Section 4. Participant Accrual

This section covers general guidelines for accrual and recruitment methods at each site. Additional information regarding participant accrual can be found in the MTN-016 Protocol Section 10.5.

4.1 Study Accrual Plan

MTN-016 study staff will recruit all women who become pregnant during participation in HIV prevention trials or who have or had planned exposures in pregnancy safety studies (provided pregnancy outcome was less than 1 year from the date of the enrollment/screening visit). There is no time limit for accrual into MTN-016; accrual will remain open for the duration of MTN funding, which currently is expected through May 2013. All infants born to women enrolled in MTN-016 are to be enrolled, as well.

Potential participants will be recruited into MTN-016 as soon as possible after confirmation of the diagnosis of pregnancy and/or the pregnancy outcome is made by staff of the parent protocol. For microbicide trial participants who become pregnant prior to site-specific activation of MTN-016, study staff will retrospectively contact the participants for possible enrollment in MTN-016 (unless the participants have refused further contact with study staff). For microbicide trial participants who become pregnant after activation of MTN-016, study staff will prospectively contact the participants for possible enrollment in MTN-016. Eligible participants may be enrolled in MTN-016 up to one year from the time of diagnosis of the outcome of pregnancy. Infants may be enrolled in MTN-016 provided that they have not reached their 1 year birth date.

Per the reporting plan in Section 15 of this manual, the MTN Statistical and Data Management Center (SDMC) will routinely provide the MTN-016 Protocol Team with progress reports on the status of participant accrual at each study site.

4.2 Screening and Enrollment: Definitions and Procedures

The term “screening” refers to procedures performed to determine whether a potential participant is eligible to take part in MTN-016. The study eligibility criteria are defined in Protocol Section 5 and listed in Figure 4-1.

The study eligibility criteria for the woman are listed in Protocol Sections 5.2 and 5.3 and for the infant in Sections 5.4 and 5.5. The screening and enrollment procedures for the woman are described in protocol Section 7.1 and for the infant in protocol Section 7.6; Figure 4-1 (below) lists the eligibility criteria to be assessed at the screening and enrollment visit.

Figure 4-1 Eligibility Assessments for MTN-016
Inclusion and Exclusion Criteria Assessed at Screening and Enrollment Visit (Woman)
Be willing and able to provide written informed consent
History of participation in an HIV prevention agent trial OR planned exposure to an HIV prevention agent in a pregnancy safety trial
During participation in parent trial has or had known pregnancy confirmed by: A: two consecutive monthly study visits with positive pregnancy tests* OR B: one or more of the following: • Auscultation of fetal heart tones • Positive pregnancy confirmed by clinic staff in the presence of a clinically confirmed enlarged uterus • Positive pregnancy confirmed by clinic staff in the presence of a missed** menses by participant report • Clinical assessment of fetal movement • Demonstration of pregnancy by ultrasound
Able and willing to provide adequate locator information
Has no condition that would complicate interpretation of study outcome data, make participation unsafe or would otherwise interfere with achieving study objectives
Pregnancy outcome was diagnosed 1 year ago or less
Inclusion and Exclusion Criteria Assessed at Initial Visit (Infant)
Informed consent for participation provided by parent(s)/guardians
Born to EMBRACE participant from pregnancy concurrent with participation in parent study
Has no condition that would complicate interpretation of study outcome data, make participation unsafe or would otherwise interfere with achieving study objectives
Is less than 1 year of age

* Two consecutive monthly study visits (at least 14 days apart) in the absence of signs/symptoms of miscarriage or participant report of TOP.

** Missed menses is defined as no menses occurring at least 60 days from the first day of last menses. For amenorrheic or irregularly cycling women, two consecutive positive hCG tests (criterion A) or any of the other clinical signs of pregnancy included under the criteria B listing will be used to confirm MTN-016 eligibility.

If a participant reports recent TOP, a positive pregnancy test result may be expected. In the event of a positive pregnancy test occurring less than 60 days from reported date of TOP, delay eligibility assessment until ongoing pregnancy is confirmed at the subsequent visit and contact mtn016mgmt@mtnstopshiv.org<mailto:mtn016mgmt@mtnstopshiv.org> for guidance.

Should a participant have a positive pregnancy test later than 60 days from date of TOP (per participant report), this will serve as the first positive pregnancy test for a new pregnancy, and eligibility should be assessed per eligibility criteria in Figure 4-1.

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 CORE (mtn016mgmt@mtnstopshiv.org) for guidance on the subsequent action to be taken.

4.2.3 Screening and Enrollment Timeframe

Screening and enrollment for the woman may be at any time during the pregnancy up to and/or within 1 year of the outcome of the pregnancy. Participants are considered enrolled in MTN-016 when they have been assigned an MTN-016 PTID.

Screening and enrollment of the infant may take place from the time of birth up to but excluding the first birthday.

4.2.4 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. Appendices 4-1 and 4-2 present sample screening and enrollment logs suitable for use in MTN-016.

4.2.5 Assignment of Participant ID Numbers

Participant IDs will be assigned to each woman participant who provides informed consent. SCHARP will provide the study site with a listing of Woman Participant ID (PTID) numbers for use in MTN-016. Infant Participant IDs will correspond directly with the woman's PTID and will be assigned when the infant is enrolled in MTN-016. As shown in Figure 4-2, 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-016 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; she will maintain this PTID for all subsequent pregnancies. 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 4-2
Sample Site-Specific PTID List for MTN-016

	Woman ID	Infant ID	Participant Name	Date*	Staff Initials
1	WWW-0001-Z-0				
		WWW-0001-Z-1			
		WWW-0001-Z-2			
2	WWW-0002-Z-0				
		WWW-0002-Z-1			
3	WWW-0003-Z-0				
		WWW-0003-Z-1			
4	WWW-0004-Z-0				
		WWW-0004-Z-1			
5	WWW-0005-Z-0				
		WWW-0005-Z-1			

*If name is unknown at the time that infant ID is assigned, please include here date of ID assignment
Note: For multiple gestations, increase ID suffix by one (see WWW-0001-Z-1 and -2).