



MTN-011 (135)

PH-1 (410)

Note: Number pages sequentially (01, 02, 03) for each participant.

Page

Participant ID

- - - 0

Protocol PTID Chk Cohort

Product Hold/Discontinuation Log

1. Date and visit code when study product hold was initiated:

dd MMM yy visit code

2. Why is study product being held? *Mark only one per page.*

- pregnancy
- positive or indeterminate HIV test result
- adverse experience —————> *AE Log page #*
- participant report of non-monogamy
- report of PEP use for HIV exposure
- reported use of prohibited medications
- IoR/designee decision
- male partner-related, specify: _____
- other, specify: _____

3. Date of last study product use:

dd MMM yy

4. Was the participant instructed to resume study product use?

- yes —————> Date:
- no – hold continuing for another reason —————> Date:
- no – early termination —————> Date:
- no – hold continuing at scheduled termination —————> Date:
- no – permanently discontinued —————> Date:

Comments: _____

Product Hold/Discontinuation Log (PH-1)

Purpose: This form is used to document temporary clinical holds and clinical permanent discontinuations of study product use as instructed by study site staff. This form is completed each time a female participant is instructed by study staff to temporarily stop (hold) or permanently discontinue study product use. If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete one Product Hold/Discontinuation Log page for each reason. The same visit code should be used on each Log page.

Do not complete this form in cases where a participant has decided herself to not use study product.

Item-specific Instructions:

Page: Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers.

Item 2: Note that participant decline or refusal of study product is not documented as a product hold. Do not record this as a reason in "other, specify."

Item 3: Record the last date the study product was present in the vagina. Use a best estimate if the actual date cannot be determined.

***Note:** Do not wait for information about product resumption or permanent discontinuation to fax the form—fax this form to SCHARP DataFax as soon as items 1 through 3 have been completed. Refax the page once item 4 has been completed.*

Item 4: If "no - hold for another reason" is marked, record the date that the participant would have been instructed to resume study product use based on resolution of the reason indicated in item 2.

If "no – permanently discontinued" is marked, record the date the permanent discontinuation was initiated.