Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at HPTN 035 study visits. The checklists also specify the data collection forms that must be completed at each visit. Figure 7-1 lists the checklists in the order in which they appear in this section (following page 7-3).

NOTES: Effective with Version 2.0 of this section, prior references to the HIV Prevention Trials Network (HPTN) have been replaced where applicable with references to the Microbicide Trials Network (MTN). Also, all Phase II checklists and Phase II procedural items on the Screening Part 1 and Screening Pelvic Exam checklists have been removed from this section. For reference, Phase II checklists and procedural items can be found in prior versions of this section.

Effective with Version 2.1 of this section, because participant accrual was completed on 26 July 2007, all screening and enrollment visit checklists have been removed from this section. For reference, screening and enrollment checklists and procedural items can be found in prior versions of this section.

Figure 7-1
HPTN 035 Visit Checklists (as of 1 April 2008)

Monthly Visits — Phase IIb — Non-US (Version 2.1)
Monthly Visits — Phase IIb — US (Version 2.0)
Month 3 for Phase IIb Participants — Non-US (Version 2.1)
Month 3 for Phase IIb Participants — US (Version 2.0)
Follow-Up Pelvic Exam — Phase IIb (Version 2.1)
Quarterly Visits — Phase IIb — Non-US (Version 2.1)
Quarterly Visits — Phase IIb — US (Version 2.0)
Study Exit Visit — Phase IIb — Non-US (Version 2.3)
Study Exit Visit — Phase IIb — US (Version 2.2)

In addition to the guidance provided on the checklists, detailed procedural guidance for performing clinical and laboratory procedures is provided in Sections 10 and 12, respectively. Detailed form completion instructions are provided in Section 13.6.

7.1 Use of Checklists

The visit checklists included in this section are designed to guide site staff in proper study procedures as well as to serve as source documentation of procedures performed at study visits. Note, however, that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to:

- Explain why procedures in addition to those listed on a checklist were performed
- Explain why procedures listed on a checklist were not performed
- Document procedures performed at interim visits
- Document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements)

See Sections 3 and 16 for detailed information on source documentation requirements. Tips for completing visit checklists in accordance with these requirements are as follows:

- Enter the participant identification number (PTID) and visit date in the top section of each checklist. If information is written on the front and back of the checklist, enter the PTID and visit date on both sides.

- For screening visits, enter the screening attempt number in the top section of the checklist and mark the study phase (II or IIb) for which the participant is screening.

- For follow-up visits, enter the visit code in the top section of each checklist (per the instructions in Section 13.3.3) and mark whether the visit is a study exit visit.

- Enter your initials only beside the procedures that you perform. Do not enter your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by lab staff.”

- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.

- If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why on the checklist (if not self-explanatory); initial and date this entry.

7.2 Sequence of Procedures

The sequence of procedures presented on the visit checklists is a suggested ordering. In consultation with the MTN CORE, site staff may modify the checklists included in this section to maximize the efficiency of site-specific study operations. Sites may alter the sequence of procedures to suit local staffing and logistical requirements, with the following exceptions:

- Informed consent for screening must be obtained before any screening procedures are performed.

- Informed consent for enrollment must be obtained before conduct of any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in the Enrollment sub-sections of protocol Sections 5.3.1-5.3.3. Follow-up procedures are listed in protocol Section 5.4.

- On the day of enrollment, random assignment must take place after administration of the Enrollment Behavior Assessment form and collection of blood for plasma archive.

- Pelvic exam procedures must be performed in the sequence shown on the pelvic exam checklists.

- At quarterly follow-up visits, Follow-up Behavioral Assessment forms must be administered prior to the delivery of HIV counseling.

Monthly Visits — Phase IIb — Non-US

PTID:	**Visit Date:**
Visit Code:	**Study Exit Visit?** No Yes ⇒ Stop. Use Study Exit Checklist.

1._____ Complete participant registration, confirm the participant's identity, and verify her PTID.

2._____ Review chart notes and other relevant documentation from previous visit(s).

3._____ Review elements of informed consent as needed.

4._____ Explain the content and sequence of procedures for today's visit.

5._____ Review/update locator information.

6._____ Collect ~20 mL urine and:
6a._____ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
6b._____ Complete testing logs and transcribe result onto the **Monthly or Quarterly Visit** form.

If the participant is newly identified as pregnant at this visit:
6c._____ Complete a **Pregnancy Report and History** form

If the participant is newly identified as pregnant at this visit AND is in a gel group:
6d._____ Inform the participant that she must discontinue gel use; arrange to collect her unused gel.
6e._____ Complete items 1-2 of a **Product Hold/Discontinuation** form.
6f._____ Complete a **Study Product Request Slip**, marked "HOLD." Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.

☞ *Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.*

7._____ Perform interval medical/menstrual history with active review of genital symptoms; record findings on the **Follow-up Medical History** form. Review and update the **Concomitant Medications Log**.

7a.____If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form.
7b.____If applicable, review the status of previously-reported adverse events and update previously-completed **Adverse Experience Log** forms.

8._____ If applicable, assess genital symptoms reported in the participant's interval medical/menstrual history by performing a pelvic exam per the Phase IIb Follow-Up Pelvic Exam Checklist. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

9._____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

10.____ Provide and explain available exam and lab test results.

Monthly Visits — Phase IIb — Non-US
page 2 of 4

PTID:	Visit Date:

11.____ Provide treatment for RTIs/STDs if needed. Document treatment on the **Concomitant Medications Log**.

12._____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.

13.____ Complete items 2-3 of the **Monthly or Quarterly Visit** form.

14.____ For participants assigned to gel, administer the **Gel Re-Supply Worksheet**, complete a **Study Product Request Slip**, and:

OPTION A:

_____ Give the completed white original Study Product Request Slip to the participant to deliver to the study pharmacy (where she will obtain gel supplies herself). Retain the yellow clinic copy of the Study Product Request Slip in the participant's study notebook.

OPTION B:

_____ Optional: Fax a copy of the Study Product Request Slip to the pharmacy.
_____ Deliver the completed white Study Product Request Slip to the pharmacy. Retain the clinic copy of the Study Product Request Slip in the participant's study notebook.
_____ Receive requested gel supplies.
_____ Provide gel supplies to the participant.
_____ Document the number of cartons provided to the participant here ⇒ ☐ [or in chart notes]

14a.____ Complete items 4-5 of the **Monthly or Quarterly Visit** form.

15.____ For participants assigned to gel, if gel use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents. Also document the hold/discontinuation or resumption on a **Product Hold/Discontinuation** form a **Study Product Request Slip**. Deliver the white original Study Product Request Slip to the pharmacy; retain the yellow clinic copy in the participant's study notebook.

16.____ Provide condoms, other applicable prevention supplies (if any), and/or referrals if needed/requested.

17.____ Provide HIV/STD and/or adherence counseling if needed/requested.

18.____ Reinforce availability of HIV/STD counseling, testing, and potential STD treatment for partners.

Monthly Visits — Phase IIb — Non-US

PTID:	Visit Date:

19.____Reinforce site contact information and instructions to contact the site to report symptoms — *especially genital symptoms and intermenstrual genital bleeding* — and/or to request additional information, HIV/STD counseling, and/or condoms, if needed, prior to the next visit.

19a. _____ For participants assigned to gel, reinforce the instructions to contact the site to request additional gel, if needed, prior to the next visit and remind the participant that she will be asked for information on the number of applicators she has remaining at her next visit.

Additionally Only If Clinically Indicated (C1-C8):

C1.____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe results onto the **Follow-up Laboratory Results** form.

C1a.____ If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.

C2.____ Prepare urine remaining after aliquoting for pregnancy testing for gonorrhea and chlamydia SDA at the local lab.

C3.____ Collect and prepare blood for hematology and/or coagulation testing at the local lab. Record the PTID, visit code, initial collection date, and staff initials/date on a **Safety Laboratory Results** form. Retain the form in the participant notebook for completion when results are available.

