SAMPLE: DO NOT FAX TO DATAFAX

MTN 008 (180) DEM-1 (001)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Demographics

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

1. What is the participant's date of birth?..... [ ][ ] [ ][ ][ ] [ ][ ] → If unknown, record age: [ ][ ]

dd *MMM* *yy* *years*

male *female*

2. What is the participant's gender? ..... [ ] [X]

3. Does the participant consider herself to be Latina or of Hispanic origin? ..... *yes* [ ] *no* [ ]

4. What does the participant report as her race? *Mark all that apply.*

- [ ] 4a. American Indian or Alaskan Native
- [ ] 4b. Asian
- [ ] 4c. Black or African American
- [ ] 4d. Native Hawaiian or other Pacific Islander
- [ ] 4e. White
- [ ] 4f. other, specify: _____

*(**Note**: Latina is not a race.)*

Comments: _____

[ ][ ][ ][X] 14-FEB-11

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[0][1] Language

_____ Staff Initials / Date

Demographics (DEM-1)

Purpose: This form is used to document maternal participant demographic information.

General Information/Instructions: This form is completed only once for each maternal study participant, at the Screening Visit.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant's estimate of their age. Do not complete both answers.
- **Item 2:** This item does not require a response. This item (gender) has been hard-coded as "female" for all study participants.
- **Item 4:** Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background.

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MTN 008 (180)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Enrollment Eligibility—Pregnancy Cohort

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

		yes	*no*
1.	Is the participant age 18 through 40 years (inclusive) at screening?	☐	☐
2.	Is the participant willing and able to provide written informed consent to be screened for and take part in the study, including participation of the infant after delivery?	☐	☐
3.	Is the participant willing and able to provide adequate locator information, as defined in site SOP?	☐	☐
4.	Is the participant willing and able to communicate in written and spoken English?	☐	☐
5.	Is the participant HIV-uninfected (per HIV Testing Algorithm, Appendix II)?	☐	☐
6.	Is the participant currently pregnant with the following characteristics?		
6a.	viable	☐	☐
6b.	singleton	☐	☐

If no, participant is ineligible.

		yes	*no*	*N/A*
7.	Is the gestational age consistent with the following guidelines?			
7a.	for Pregnancy Cohort Group 1, between 37 0/7 and 39 1/7 weeks (inclusive) at the Enrollment Visit (Day 0)	☐	☐	☐
7b.	for Pregnancy Cohort Group 2, between 34 0/7 and 36 6/7 weeks (inclusive) at the Enrollment Visit (Day 0)	☐	☐	☐

If no, participant is ineligible.

		yes	*no*
8.	Does the participant have a Pap test result consistent with Grade 0 according to the *Female Genital Grading Table for Use in Microbicide Studies* or satisfactory evaluation of a non-Grade 0 Pap result, per clinical judgment of Site Investigator or Record (IoR)/designee) within the 12 calendar months prior to enrollment?	☐	☐
9.	Is the participant willing to abstain from the following during study participation?		
9a.	non-prescribed intravaginal products and practices (including douching and sex toys)	☐	☐
9b.	other investigational agent or device study	☐	☐

If no, participant is ineligible.

		yes	*no*
10.	Does the participant report of any of the following?		
10a.	history of adverse reaction to any component of tenofovir 1% gel	☐	☐
10b.	enrollment in any other investigational drug or device trial within 30 days prior to the Enrollment Visit (Day 0)	☐	☐
10c.	currently breastfeeding	☐	☐
10d.	within 48 hours prior to Screening or Enrollment (Day 0), use of vaginal medications (participant may return to complete study procedures after 48 hours have passed since use of vaginal medication)	☐	☐

If yes, participant is ineligible.

Enrollment Eligibility—Pregnancy Cohort (non-DataFax) - Page 1 of 2

Purpose: This form is used to document the maternal participant's eligibility for the Pregnancy Cohort. This form is completed based on review of all clinical and lab test results documentation from the participant's Screening and Enrollment Visits in addition to other protocol-specified inclusion and exclusion criteria.

