Protocol Section 10.5.

### 4.1 Study Accrual Plan and Site-Specific Accrual Targets

The accrual period will be eighteen months. The site will recruit and enroll a total of 16 participants.

The site will report the number of participants screened for and enrolled in the study to the MTN CORE on a weekly basis throughout the accrual period. Based on this information, the CORE will distribute a weekly accrual report to the Protocol Team. In addition, on a monthly basis, the SDMC will report to the Protocol Team the number of participants enrolled based on data received and entered into the study database.

Site staff are responsible for developing a standard operating procedure (SOP) for participant accrual and ensuring appropriate recruitment efforts undertaken to meet site-specific accrual goals. The accrual SOP should minimally contain the following elements:

- Site-specific accrual goals
- Methods for tracking accrual goals versus actual accrual
- Recruitment methods and venues
- Methods for identifying the recruitment source of participant who present to the site for screening
- Methods for timely evaluation of the utility of recruitment methods and venues
- Pre-screening procedures (if any)
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements (if not specified elsewhere)
- QC/QA procedures related to the above (if not specified elsewhere)

### 4.2 Screening and Enrollment

It is the responsibility of the site Investigator of Record and other designated staff to ensure that only participants who meet the study eligibility criteria are enrolled in the study. The study site must establish an SOP that describes how study staff will fulfill this responsibility. This SOP minimally should contain the following elements:

- Eligibility determination procedures, including:
  - During-visit eligibility assessment procedures
  - Post-visit eligibility assessment and confirmation procedures
  - Final confirmation and sign-off procedures prior to enrollment
  - Documentation
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements (if not specified elsewhere)
- QC/QA procedures related to the above (if not specified elsewhere)

Should site staff identify that an ineligible participant has inadvertently been enrolled in the study, the Investigator of Record or designee should contact the MTN 002 Protocol Safety Review Team (PSRT) for guidance on the specific action to be taken. PSRT contact details are provided in Section 11 of this manual.

#### **4.2.1 Screening and Enrollment Visit**

The term “screening” refers to all procedures undertaken to determine whether a potential participant is eligible to take part in MTN 002. For this study, both screening and enrollment procedures can occur at the same study visit. However, in some cases the screening date will be different from the enrollment date (See Section 5 on informed consent procedures for more details).

The study eligibility criteria are listed in protocol Sections 5.2 and 5.3. The Study Eligibility non-DataFax case report form also lists all of the study eligibility criteria, and can be used to document the eligibility criteria assessment for each participant. The screening and enrollment procedures are described in protocol Section 7.1, and Figure 4-2 lists the eligibility criteria to be assessed at the screening and enrollment visit.

In the case where an eligibility laboratory result is not available on the day of the screening and enrollment visit, and once the result is available it indicates the participant is not eligible, the site will notify the PSRT to request immediate termination of the participant. Once approval to terminate has been received from the PSRT, the site will contact the SDMC for instructions on how to complete the case report forms.

#### **4.2.2 Scheduled Cesarean Section (Gel Administration Visit)**

Once all lab results are received, site staff will confirm that the participant can move forward with study procedures and be scheduled for the next visit. If not confirmed at the screening and enrollment visit, study staff must confirm the date of the scheduled Cesarean section (Gel Administration Visit) within one week of its scheduled date and time of the procedure.

If the participant does not meet all eligibility criteria, she will be discontinued from the study. Study staff will not have to confirm date and time of scheduled Cesarean section for participants who are discontinued from the study.