C4.____ Collect and prepare blood for syphilis serology at the local lab.

C5.____ Provide HIV pre-test counseling.

C6.____ Collect blood and perform HIV serology.

C6a. ____ If clinically indicated and/or requested by the participant, continue providing counseling while waiting for rapid HIV test result[s].

C7.____ Complete HIV testing logs and transcribe result[s] onto the **Follow-Up Laboratory Results** form. Before disclosing result[s] to the participant, obtain independent review, verification, and sign-off of result[s]; if result[s] is[are] HIV-positive, review, verification, and sign-off must be obtained from a clinician.

C7a.____ If [at least one] rapid HIV test is positive, prepare blood for HIV WB at the local lab. Record the PTID, visit code, sample 1 specimen collection date, and staff initials/date on an **HIV Test Results** form. Retain the form in the participant notebook for completion when WB results are available.

C8.____ Provide rapid HIV test result[s] and post-test counseling; provide referrals if needed/requested.

Monthly Visits — Phase IIb — Non-US

PTID:	Visit Date:

22.____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:

- ❒ Follow-up Medical History
- ❒ Gel Re-Supply Worksheet (only for participants in a gel group)
- ❒ Study Product Request Slip (only for participants in a gel group)
- ❒ Pelvic Exam Diagrams (only if pelvic exam performed to assess genital symptoms)
- ❒ Genital Bleeding Assessment (only if genital bleeding/blood reported or observed at this visit)
- ❒ LDMS Specimen Tracking Sheet (only if specimens required to be entered into LDMS were collected at this visit)
- ❒ [sites may list alternative/additional local source documents here if desired]

23.____ Fax all required DataFax forms to SCHARP DataFax:

- ❒ Monthly or Quarterly Visit

Optional:

- ❒ Concomitant Medications Log (required for updated or new pages)
- ❒ Pelvic Exam (required if pelvic exam performed to assess genital symptoms)
- ❒ Vaginal Swab Collection (required if pelvic exam performed and participant has consented to swab collection and archive)
- ❒ Pelvic Laboratory Results (required if wet prep performed to assess genital symptoms)
- ❒ Safety Laboratory Results (required if unscheduled safety laboratory tests performed at this visit)
- ❒ Follow-up Laboratory Results (required if other unscheduled laboratory tests performed at this visit)
- ❒ HIV Test Results (required if a rapid HIV test is positive)
- ❒ Adverse Experience Log (required if any AEs identified or updated at this visit)
- ❒ Product Hold/Discontinuation (required if product use held/discontinued or resumed at this visit)
- ❒ Pregnancy Report and History (required if pregnancy identified at this visit)
- ❒ Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

Monthly Visits — Phase IIb — US

PTID:	Visit Date:
Visit Code:	Study Exit Visit? No Yes ⇒ Stop. Use Study Exit Checklist.

1._____ Complete participant registration, confirm the participant's identity, and verify her PTID.

2._____ Review chart notes and other relevant documentation from previous visit(s).

3._____ Review elements of informed consent as needed.

4._____ Explain the content and sequence of procedures for today's visit.

5._____ Review/update locator information.

6._____ Collect ~20 mL urine and:
6a._____ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
6b._____ Complete testing logs and transcribe result onto the **Monthly or Quarterly Visit** form.

If the participant is newly identified as pregnant at this visit:
6c._____ Complete a **Pregnancy Report and History** form

If the participant is newly identified as pregnant at this visit AND is in a gel group:
6d._____ Inform the participant that she must discontinue gel use; arrange to collect her unused gel.
6e._____ Complete items 1-2 of a **Product Hold/Discontinuation** form.
6f._____ Complete a **Study Product Request Slip**, marked "HOLD." Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.

☞ *Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.*

7._____ Perform interval medical/menstrual history with active review of genital symptoms; record findings on the **Follow-up Medical History** form. Review and update the **Concomitant Medications Log**.

7a.____If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form.
7b.____If applicable, review the status of previously-reported adverse events and update previously-completed **Adverse Experience Log** forms.

8._____ If applicable, assess genital symptoms reported in the participant's interval medical/menstrual history by performing a pelvic exam per the Phase IIb Follow-Up Pelvic Exam Checklist. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

9._____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

Monthly Visits — Phase IIb — US
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PTID:	Visit Date:

10.____ Provide and explain available exam and lab test results.

11.____ Provide treatment for RTIs/STDs if needed. Document treatment on the **Concomitant Medications Log**.

12._____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.

13.____ Complete items 2-3 of the **Monthly or Quarterly Visit** form.

14.____ <u>For participants assigned to gel:</u>

14a. _____ Administer the **Gel Re-Supply Worksheet**.

14b. _____ Complete a **Study Product Request Slip**.

14c. _____ Fax a copy of the Study Product Request Slip to the pharmacy. Arrange for delivery of the white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.

14d. _____ While waiting for gel supplies to be delivered, continue with the remainder of this checklist. After gel supplies are received, provide the supplies to the participant and document the number of cartons provided here → ☐

14e. _____ Complete items 4-5 of the **Monthly or Quarterly Visit** form.

15.____ <u>For participants assigned to gel</u>, if gel use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents. Also document the hold/discontinuation or resumption on a **Product Hold/Discontinuation** form a **Study Product Request Slip**. Deliver the white original Study Product Request Slip to the pharmacy; retain the yellow clinic copy in the participant's study notebook.

16.____ Provide condoms, other applicable prevention supplies (if any), and/or referrals if needed/requested.

17.____ Provide HIV/STD and/or adherence counseling if needed/requested.

18.____ Reinforce availability of HIV/STD counseling, testing, and potential STD treatment for partners.

19.____Reinforce site contact information and instructions to contact the site to report symptoms — *especially genital symptoms and intermenstrual genital bleeding* — and/or to request additional information, HIV/STD counseling, and/or condoms, if needed, prior to the next visit.

19a. _____ <u>For participants assigned to gel</u>, reinforce the instructions to contact the site to request additional gel, if needed, prior to the next visit and remind the participant that she will be asked for information on the number of applicators she has remaining at her next visit.

Monthly Visits — Phase IIb — US

PTID:	Visit Date:

Additionally Only If Clinically Indicated (C1-C8):

C1.____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe results onto the **Follow-up Laboratory Results** form.

C1a.____ If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.

C2.____ Transfer remaining (~15 mL) urine to conical tube and refrigerate pending delivery to the local lab for shipment to the Central Lab for gonorrhea and chlamydia SDA.

C3.____ Collect and prepare blood for hematology and/or coagulation testing at the at the local lab. Record the PTID, visit code, initial collection date, and staff initials/date on a **Safety Laboratory Results** form. Retain the form in the participant notebook for completion when results are available.

C4.____ Collect and prepare blood for syphilis serology at the local lab.

C5.____ Provide HIV pre-test counseling.

C6.____ Collect blood and perform HIV serology.

C6a. ____ If clinically indicated and/or requested by the participant, continue providing counseling while waiting for rapid HIV test result.

C7.____ Complete HIV testing logs and transcribe result onto the **Follow-Up Laboratory Results** form. Before disclosing result to the participant, obtain independent review, verification, and sign-off of result; if result is HIV-positive, review, verification, and sign-off must be obtained from a clinician.

C7a.____ If the rapid HIV test is positive, prepare remaining blood for HIV WB. Record the PTID, visit code, sample 1 specimen collection date, and staff initials/date on an **HIV Test Results** form. Retain the form in the participant notebook for completion when WB results are available.

C8.____ Provide rapid HIV test result and post-test counseling; provide referrals if needed/requested.