General Information/Instructions: Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

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MTN 008 (180)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Enrollment Eligibility—Pregnancy Cohort

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

11. Is the participant documented to have any of the following during the current pregnancy?

	yes	no
11a. ultrasound evidence of significant fetal congenital anomaly (in the opinion of the IoR or designee)	☐	☐
11b. known rupture of the amniotic membranes	☐	☐
11c. known placental/fetal abnormalities that could affect placental transfer (e.g., placental abruption, placenta previa, placenta accreta, intrauterine growth restriction, two-vessel cord, etc.)	☐	☐
11d. known maternal disease with predictable negative effect on placental function (e.g., hypertension, diabetes mellitus, collagen vascular disease)	☐	☐

If yes, participant is ineligible.

12. Does the participant have any of the following laboratory abnormalities noted at screening?

	yes	no
12a. hemoglobin value of Grade 3 or higher according to *DAIDS Toxicity Table*	☐	☐
12b. serum creatinine greater than 1.0 mg/deciliter (dL)	☐	☐
12c. AST and/or ALT greater than 1.5 ULN (upper limit of normal)	☐	☐
12d. Hepatitis B surface antigen (HBsAg) positivity	☐	☐

If yes, participant is ineligible.

	yes	no
13. By participant report or review of medical record, in the past 8 weeks prior to enrollment (Day 0), does the participant have a diagnosis of sexually transmitted infection, including chlamydia, gonorrhea, and/or trichomoniasis?	☐	☐
14. At the time of enrollment (Day 0), does the participant have a diagnosis of symptomatic vaginitis, including bacterial vaginosis and vulvovaginal candidiasis (asymptomatic evidence of bacterial vaginosis and/or yeast is not exclusionary)?	☐	☐
15. At enrollment (Day 0) , does the participant have a clinically apparent Grade 2 or higher pelvic exam finding?	☐	☐
16. At screening or within 7 days of enrollment (Day 0), has the participant used oral and/or vaginal preparations of antibiotic or antifungal medications?	☐	☐
17. At screening or enrollment (Day 0), does the participant have any social or medical condition that, in the investigator's opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?	☐	☐

If yes, participant is ineligible.

No additional instructions.

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MTN 008 (180)

Participant ID

Site Number – Participant Number – Chk – Who (0)

Enrollment Eligibility—Lactation Cohort: Mother

Visit Date dd MMM yy

		yes	no
1.	Is the participant age 18 through 40 years (inclusive) at screening?	☐	☐
2.	Is the participant willing and able to provide written informed consent to be screened for and take part in the study?	☐	☐
3.	Is the participant willing and able to provide adequate locator information, as defined in site SOP?	☐	☐
4.	Is the participant willing and able to communicate in written and spoken English?	☐	☐
5.	Is the participant HIV-uninfected (per HIV Testing Algorithm, Appendix II)?	☐	☐
6.	Is the participant currently primarily breastfeeding a single healthy infant between the ages of 4 and 26 weeks (inclusive) according to guidelines specified in the *MTN-008 SSP Manual*?	☐	☐
7.	Is the participant intending to breastfeed during the period of anticipated study participation?	☐	☐
8.	Is the participant using an effective method of contraception at enrollment (Day 0), and intending to use an effective method for the duration of scheduled study participation; effective methods include hormonal methods, abstinence, male condoms, intrauterine device, and sterilization (of participant or her sexual partner or partners, as applicable and with verification as defined in site SOPs)?	☐	☐
9.	Does the participant have a Pap result consistent with Grade 0 according the Female Genital Grading Table for Use in Microbicide Studies or satisfactory evaluation of a non-Grade 0 Pap result, per clinical judgment of Site Investigator or Record (IoR)/designee) within the 12 calendar months prior to Enrollment (Day 0)?	☐	☐
10.	Is the participant willing to abstain from the following during study participation?		
10a.	non-prescribed intravaginal products and practices (including douching and sex toys)	☐	☐
10b.	other investigational agent or device study	☐	☐ → ***If no, participant is ineligible.***

		yes	no
11.	Was the participant enrolled in the Pregnancy Cohort?	☐	☐
12.	Is the infant excluded from participation in the MTN 008 Lacatation Cohort?	☐	☐
13.	Does the participant report of any of the following?		
13a.	history of adverse reaction to any component of tenofovir 1% gel	☐	☐
13b.	enrollment in any other investigational drug or device trial within 30 days prior to the Enrollment Visit (Day 0)	☐	☐
13c.	within 48 hours prior to Screening or Enrollment (Day 0), use of vaginal medication(s) (participant may return to complete study procedures after 48 hours have passed since use of vaginal medication)	☐	☐
13d.	within 7 days prior to Screening or Enrollment (Day 0), more than two infant feedings in a single day with nutrition other than own breast milk (e.g., formula, solids)	☐	☐ → ***If yes, participant is ineligible.***

