



MTN 012/IPM 010 (187)

PH-1 (410)

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

Page

Participant ID

- -
Site Number Participant Number Chk

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 all that apply.

2a. participant unable or unwilling to comply with required study procedures

2b. participant may be put at undue risk

2c. participant reports the use of PEP for possible HIV-1 exposure.

2d. adverse experience \longrightarrow
AE Log page # AE Log page # AE Log page #

2e. other, specify: _____

3. Date of last study product use:
dd MMM yy

4. Was the participant instructed to resume study product use?
yes no (permanently discontinued)

4a. Date and visit code when participant was instructed to resume or permanently discontinue study product use:
dd MMM yy visit code

Comments: _____

Product Hold/Discontinuation Log (PH-1)

Purpose: This form is used to document temporary holds and early permanent discontinuations of study product use for participants.

General Information/Instructions: This form is completed each time a participant is instructed to temporarily stop (hold) or permanently discontinue study product use prior to his Day 6 Visit. If, at the same study visit, a product hold/discontinuation is initiated for more than one reason, complete a single Product Hold/Discontinuation Log page and mark all applicable reasons.

In the case of temporary product holds, do not wait for information about product resumption to fax the form—fax this form to SCHARP DataFax as soon as items 1–3 have been completed. Refax the page once item 4 has been completed.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Product Hold/Discontinuation Log pages after faxing, unless instructed by SCHARP.
- **Item 2:** Mark the box to the left of the reason why the participant is being instructed to hold or permanently discontinue study product use. If product is being held or discontinued due to an adverse experience, record the page number of the AE Log documenting the product hold or permanent discontinuation. If the product hold/discontinuation is due to a reason other than the ones listed, mark the “other, specify” box and record the reason for the hold/discontinuation on the line provided.
- **Item 3:** Record the date the participant last used study product. Use a best estimate if the actual date cannot be determined.
- **Item 4:** Complete this item once study staff have determined that the participant can resume study product use or have determined that he is permanently discontinued from study product use. Mark the “yes” box if study staff instructed the participant that he can resume use of study product. If the participant was permanently discontinued from study product use, mark the “no (permanently discontinued)” box.
- **Item 4a:** Record the date and visit code on which the participant was told by a study staff member that he could resume or that he should permanently discontinue study product use.