Monthly Visits — Phase IIb — US
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PTID:	Visit Date:

20.____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:

- ❒ Follow-up Medical History
- ❒ Gel Re-Supply Worksheet (only for participants in a gel group)
- ❒ Study Product Request Slip (only for participants in a gel group)
- ❒ Pelvic Exam Diagrams (only if pelvic exam performed to assess genital symptoms)
- ❒ Genital Bleeding Assessment (only if genital bleeding/blood reported or observed at this visit)
- ❒ LDMS Specimen Tracking Sheet (only if specimens required to be entered into LDMS were collected at this visit)
- ❒ [sites may list alternative/additional local source documents here if desired]

21.____ Fax all required DataFax forms to SCHARP DataFax:

- ❒ Monthly or Quarterly Visit

Optional:

- ❒ Concomitant Medications Log (required for updated or new pages)
- ❒ Pelvic Exam (required if pelvic exam performed to assess genital symptoms)
- ❒ Pelvic Laboratory Results (required if wet prep performed to assess genital symptoms)
- ❒ Safety Laboratory Results (required if unscheduled safety laboratory tests performed at this visit)
- ❒ Follow-up Laboratory Results (required if other unscheduled laboratory tests performed at this visit)
- ❒ HIV Test Results (required if rapid HIV test is positive)
- ❒ Adverse Experience Log (required if any AEs identified or updated at this visit)
- ❒ Product Hold/Discontinuation (required if product use held/discontinued or resumed at this visit)
- ❒ Pregnancy Report and History (required if pregnancy identified at this visit)
- ❒ Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

Month 3 for Phase IIb Participants — Non-US

PTID:	Visit Date:
Visit Code:	Study Exit Visit? No Yes ⇒ Stop. Use Study Exit Checklist.

1._____ Complete participant registration, confirm the participant's identity, and verify her PTID.

2._____ Review chart notes and other relevant documentation from previous visit(s).

3._____ Review elements of informed consent as needed.

4._____ Explain the content and sequence of procedures for today's visit.

5._____ Review/update locator information.

6._____ Administer the **Follow-up Behavior Assessment** and **Acceptability Assessment**.
☞ *These forms must be administered prior to the delivery of HIV/STD counseling, by a staff member who has not previously provided HIV/STD counseling to the participant.*

7._____ Provide HIV pre-test and risk reduction counseling. Provide condoms, other applicable prevention supplies (if any), and/or referrals if needed/requested. Reinforce availability of HIV/STD counseling, testing, and potential STD treatment for partners.

8._____ Collect blood:
❒ 3 mL in lavender top tube (EDTA)
❒ 3 mL in blue top tube (sodium citrate)

9._____ Perform HIV serology.

9a. ____ If clinically indicated and/or requested by the participant, continue providing counseling while waiting for rapid HIV test result[s].

10.____ Complete HIV testing logs and transcribe result[s] onto the **Follow-Up Laboratory Results** form. Before disclosing result[s] to the participant, obtain independent review, verification, and sign-off of result[s]; if result[s] is[are] HIV-positive, review, verification, and sign-off must be obtained from a clinician.

11.____ Provide rapid HIV test result[s] and post-test counseling; provide referrals if needed/requested.

12.____ Prepare remaining blood for hematology and coagulation testing at the local lab.

12a.____ If [at least one] rapid HIV test is positive, an HIV WB also will be performed at the local lab. Record the PTID, visit code, sample 1 specimen collection date, and staff initials/date on an **HIV Test Results** form. Retain the form in the participant notebook for completion when WB results are available.

Month 3 for Phase IIb Participants — Non-US

PTID:	Visit Date:

13.____ Collect ~20 mL urine and:
13a.____ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
13b.____ Complete testing logs and transcribe result onto the **Monthly or Quarterly Visit** form.

If the participant is newly identified as pregnant at this visit:
13c.____ Complete a **Pregnancy Report and History** form.

If the participant is newly identified as pregnant at this visit AND is in a gel group:
13d.____ Inform the participant that she must discontinue gel use; arrange to collect her unused gel.
13e.____ Complete items 1-2 of a **Product Hold/Discontinuation** form.
13f.____ Complete a **Study Product Request Slip**, marked "HOLD." Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.

☞ *Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.*

14.____ Perform interval medical/menstrual history with active review of genital symptoms; record findings on the **Follow-up Medical History** form. Review and update the **Concomitant Medications Log**.

14a.____ If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form.
14b.____ If applicable, review the status of previously-reported adverse events and update previously-completed **Adverse Experience Log** forms.

15.____ Perform pelvic exam per the Follow-Up Pelvic Exam Checklist. During exam, if applicable, assess genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

16.____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

17.____ Provide and explain available exam and lab test results.

18.____ Provide treatment for RTIs/STDs if needed. Document treatment on the **Concomitant Medications Log**.

19._____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.

20.____ Complete items 2-3 of the **Monthly or Quarterly Visit** form.

Month 3 for Phase IIb Participants — Non-US
page 3 of 5

PTID:	Visit Date:

21.____ For participants assigned to gel, administer the **Gel Re-Supply Worksheet**, complete a **Study Product Request Slip**, and:

OPTION A:

_____ Give the completed white original Study Product Request Slip to the participant to deliver to the study pharmacy (where she will obtain gel supplies herself). Retain the yellow clinic copy of the Study Product Request Slip in the participant's study notebook.

OPTION B:

_____ Optional: Fax a copy of the Study Product Request Slip to the pharmacy.
_____ Deliver the completed white Study Product Request Slip to the pharmacy. Retain the clinic copy of the Study Product Request Slip in the participant's study notebook.
_____ Receive requested gel supplies.
_____ Provide gel supplies to the participant.
_____ Document the number of cartons provided to the participant here ⇒ ☐ [or in chart notes]

21a.____ Complete items 4-5 of the **Monthly or Quarterly Visit** form.

22.____ For participants assigned to gel, if gel use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents. Also document the hold/discontinuation or resumption on a **Product Hold/Discontinuation** form a **Study Product Request Slip**. Deliver the white original Study Product Request Slip to the pharmacy; retain the yellow clinic copy in the participant's study notebook.

23.____ Provide adherence counseling if needed/requested.

24.____ Reinforce site contact information and instructions to contact the site to report symptoms — *especially genital symptoms and intermenstrual genital bleeding* — and/or to request additional information, HIV/STD counseling, and/or condoms, if needed, prior to the next visit.

24a. _____ For participants assigned to gel, reinforce the instructions to contact the site to request additional gel, if needed, prior to the next visit and remind the participant that she will be asked for information on the number of applicators she has remaining at her next visit.

Month 3 for Phase IIb Participants — Non-US

PTID:	Visit Date:

Additionally Only If Clinically Indicated (C1-C3):

C1.____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe results onto the **Follow-up Laboratory Results** form.

C1a.____ If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.

C2.____ Prepare urine remaining after aliquoting for pregnancy testing for gonorrhea and chlamydia SDA at the local lab.

C3.____ Collect and prepare blood for syphilis serology at the local lab.

Month 3 for Phase IIb Participants — Non-US

PTID:	Visit Date:

25.____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:

- ❒ Follow-up Medical History
- ❒ Pelvic Exam Diagrams
- ❒ Gel Re-Supply Worksheet (only for participants in a gel group)
- ❒ Study Product Request Slip (only for participants in a gel group)
- ❒ Genital Bleeding Assessment (only if genital bleeding/blood reported or observed at this visit)
- ❒ LDMS Specimen Tracking Sheet
- ❒ [sites may list alternative/additional local source documents here if desired]

26.____ Fax all required DataFax forms to SCHARP DataFax:

- ❒ Monthly or Quarterly Visit
- ❒ Follow-up Behavioral Assessment
- ❒ Acceptability Assessment
- ❒ Pelvic Exam
- ❒ Pelvic Laboratory Results
- ❒ Vaginal Swab Collection (if participant has consented to swab collection and archive)
- ❒ Follow-up Laboratory Results (when all results available)
- ❒ Safety Laboratory Results (when all results available)

Optional:

- ❒ Concomitant Medications Log (required for updated or new pages)
- ❒ HIV Test Results (required if rapid HIV test is positive)
- ❒ Adverse Experience Log (required if any AEs identified or updated at this visit)
- ❒ Product Hold/Discontinuation (required if product use held/discontinued or resumed at this visit)
- ❒ Pregnancy Report and History (required if pregnancy identified at this visit)
- ❒ Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

Month 3 for Phase IIb Participants — US

PTID:	Visit Date:
Visit Code:	Study Exit Visit? No Yes ⇒ Stop. Use Study Exit Checklist.