☐ ☐ ☐ ☒ 14-FEB-11

0 1 Language

Staff Initials / Date

Enrollment Eligibility—Lactation Cohort: Mother (non-DataFax) - Page 1 of 2

Purpose: This form is used to document the maternal participant's eligibility for the Lactation Cohort. This form is completed based on review of all clinical and lab test results documentation from the participant's Screening and Enrollment Visits in addition to other protocol-specified inclusion and exclusion criteria.

General Information/Instructions: Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

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MTN 008 (180)

Participant ID

[ ][ ][ ]-[ ][ ][ ][ ]-[ ]-[0]

Site Number Participant Number Chk Who

Enrollment Eligibility—Lactation Cohort: Mother

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

	yes	no
14. Does the participant, at the time of Enrollment (Day 0), report or have clinical evidence according to the judgment of the IoR/designee of any of the following conditions?		
14a. insufficient milk supply	☐	☐
14b. mastitis	☐	☐
15. As determined by the IoR/designee, does the participant have any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease?	☐	☐
16. Does the participant have any of the following laboratory results?		
16a. positive urine pregnancy test	☐	☐
16b. serum creatinine at screening greater than 1.0 mg/dL	☐	☐
16c. AST and/or ALT at screening greater than 1.5 ULN (upper limit of normal)	☐	☐
16d. Hepatitis B surface antigen (HBsAg) positivity at screening	☐	☐
17. By participant report or review of medical record, in the past 8 weeks prior to Day 0, does the participant have a diagnosis of sexually transmitted infection, including chlamydia, gonorrhea, and/or trichomoniasis?	☐	☐
18. At the time of Enrollment (Day 0), does the participant have a diagnosis of symptomatic vaginitis, including bacterial vaginosis and vulvovaginal candidiasis (asymptomatic evidence of bacterial vaginosis and/or yeast is not exclusionary)?	☐	☐
19. At Screening and Enrollment (Day 0) , on pelvic exam does the participant have…	☐	☐
19a. incomplete postpartum involution of the uterus?	☐	☐
19b. a clinically apparent Grade 2 or higher pelvic exam finding?	☐	☐
20. At screening or within 7 days of enrollment (Day 0), has the participant used oral and/or vaginal preparations of antibiotic or antifungal medications?	☐	☐
21. At Screening or Enrollment (Day 0), does the participant have any social or medical condition that, in the investigator's opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?	☐	☐

If yes, participant is ineligible.

No additional instructions.

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MTN 008 (180)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [1]

Site Number | Participant Number | Chk | Who

Enrollment Eligibility—Lactation Cohort: Infant

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

		yes	*no*	
1.	Did mother consent for participation of both self **and infant** in Lactation Cohort?	☐	☐	
2.	Is the infant in general good health, as determined by clinical judgment of IoR/designee?	☐	☐	
3.	Is the infant between the ages of 4 and 26 weeks (inclusive) at Screening and Enrollment (Day 0)?	☐	☐	***If no, participant is ineligible.***
4.	At screening or enrollment (Day 0), does the infant have any social or medical condition that, in the investigator's opinion, would make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?	*yes* ☐	*no* ☐	***If yes, participant is ineligible.***

Enrollment Eligibility—Lactation Cohort: Infant (non-DataFax) - Page 1 of 1

Purpose: This form is used to document the infant participant's eligibility for the Lactation Cohort. This form is completed based on review of all clinical documentation from the participant's Screening and Enrollment Visits in addition to other protocol-specified inclusion and exclusion criteria.

General Information/Instructions: Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.