Visit Code ☐☐.☐ 1

MTN-011 (135) PCI-1 (139)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 0
Protocol PTID Chk Cohort

Pelvic Exam—Clinically-indicated

Exam Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1. Pelvic exam assessment: ☐ *not done* ☐ *abnormal findings* ☐ *no abnormal findings* → *If no abnormal findings, go to item 2.*
   → *If not done, end of form.*

1a. Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
☐ vulvar edema	☐ vaginal edema	☐ cervical edema and/or friability	☐ odor (vaginal)
☐ vulvar erythema	☐ vaginal erythema	☐ cervical erythema	☐ condyloma, specify location: _____
☐ vulvar rash	☐ vaginal masses (polyps, myomas, possible malignancy)	☐ cervical masses (polyps, myomas, possible malignancy)	☐ adnexal masses (based on bimanual exam; not pregnancy or infection-related)
☐ vulvar tenderness	☐ vaginal abrasions or lacerations	☐ cervical motion tenderness	☐ uterine masses (based on bimanual exam)
☐ Bartholin's or Skene's gland abnormality	☐ vaginal tenderness	☐ cervical discharge	☐ uterine tenderness
Vulvar lesions	Abnormal vaginal discharge	Cervical lesions	☐ adnexal tenderness
☐ ulcer	☐ slight	☐ ulcer	☐ observed blood or bleeding; describe:
☐ blister	☐ moderate	☐ blister	_____
☐ pustule	☐ pooling	☐ pustule	_____
☐ peeling	Vaginal lesions	☐ peeling	_____
☐ ecchymosis	☐ ulcer	☐ ecchymosis	_____
	☐ blister		_____
	☐ pustule		
	☐ peeling		
	☐ ecchymosis		

☐ 1b. Other abnormal findings, specify (include anatomical location): _____

Complete or update Adverse Experience Log as applicable.

2. Were any new pelvic finding AEs reported at this visit? ☐ *yes* ☐ *no* → *If no, go to item 3.*

2a. AE Log page (#)s: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

3. Cervical ectopy: ☐ *not assessed* ☐ *0%* ☐ *1–25%* ☐ *26–50%* ☐ *51–75%* ☐ *76–100%*

☐ ☐ ☒ ☐ 14-FEB-13

01 English

Staff Initials / Date

Pelvic Exam—Clinically-indicated (PCI-1)	
Purpose:	This form is used to document the participant's clinically-indicated pelvic exam assessments. This form must be used when two pelvic exams are done on the same day.
General Information/ Instructions:	Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to SCHARP DataFax.
Item-specific Instructions:	
Item 1:	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark the "abnormal findings" box and in item 1a, mark the "observed blood or bleeding; describe" box and describe on the lines provided.
Item 1a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box and describe the abnormal finding on the line provided, including anatomical location. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 1a as AE descriptive text finding (this does not apply to observances of blood or bleeding). Observed blood or bleeding; describe: If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for AE reporting purposes. Per Study-specific Procedures (SSP) manual section 10.6, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline. Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)*. Refer to SSP manual section 10.6 for more information/guidance as needed.