1._____ Complete participant registration, confirm the participant's identity, and verify her PTID.

2._____ Review chart notes and other relevant documentation from previous visit(s).

3._____ Review elements of informed consent as needed.

4._____ Explain the content and sequence of procedures for today's visit.

5._____ Review/update locator information.

6._____ Administer the **Follow-up Behavior Assessment** and **Acceptability Assessment**.
☞ *These forms must be administered prior to the delivery of HIV/STD counseling, by a staff member who has not previously provided HIV/STD counseling to the participant.*

7._____ Provide HIV pre-test and risk reduction counseling. Provide condoms, other applicable prevention supplies (if any), and/or referrals if needed/requested. Reinforce availability of HIV/STD counseling, testing, and potential STD treatment for partners.

8._____ Collect blood:
❒ 3 mL in lavender top tube (EDTA)
❒ 2 mL in lavender top tube (EDTA)
❒ 2.7 ml in blue top tube (sodium citrate)

9._____ Perform HIV serology.

9a. ____ If clinically indicated and/or requested by the participant, continue providing counseling while waiting for rapid HIV test result.

10.____ Complete HIV testing logs and transcribe result onto the **Follow-Up Laboratory Results** form. Before disclosing result to the participant, obtain independent review, verification, and sign-off of result; if result is HIV-positive, review, verification, and sign-off must be obtained from a clinician.

11.____ Provide rapid HIV test result and post-test counseling; provide referrals if needed/requested.

12.____ Prepare remaining blood for hematology and coagulation testing.

12a.____ If the rapid HIV test is positive, an HIV WB also will be performed. Record the PTID, visit code, sample 1 specimen collection date, and staff initials/date on an **HIV Test Results** form. Retain the form in the participant notebook for completion when WB results are available.

Month 3 for Phase IIb Participants — US
page 2 of 4

PTID:	Visit Date:

13.____ Collect ~20 mL urine and:
13a.____ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
13b.____ Complete testing logs and transcribe result onto the **Monthly or Quarterly Visit** form.

If the participant is newly identified as pregnant at this visit:
13c.____ Complete a **Pregnancy Report and History** form.

If the participant is newly identified as pregnant at this visit AND is in a gel group:
13d.____ Inform the participant that she must discontinue gel use; arrange to collect her unused gel.
13e.____ Complete items 1-2 of a **Product Hold/Discontinuation** form.
13f.____ Complete a **Study Product Request Slip**, marked "HOLD." Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.

☞ *Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.*

14.____ Perform interval medical/menstrual history with active review of genital symptoms; record findings on the **Follow-up Medical History** form. Review and update the **Concomitant Medications Log**.

14a.____ If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form.
14b.____ If applicable, review the status of previously-reported adverse events and update previously-completed **Adverse Experience Log** forms.

15.____ Perform pelvic exam per the Follow-Up Pelvic Exam Checklist. During exam, if applicable, assess genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

16.____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

17.____ Provide and explain available exam and lab test results.

18.____ Provide treatment for RTIs/STDs if needed. Document treatment on the **Concomitant Medications Log**.

19.____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.

20.____ Complete items 2-3 of the **Monthly or Quarterly Visit** form.

Month 3 for Phase IIb Participants — US
page 3 of 4

PTID:	Visit Date:

21.____ For participants assigned to gel:
- 21a. _____ Administer the **Gel Re-Supply Worksheet**.
- 21b. _____ Complete a **Study Product Request Slip**.
- 21c. _____ Fax a copy of the Study Product Request Slip to the pharmacy. Arrange for delivery of the white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.
- 21d. _____ While waiting for gel supplies to be delivered, continue with the remainder of this checklist. After gel supplies are received, provide the supplies to the participant and document the number of cartons provided here → ☐
- 21e. _____ Complete items 4-5 of the **Monthly or Quarterly Visit** form.

22.____ For participants assigned to gel, if gel use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents. Also document the hold/discontinuation or resumption on a **Product Hold/Discontinuation** form a **Study Product Request Slip**. Deliver the white original Study Product Request Slip to the pharmacy; retain the yellow clinic copy in the participant's study notebook.

23.____ Provide adherence counseling if needed/requested.

24.____ Reinforce site contact information and instructions to contact the site to report symptoms — *especially genital symptoms and intermenstrual genital bleeding* — and/or to request additional information, HIV/STD counseling, and/or condoms, if needed, prior to the next visit.

- 24a. _____ For participants assigned to gel, reinforce the instructions to contact the site to request additional gel, if needed, prior to the next visit and remind the participant that she will be asked for information on the number of applicators she has remaining at her next visit.

Additionally Only If Clinically Indicated (C1-C3):

C1.____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe results onto the **Follow-up Laboratory Results** form.

- C1a.____ If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.

C2.____ Transfer remaining (15 mL) urine to conical tube and refrigerate pending delivery to the local lab for shipment to the Central Lab for gonorrhea and chlamydia SDA.

C3.____ Collect and prepare blood for syphilis serology at the local lab.

Month 3 for Phase IIb Participants — US
page 4 of 4

PTID:	Visit Date:

25.____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:

- ❒ Follow-up Medical History
- ❒ Pelvic Exam Diagrams
- ❒ Gel Re-Supply Worksheet (only for participants in a gel group)
- ❒ Study Product Request Slip (only for participants in a gel group)
- ❒ Genital Bleeding Assessment (only if genital bleeding/blood reported or observed at this visit)
- ❒ LDMS Specimen Tracking Sheet
- ❒ [sites may list alternative/additional local source documents here if desired]

26.____ Fax all required DataFax forms to SCHARP DataFax:

- ❒ Monthly or Quarterly Visit
- ❒ Follow-up Behavioral Assessment
- ❒ Acceptability Assessment
- ❒ Pelvic Exam
- ❒ Pelvic Laboratory Results
- ❒ Follow-up Laboratory Results (when all results available)
- ❒ Safety Laboratory Results (when all results available)

Optional:

- ❒ Concomitant Medications Log (required for updated or new pages)
- ❒ HIV Test Results (required if rapid HIV test is positive)
- ❒ Adverse Experience Log (required if any AEs identified or updated at this visit)
- ❒ Product Hold/Discontinuation (required if product use held/discontinued or resumed at this visit)
- ❒ Pregnancy Report and History (required if pregnancy identified at this visit)
- ❒ Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

FOLLOW-UP Pelvic Exam — Phase IIb

PTID:	Exam Date:
Last Scheduled Pelvic Exam? Yes No	

1._____ Review chart notes and other relevant documentation from previous visit(s).

2._____ Using a pencil, write the PTID and specimen collection date on the frosted side of two microscope slides. Then affix a SCHARP-provided PTID label to the other side of each slide (under the pencil markings) and write the specimen collection date in ink on each label.

3._____ Affix a SCHARP-provided PTID label to a glass or plastic tube containing approximately six drops (100 µL) of saline. Write the specimen collection date in ink on the label.

4._____ Explain the exam procedures to the participant and answer any participant questions.

5._____ Position and drape the participant comfortably.

6._____ Palpate inguinal lymph nodes. Document abnormal findings on the **Pelvic Exam** form.

7._____ Inspect external genitalia. Note all findings on the Pelvic Exam Diagrams. Document abnormal findings on the **Pelvic Exam** form.

8._____ Insert speculum, using warm water as lubricant if needed. Observe general state of the cervix.

9._____ Assess for homogenous discharge. Record observation on the **Pelvic Laboratory Results** form. If homogenous discharge is present, document on the Pelvic Exam Diagrams and **Pelvic Exam** form.