**Figure 4-2  
Eligibility Assessments for MTN 002**

<b>Inclusion and Exclusion Criteria Assessed at Screening and Enrollment Visit</b>
Between the ages of 18 and 45, inclusive, at the time of screening and enrollment as verified by site SOP.
Be willing and able to provide written informed consent
Be in general good health
Be HIV uninfected
Be pregnant with the following characteristics – Viable, singleton, without ultrasound of significant fetal congenital anomaly, term, planned C/S
Have a normal Pap
Agrees to not participate in other investigational drug or device research studies for the duration of study participation
Be willing to undergo all study related assessments (clinical and laboratory), adhere to follow up schedule as required by the protocol
Willing to comply with study gel administration as required per protocol
Has not participated in any other device or drug study in the 30 days prior to enrollment
Be willing to abstain from vaginal sex, anal sex, or oral receptive sex two weeks after gel placement
Be willing to abstain from intravaginal practices and products
No abnormal finding on physical or pelvic examination which precludes participation in the trial
Any liver function test result greater than 1.5 X the site laboratory ULN*
Serum creatinine greater than 1.0 mg/dL*
Negative for Hepatitis B surface antigen (HBsAg)*
Current or recent use of vaginal medications
No UTI/RTI or partner exposure to UTI/RTI at screening or enrollment requiring treatment. (See protocol Section 5.3 for details)*
Have maternal or fetal condition that necessitates urgent cesarean section
Have documented rupture of the amniotic membranes, as defined in the SOP
Have known maternal disease with predictable negative affect on placental function
Have known placental/fetal abnormalities that could affect placental transfer
Have previously demonstrated hypersensitivity to any components of tenofovir 1% gel

\*Lab results may be received after the screening and enrollment visit (after enrollment into the study).

#### **4.2.3 Screening/Enrollment HIV Testing**

HIV infection status at screening will be assessed using a rapid HIV test. Any test that has been validated at the study site may be selected from among the following three tests:

- Abbott Determine
- OraSure OraQuick
- Uni-Gold Recombigen

If the site chooses to use the OraSure OraQuick and Uni-Gold Recombigen tests, FDA-approved test kits must be used.

Further instructions for performing HIV tests are provided in Section 12. All tests must be documented on local laboratory log sheets or other laboratory source documents. A second independent clinic or laboratory staff member trained in proper HIV testing and result recording procedures must review, verify, and sign-off on test results within the timeframe of the tests and prior to disclosure of results to participants. In addition to initialing or signing the testing logs to document review and verification of the results, the second staff member must also record the time at which the results were reviewed and verified

#### 4.2.4 Screening and Enrollment Timeframe

The planned cesarean section or Gel Administration day must occur no more than four weeks (28 days) after screening and enrollment procedures.

#### 4.2.5 Screening and Enrollment Logs

The DAIDS SOP for Essential Documents requires study sites to document screening and enrollment activity on screening and enrollment logs. Screening and enrollment logs may be maintained separately or combined into one log. Figure 4-3 presents a sample screening and enrollment log suitable for use in MTN 002. The study site is encouraged to reference the item numbers on the Screening Summary non-DataFax form (see Section 13) when recording the reason for screening failure/discontinuation on the screening and enrollment logs.

**Figure 4-3  
Sample Screening and Enrollment Log for MTN 002**

Sample MTN 002 Screening and Enrollment Log							
Site Name, Clinic Name, and Location:							
	Participant ID	Participant Initials	Date Study Informed Consent Signed*	Eligible?	Enrollment Date	If not enrolled, specify reason	Staff Initials
1				Y N			
2				Y N			

\* Note: Women should not be considered screened unless they have completed the screening and enrollment informed consent process.

#### 4.2.6 Assignment of Participant ID Numbers

SCHARP will provide the study site with a listing of Participant ID (PTID) numbers for use in MTN 002. As shown in Figure 4-4, the listing will be formatted such that it may be used as the log linking PTIDs and participant names at each site.

Further information regarding the structure of PTIDs for MTN 002 can be found in Section 13. PTIDs will be assigned to all potential participants who provide written informed consent for the study, regardless of whether they enroll in the study. Only one PTID will be assigned to each potential participant. Site staff is responsible for establishing SOPs and staff responsibilities for proper storage, handling, and maintenance of the PTID list such that participant confidentiality is maintained, individual PTIDs are assigned to only one participant, and individual participants are assigned only one PTID.

**Figure 4-4  
Sample Site-Specific PTID List for MTN 002**

	<b>Participant ID</b>	<b>Participant Name</b>	<b>Date</b>	<b>Staff Initials</b>
1	XXX-00001-Z			
2	XXX-00002-Z			
3	XXX-00003-Z			
4	XXX-00004-Z			
5	XXX-00005-Z			
6	XXX-00006-Z			
7	XXX-00007-Z			
8	XXX-00008-Z			
9	XXX-00009-Z			
10	XXX-00010-Z			