10.____ Place pH strip against the lateral vaginal wall until moistened. Alternatively, collect vaginal fluids from the lateral vaginal wall via swab and swab fluids onto the pH strip. Record on the **Pelvic Laboratory Results** form.

11.____ Swab vaginal fluids from the lateral vaginal wall for Gram stain; do not place the swab in saline, transport medium, or a transport container prior to slide preparation (see also SSP Section 12.6.3):
11a.____ Roll the swab across two labeled slides and then allow the specimens to air dry.
11b.____ Document specimen collection on the **Pelvic Exam** form and the **LDMS Specimen Tracking Sheet**.

FOLLOW-UP Pelvic Exam — Phase IIb
page 2 of 2

PTID:	Exam Date:

12.____ Swab vaginal fluids from the lateral vaginal wall for wet prep; proceed immediately to Step 12a or placed the swab in a glass or plastic tube containing approximately six drops (100 µL) of saline to allow for non-immediate slide preparation and evaluation, as follows (see also SSP Section 12.6.2):

12a.____ Smear vaginal fluids from the swab onto two labeled slides.

12b.____ Apply KOH to one slide, perform whiff test, then apply coverslip.

12c.____ Apply saline to the second slide, emulsify, and apply coverslip. Immediately evaluate for trichomonads, yeast buds, pseudohyphae, and clue cells.

12d.____ Evaluate KOH slide for yeast buds and pseudohyphae.

12e.____ If slides are read in-clinic by clinical staff, record results directly onto the **Pelvic Laboratory Results** form. If slides are read by lab staff (either in the local lab or a designated in-clinic lab area) complete testing logs and then transcribe results onto the **Pelvic Laboratory Results** form.

13.____ At non-US sites, if participant has consented, swab vaginal fluids from the posterior fornix for specimen archive. After the tip of the swab is saturated:

13a.____ Place the swab in a cryovial labeled with a SCHARP-provided PTID label and containing 0.4 mL of phosphate buffered saline.

13b.____ Document specimen collection on the **Vaginal Swab Collection** form and the **LDMS Specimen Tracking Sheet**.

14.____ Inspect cervix and vagina. Note all findings on the Pelvic Exam Diagrams. Document abnormal findings on the **Pelvic Exam** form.

15.____ If bleeding, blood, and/or blood-tinged discharge are observed, complete a **Genital Bleeding Assessment** form.

16.____ If one or more genital ulcers are observed:

16a.____ Swab each ulcer. If a cluster of ulcers is observed, each ulcer in the cluster should be sampled with the same swab. Otherwise a different swab should be used for each ulcer.

16b.____ Place (each) swab in a cryovial labeled with a SCHARP-provided PTID label.

16c.____ Document specimen collection on the **Pelvic Exam** form and the **LDMS Specimen Tracking Sheet**.

17.____ At last scheduled pelvic exam, and when clinically indicated, collect ecto- and endocervical cells for Pap smear per site SOP. Document specimen collection on the **Pelvic Exam** form.

18.____ Perform bimanual exam. Document abnormal findings on the **Pelvic Exam** form.

Quarterly Visits — Phase IIb — Non-US

PTID:	Visit Date:
Visit Code:	Study Exit Visit? No Yes ⇒ Stop. Use Study Exit Checklist.

1._____ Complete participant registration, confirm the participant's identity, and verify her PTID.

2._____ Review chart notes and other relevant documentation from previous visit(s).

3._____ Review elements of informed consent as needed.

4._____ Explain the content and sequence of procedures for today's visit.

5._____ Review/update locator information.

6._____ Administer the **Follow-up Behavior Assessment**.
☞ *This form must be administered prior to the delivery of HIV/STD counseling, by a staff member who has not previously provided HIV/STD counseling to the participant.*

7._____ Provide HIV pre-test and risk reduction counseling. Provide condoms, other applicable prevention supplies (if any), and/or referrals if needed/requested. Reinforce availability of HIV/STD counseling, testing, and potential STD treatment for partners.

8._____ Collect blood:

Months 6, 9, 15, 18, 21, and 27
❒ 5 ml in lavender top tube (EDTA)

Months 12 and 24
❒ 2 ml in red to tube (no additive)
❒ 5 mL in lavender top tube (EDTA)
❒ 3 ml in blue top tube (sodium citrate)

9._____ Perform HIV serology.

9a. ____ If clinically indicated and/or requested by the participant, continue providing counseling while waiting for rapid HIV test result[s].

10.____ Complete HIV testing logs and transcribe result[s] onto the **Follow-Up Laboratory Results** form. Before disclosing result[s] to the participant, obtain independent review, verification, and sign-off of result[s]; if result[s] is[are] HIV-positive, review, verification, and sign-off must be obtained from a clinician.

11.____ Provide rapid HIV test result[s] and post-test counseling; provide referrals if needed/requested.

Quarterly Visits — Phase IIb — Non-US

PTID:	Visit Date:

12.____ Prepare remaining blood for further testing, if applicable:

12a.____ If Month 12 or 24, syphilis serology, hematology, and coagulation testing will be performed. Record the PTID, visit code, initial collection date, and staff initials/date on a **Safety Laboratory Results** form. Retain the form in the participant notebook for completion when results are available.

12b.____ If [at least one] rapid HIV test is positive, an HIV WB will be performed. Record the PTID, visit code, sample 1 specimen collection date, and staff initials/date on an **HIV Test Results** form. Retain the form in the participant notebook for completion when WB results are available.

13.____ Collect ~20 mL urine and:
13a.____ Aliquot ~5 mL and perform pregnancy test.
13b.____ Complete testing logs and transcribe result onto the **Monthly or Quarterly Visit** form.
13c.____ Retain remaining urine (~15 mL) for remainder of visit. If Month 12 or 24, prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing.

<u>If the participant is newly identified as pregnant at this visit</u>:
13d.____ Complete a **Pregnancy Report and History** form.

<u>If the participant is newly identified as pregnant at this visit AND is in a gel group</u>:
13e.____ Inform the participant that she must discontinue gel use; arrange to collect her unused gel.
13f.____ Complete items 1-2 of a **Product Hold/Discontinuation** form.
13g.____ Complete a **Study Product Request Slip**, marked "HOLD." Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.

☞ *Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.*

14.____ Perform interval medical/menstrual history with active review of genital symptoms; record findings on the **Follow-up Medical History** form. Review and update the **Concomitant Medications Log**.

14a.____ If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form.
14b.____ If applicable, review the status of previously-reported adverse events and update previously-completed **Adverse Experience Log** forms.

15.____ Perform pelvic exam per the Phase IIb Follow-Up Pelvic Exam Checklist. During exam, if applicable, assess genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

16.____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

17.____ Provide and explain available exam and lab test results.

Quarterly Visits — Phase IIb — Non-US

PTID:	Visit Date:

18.____ Provide treatment for RTIs/STDs if needed. Document treatment on the **Concomitant Medications Log**.

19.____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.

20.____ Complete items 2-3 of the **Monthly or Quarterly Visit** form.

21.____ For participants assigned to gel, administer the **Gel Re-Supply Worksheet**, complete a **Study Product Request Slip**, and:

OPTION A:

_____ Give the completed white original Study Product Request Slip to the participant to deliver to the study pharmacy (where she will obtain gel supplies herself). Retain the yellow clinic copy of the Study Product Request Slip in the participant's study notebook.

OPTION B:

_____ Optional: Fax a copy of the Study Product Request Slip to the pharmacy.
_____ Deliver the completed white Study Product Request Slip to the pharmacy. Retain the clinic copy of the Study Product Request Slip in the participant's study notebook.
_____ Receive requested gel supplies.
_____ Provide gel supplies to the participant.
_____ Document the number of cartons provided to the participant here ⇒ ☐ [or in chart notes]

21a.____ Complete items 4-5 of the **Monthly or Quarterly Visit** form.

22.____ For participants assigned to gel, if gel use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents. Also document the hold/discontinuation or resumption on a **Product Hold/Discontinuation** form a **Study Product Request Slip**. Deliver the white original Study Product Request Slip to the pharmacy; retain the yellow clinic copy in the participant's study notebook.

23.____ Provide adherence counseling if needed/requested.

24.____ Reinforce site contact information and instructions to contact the site to report symptoms — *especially genital symptoms and intermenstrual genital bleeding* — and/or to request additional information, HIV/STD counseling, and/or condoms, if needed, prior to the next visit.

24a. _____ For participants assigned to gel, reinforce the instructions to contact the site to request additional gel, if needed, prior to the next visit and remind the participant that she will be asked for information on the number of applicators she has remaining at her next visit.

Quarterly Visits — Phase IIb — Non-US

PTID:	Visit Date:

Additionally Only If Clinically Indicated (C1-C4):

C1.____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe results onto the **Follow-up Laboratory Results** form.

C1a.____ If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.

C2.____ Prepare urine remaining after aliquoting for pregnancy testing for gonorrhea and chlamydia SDA at the local lab.

C3.____ Collect and prepare blood for hematology and/or coagulation testing at the at the local lab. Record the PTID, visit code, initial collection date, and staff initials/date on a **Safety Laboratory Results** form. Retain the form in the participant notebook for completion when results are available.

C4.____ Collect and prepare blood for syphilis serology at the local lab.

☞ *Items C2, C3, and C4 are required at Months 12 and 24; see items 12 and 13 on page 2 of this checklist.*

Quarterly Visits — Phase IIb — Non-US

PTID:	Visit Date:

25.____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:

- ❒ Follow-up Medical History
- ❒ Pelvic Exam Diagrams
- ❒ Gel Re-Supply Worksheet (only for participants in a gel group)
- ❒ Study Product Request Slip (only for participants in a gel group)
- ❒ Genital Bleeding Assessment (only if genital bleeding/blood reported or observed at this visit)
- ❒ LDMS Specimen Tracking Sheet
- ❒ [sites may list alternative/additional local source documents here if desired]

26.____ Fax all required DataFax forms to SCHARP DataFax:

- ❒ Monthly or Quarterly Visit
- ❒ Follow-up Behavioral Assessment
- ❒ Pelvic Exam
- ❒ Pelvic Laboratory Results
- ❒ Vaginal Swab Collection (if participant has consented to swab collection and archive)
- ❒ Follow-up Laboratory Results (when all results available)
- ❒ Safety Laboratory Results (at Months 12 and 24, when all results available)

Optional:

- ❒ Concomitant Medications Log (required for updated or new pages)
- ❒ Safety Laboratory Results (required when unscheduled safety laboratory tests are performed)
- ❒ HIV Test Results (required if rapid HIV test is positive)
- ❒ Adverse Experience Log (required if any AEs identified or updated at this visit)
- ❒ Product Hold/Discontinuation (required if product use held/discontinued or resumed at this visit)
- ❒ Pregnancy Report and History (required if pregnancy identified at this visit)
- ❒ Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

Quarterly Visits — Phase IIb — US

PTID:	**Visit Date:**
Visit Code:	**Study Exit Visit?** No Yes ⇒ Stop. Use Study Exit Checklist.

1._____ Complete participant registration, confirm the participant's identity, and verify her PTID.

2._____ Review chart notes and other relevant documentation from previous visit(s).

3._____ Review elements of informed consent as needed.

4._____ Explain the content and sequence of procedures for today's visit.

5._____ Review/update locator information.

6._____ Administer the **Follow-up Behavior Assessment**.
☞ *This form must be administered prior to the delivery of HIV/STD counseling, by a staff member who has not previously provided HIV/STD counseling to the participant.*

7._____ Provide HIV pre-test and risk reduction counseling. Provide condoms, other applicable prevention supplies (if any), and/or referrals if needed/requested. Reinforce availability of HIV/STD counseling, testing, and potential STD treatment for partners.

8._____ Collect blood:

Months 6, 9, 15, 18, 21, and 27
❒ 5 ml in lavender top tube (EDTA)

Months 12 and 24
❒ 5 ml in gold top tube (no additive)
❒ 3 mL in lavender top tube (EDTA)
❒ 2 mL in lavender top tube (EDTA)
❒ 2.7 ml in blue top tube (sodium citrate)

9._____ Perform HIV serology.

9a._____ If clinically indicated and/or requested by the participant, continue providing counseling while waiting for rapid HIV test result.

10.____ Complete HIV testing logs and transcribe result onto the **Follow-Up Laboratory Results** form. Before disclosing result to the participant, obtain independent review, verification, and sign-off of result; if result is HIV-positive, review, verification, and sign-off must be obtained from a clinician.

11.____ Provide rapid HIV test result and post-test counseling; provide referrals if needed/requested.

Quarterly Visits— Phase IIb — US

PTID:	Visit Date:

12.____ Prepare remaining blood for further testing, if applicable:

12a.____ If Month 12 or 24, syphilis serology, hematology, and coagulation testing will be performed. Record the PTID, visit code, initial collection date, and staff initials/date on a **Safety Laboratory Results** form. Retain the form in the participant notebook for completion when results are available.

12b.____ If the rapid HIV test is positive, an HIV WB will be performed. Record the PTID, visit code, sample 1 specimen collection date, and staff initials/date on an **HIV Test Results** form. Retain the form in the participant notebook for completion when WB results are available.

13.____ Collect ~20 mL urine and:
13a.____ Aliquot ~5 mL and perform pregnancy test.
13b.____ Complete testing logs and transcribe result onto the **Monthly or Quarterly Visit** form.
13c.____ Retain remaining urine (~15 mL) for remainder of visit. If Month 12 or 24, transfer remaining urine to conical tube and refrigerate pending delivery to the local lab for shipment to the Central Lab for gonorrhea and chlamydia SDA.

If the participant is newly identified as pregnant at this visit:
13d.____ Complete a **Pregnancy Report and History** form.

If the participant is newly identified as pregnant at this visit AND is in a gel group:
13e.____ Inform the participant that she must discontinue gel use; arrange to collect her unused gel.
13f.____ Complete items 1-2 of a **Product Hold/Discontinuation** form.
13g.____ Complete a **Study Product Request Slip**, marked "HOLD." Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.

☞ *Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.*

14.____ Perform interval medical/menstrual history with active review of genital symptoms; record findings on the **Follow-up Medical History** form. Review and update the **Concomitant Medications Log**.

14a.____ If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form.
14b.____ If applicable, review the status of previously-reported adverse events and update previously-completed **Adverse Experience Log** forms.

15.____ Perform pelvic exam per the Phase IIb Follow-Up Pelvic Exam Checklist. During exam, if applicable, assess genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

16.____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

17.____ Provide and explain available exam and lab test results.

Quarterly Visits— Phase IIb — US

PTID:	Visit Date:

18.____ Provide treatment for RTIs/STDs if needed. Document treatment on the **Concomitant Medications Log**.

19.____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.

20.____ Complete items 2-3 of the **Monthly or Quarterly Visit** form.

21.____ For participants assigned to gel:

21a. _____ Administer the **Gel Re-Supply Worksheet**.

21b. _____ Complete a **Study Product Request Slip**.

21c. _____ Fax a copy of the Study Product Request Slip to the pharmacy. Arrange for delivery of the white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.

21d. _____ While waiting for gel supplies to be delivered, continue with the remainder of this checklist. After gel supplies are received, provide the supplies to the participant and document the number of cartons provided here → ☐

21e. _____ Complete items 4-5 of the **Monthly or Quarterly Visit** form.

22.____ For participants assigned to gel, if gel use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents. Also document the hold/discontinuation or resumption on a **Product Hold/Discontinuation** form a **Study Product Request Slip**. Deliver the white original Study Product Request Slip to the pharmacy; retain the yellow clinic copy in the participant's study notebook.

23.____ Provide adherence counseling if needed/requested.

24.____ Reinforce site contact information and instructions to contact the site to report symptoms — *especially genital symptoms and intermenstrual genital bleeding* — and/or to request additional information, HIV/STD counseling, and/or condoms, if needed, prior to the next visit.

24a. _____ For participants assigned to gel, reinforce the instructions to contact the site to request additional gel, if needed, prior to the next visit and remind the participant that she will be asked for information on the number of applicators she has remaining at her next visit.

Quarterly Visits— Phase IIb — US

PTID:	Visit Date:

Additionally Only If Clinically Indicated (C1-C4):

C1.____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe results onto the **Follow-up Laboratory Results** form.

C1a.____ If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.

C2.____ Transfer remaining (~15 mL) urine to conical tube and refrigerate pending delivery to the local lab for shipment to the Central Lab for gonorrhea and chlamydia SDA.

C3.____ Collect and prepare blood for hematology and/or coagulation testing at the at the local lab. Record the PTID, visit code, initial collection date, and staff initials/date on a **Safety Laboratory Results** form. Retain the form in the participant notebook for completion when results are available.

C4.____ Collect and prepare blood for syphilis serology at the local lab.

☞ *Items C2, C3, and C4 are required at Months 12 and 24; see items 12 and 13 on page 2 of this checklist.*

Quarterly Visits— Phase IIb — US
page 5 of 5

PTID:	Visit Date:

25.____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:

- ❒ Follow-up Medical History
- ❒ Pelvic Exam Diagrams
- ❒ Gel Re-Supply Worksheet (only for participants in a gel group)
- ❒ Study Product Request Slip (only for participants in a gel group)
- ❒ Genital Bleeding Assessment (only if genital bleeding/blood reported or observed at this visit)
- ❒ LDMS Specimen Tracking Sheet
- ❒ [sites may list alternative/additional local source documents here if desired]

26.____ Fax all required DataFax forms to SCHARP DataFax:

- ❒ Monthly or Quarterly Visit
- ❒ Follow-up Behavioral Assessment
- ❒ Pelvic Exam
- ❒ Pelvic Laboratory Results
- ❒ Follow-up Laboratory Results (when all results available)
- ❒ Safety Laboratory Results (at Months 12 and 24, when all results available)

Optional:

- ❒ Concomitant Medications Log (required for updated or new pages)
- ❒ Safety Laboratory Results (required when unscheduled safety laboratory tests are performed)
- ❒ HIV Test Results (required if rapid HIV test is positive)
- ❒ Adverse Experience Log (required if any AEs identified or updated at this visit)
- ❒ Product Hold/Discontinuation (required if product use held/discontinued or resumed at this visit)
- ❒ Pregnancy Report and History (required if pregnancy identified at this visit)
- ❒ Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

Study Exit Visit – Non-US
page 1 of 5

PTID:	Visit Date:
Visit Code:	

1._____ Complete participant registration, confirm the participant's identity, and verify her PTID.

2._____ Review chart notes and other relevant documentation from previous visit(s).

3._____ Explain the content and sequence of procedures for today's visit.

4._____ Administer the **Follow-up Partner Status** form. Then administer the **Follow-up Behavior Assessment** and **Study Exit Acceptability Assessment.**

☞ *These forms must be administered prior to the delivery of HIV/STD counseling, by a staff member who has not previously provided HIV/STD counseling to the participant.*

5._____ Provide HIV pre-test and risk reduction counseling; during pre-test counseling, reinforce that although this is the participant's last scheduled study visit, additional visits and tests will be done if needed to confirm or clarify her HIV status. Provide condoms, other applicable prevention supplies (if any), and/or referrals if needed/requested. Reinforce availability of HIV/STD counseling, testing, and potential STD treatment for partners.

6._____ Collect blood:
- ❒ 2 ml in red to tube (no additive)
- ❒ 5 mL in lavender top tube (EDTA)
- ❒ 3 ml in blue top tube (sodium citrate)

7._____ Perform HIV serology.

7a. ____ If clinically indicated and/or requested by the participant, continue providing counseling while waiting for rapid HIV test result[s].

8._____ Complete HIV testing logs and transcribe result[s] onto the **Follow-Up Laboratory Results** form. Before disclosing result[s] to the participant, obtain independent review, verification, and sign-off of result[s]; if result[s] is[are] HIV-positive, review, verification, and sign-off must be obtained from a clinician.

9._____ Provide rapid HIV test result[s] and post-test counseling; provide referrals if needed/requested. If result[s] is[are] HIV-positive, again reinforce that although this is the participant's last scheduled study visit, additional visits and tests will be done if needed to confirm or clarify her HIV status.

Study Exit Visit – Non-US
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PTID:	Visit Date:

10.____ Prepare remaining blood for syphilis serology, hematology testing, coagulation testing, and plasma archive at the local lab.

10a.____ Record the PTID, visit code, initial collection date, and staff initials/date on a Safety Laboratory Results form. Retain the form in the participant notebook for completion when results are available.
10b.____ Complete an LDMS Specimen Tracking Sheet for the plasma archive specimen.
10c.____ If [at least one] rapid HIV test is positive, an HIV WB will be performed. Record the PTID, visit code, sample 1 specimen collection date, and staff initials/date on an **HIV Test Results** form. Retain the form in the participant notebook for completion when WB results are available.

11._____ Collect ~20 mL urine and:

11a.____ Aliquot ~5 mL and perform pregnancy test.
11b.____ Complete testing logs and transcribe result onto the **Monthly or Quarterly Visit** form (or Interim Visit form if applicable per SSP Section 6.12.3).
11c.____ Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing.

<u>If the participant is newly identified as pregnant at this visit</u>:

11d.____ Complete a **Pregnancy Report and History** form.
11e.____ Explain to the participant that a post-study contact will be required to ascertain the outcome of her pregnancy. Schedule this contact as part of item 21 below.

☞ *Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.*

12._____ Perform interval medical/menstrual history with active review of genital symptoms; record findings on the **Follow-up Medical History** form. Review <u>all</u> **Concomitant Medications Log** pages and update entries as needed. For each medication, either record a "Date Stopped" (if the participant is no longer taking the medication) or mark the box for "Continuing at end of study" (if the participant is still taking the medication).

12a.____ If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form.

Study Exit Visit – Non-US

PTID:	Visit Date:

13._____ If this visit occurs at a quarterly visit timepoint, and/or if clinically indicated, perform pelvic exam per the Phase IIb Follow-Up Pelvic Exam Checklist. During exam, if applicable, assess genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

14._____ If not done previously, complete item 4 of the End of Study Inventory form.

15._____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

16._____ Provide and explain available exam and lab test results.

17._____ Provide treatment for RTIs/STDs if needed. Document treatment on the **Concomitant Medications Log**.

Additionally Only If Clinically Indicated (C1):

C1.____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe results onto the **Follow-up Laboratory Results** form.

C1a.____ If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.

18._____ Complete new **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.

19._____ Review all **Adverse Experience Log** forms completed for the participant and update the forms as needed. For AEs that are "continuing" at this visit, update the status/outcome of the AE to "continuing at end of study participation."

☞ *Any SAEs or EAEs identified as continuing at this visit must be re-evaluated in 30 days. Any previously reported AEs found to have increased in severity at this visit also must be re-evaluated in 30 days. Consult with the IoR/designee to establish a clinically appropriate follow-up plan for the participant and document the plan on the Study Exit Worksheet. See SSP Section 6.12.8 for more information.*

Study Exit Visit – Non-US
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PTID:	Visit Date:

20._____ For participants assigned to gel:

20a.____ Place unused gel returned by the participant in an opaque bag/container and deliver returned supplies to the study pharmacy on the day of return.
20b.____ If the participant has not brought all unused gel to the visit, arrange to collect remaining supplies. Document plan for gel return/collection on the Study Exit Worksheet.
20b.____ Complete or update a **Product Hold/Discontinuation** form.

☞ *Include participant's PTID on weekly listing provided to pharmacy staff of participants who have exited the study.*

21._____ Explain all remaining study exit procedures to the participant and:

21a.____ Schedule a final study contact for disclosure of all remaining exam and lab test results.
21b.____ If applicable, schedule contact to ascertain the participant's pregnancy outcome.
21c.____ If applicable, schedule clinically indicated follow-up for unresolved SAEs/EAEs and previously reported AEs found to have increased severity at this visit.
21d.____ Inform the participant of planned methods and timeframes for unblinding and dissemination of study results.
21e. ____Determine and document whether participant is willing to be contacted about future studies for which she may be eligible.
21f.____ Reinforce site contact information, update participant locator information, and determine participant preferences for post-study contact.

Record information and plans related to 21a-f on the Study Exit Worksheet as applicable.

22._____ Complete the **Monthly or Quarterly Visit** form (or Interim Visit form if applicable per SSP Section 6.12.3).

Study Exit Visit – Non-US
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PTID:	Visit Date:

23.____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:
- ❒ Follow-up Medical History
- ❒ Pelvic Exam Diagrams (only if pelvic exam performed)
- ❒ Genital Bleeding Assessment (only if genital bleeding/blood reported or observed at this visit)
- ❒ LDMS Specimen Tracking Sheet
- ❒ [sites may list alternative/additional local source documents here if desired]

24.____ Fax all required DataFax forms to SCHARP DataFax:
- ❒ Monthly or Quarterly Visit (or Interim Visit if applicable per SSP Section 6.12.3)
- ❒ Follow-up Behavioral Assessment
- ❒ Study Exit Acceptability Assessment
- ❒ Product Hold/Discontinuation (only for participants in a gel group)
- ❒ Follow-up Laboratory Results (when all results available)
- ❒ Safety Laboratory Results (when all results available)
- ❒ End of Study Inventory

Optional:
- ❒ Concomitant Medications Log (required for updated or new pages)
- ❒ Pelvic Exam (required if pelvic exam performed)
- ❒ Pelvic Laboratory Results (required if pelvic exam performed)
- ❒ Vaginal Swab Collection (required if pelvic exam performed and participant has consented to swab collection and archive)
- ❒ HIV Test Results (required if rapid HIV test is positive)
- ❒ Adverse Experience Log (required if any AEs identified or updated at this visit)
- ❒ Pregnancy Report and History (required if pregnancy identified at this visit)
- ❒ Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

Study Exit Visit – US
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PTID:	Visit Date:
Visit Code:	

1._____ Complete participant registration, confirm the participant's identity, and verify her PTID.

2._____ Review chart notes and other relevant documentation from previous visit(s).

3._____ Explain the content and sequence of procedures for today's visit.

4._____ Administer the **Follow-up Partner Status** form. Then administer the **Follow-up Behavior Assessment** and **Study Exit Acceptability Assessment.**

☞ *These forms must be administered prior to the delivery of HIV/STD counseling, by a staff member who has not previously provided HIV/STD counseling to the participant.*

5._____ Provide HIV pre-test and risk reduction counseling; during pre-test counseling, reinforce that although this is the participant's last scheduled study visit, additional visits and tests will be done if needed to confirm or clarify her HIV status. Provide condoms, other applicable prevention supplies (if any), and/or referrals if needed/requested. Reinforce availability of HIV/STD counseling, testing, and potential STD treatment for partners.

6._____ Collect blood:
- ❒ 5 mL gold top tube (no additive)
- ❒ 5 mL lavender top tube (EDTA)
- ❒ 3 mL in lavender top tube (EDTA)
- ❒ 2 mL in lavender top tube (EDTA)
- ❒ 2.7 mL in blue top tube (sodium citrate)

7._____ Perform HIV serology.

7a. ____ If clinically indicated and/or requested by the participant, continue providing counseling while waiting for rapid HIV test result.

8._____ Complete HIV testing logs and transcribe result onto the **Follow-Up Laboratory Results** form. Before disclosing result to the participant, obtain independent review, verification, and sign-off of result; if result is HIV-positive, review, verification, and sign-off must be obtained from a clinician.

9._____ Provide rapid HIV test result and post-test counseling; provide referrals if needed/requested. If result is HIV-positive, again reinforce that although this is the participant's last scheduled study visit, additional visits and tests will be done if needed to confirm or clarify her HIV status.

Study Exit Visit – US
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PTID:	Visit Date:

10.____ Prepare remaining blood for syphilis serology, hematology testing, coagulation testing, and plasma archive at the local lab.

10a.____ Record the PTID, visit code, initial collection date, and staff initials/date on a Safety Laboratory Results form. Retain the form in the participant notebook for completion when results are available.
10b.____ Complete an LDMS Specimen Tracking Sheet for the plasma archive specimen.
10c.____ If the rapid HIV test is positive, an HIV WB will be performed. Record the PTID, visit code, sample 1 specimen collection date, and staff initials/date on an **HIV Test Results** form. Retain the form in the participant notebook for completion when WB results are available.

11._____ Collect ~20 mL urine and:

11a.____ Aliquot ~5 mL and perform pregnancy test.
11b.____ Complete testing logs and transcribe result onto the **Monthly or Quarterly Visit** form. (or Interim Visit form if applicable per SSP Section 6.12.3).
11c.____ Transfer remaining urine to conical tube and refrigerate pending delivery to the local lab for shipment to the MTN Network Lab for gonorrhea and chlamydia SDA.

If the participant is newly identified as pregnant at this visit:

11d.____ Complete a **Pregnancy Report and History** form.
11e.____ Explain to the participant that a post-study contact will be required to ascertain the outcome of her pregnancy. Schedule this contact as part of item 21 below.

☞ *Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.*

12._____ Perform interval medical/menstrual history with active review of genital symptoms; record findings on the **Follow-up Medical History** form. Review all **Concomitant Medications Log** pages and update entries as needed. For each medication, either record a "Date Stopped" (if the participant is no longer taking the medication) or mark the box for "Continuing at end of study" (if the participant is still taking the medication).

12a.____ If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form.

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PTID:	Visit Date:

13._____ If this visit occurs at a quarterly visit timepoint, and/or if clinically indicated, perform pelvic exam per the Phase IIb Follow-Up Pelvic Exam Checklist. During exam, if applicable, assess genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

14._____ If not done previously, complete item 4 of the End of Study Inventory form.

15._____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

16._____ Provide and explain available exam and lab test results.

17._____ Provide treatment for RTIs/STDs if needed. Document treatment on the **Concomitant Medications Log**.

Additionally Only If Clinically Indicated (C1):

C1.____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe results onto the **Follow-up Laboratory Results** form.

C1a.____ If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.

18._____ Complete new **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.

19._____ Review all **Adverse Experience Log** forms completed for the participant and update the forms as needed. For AEs that are "continuing" at this visit, update the status/outcome of the AE to "continuing at end of study participation."

☞ *Any SAEs or EAEs identified as continuing at this visit must be re-evaluated in 30 days. Any previously reported AEs found to have increased in severity at this visit also must be re-evaluated in 30 days. Consult with the IoR/designee to establish a clinically appropriate follow-up plan for the participant and document the plan on the Study Exit Worksheet. See SSP Section 6.12.8 for more information.*

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PTID:	Visit Date:

20._____ For participants assigned to gel:

20a.____ Place unused gel returned by the participant in an opaque bag/container and deliver returned supplies to the study pharmacy on the day of return.
20b.____ If the participant has not brought all unused gel to the visit, arrange to collect remaining supplies. Document plan for gel return/collection on the Study Exit Worksheet.
20c.____ Complete or update a **Product Hold/Discontinuation** form.

☞ *Include participant's PTID on weekly listing provided to pharmacy staff of participants who have exited the study.*

21._____ Explain all remaining study exit procedures to the participant and:

21a.____ Schedule a final study contact for disclosure of all remaining exam and lab test results.
21b.____ If applicable, schedule contact to ascertain the participant's pregnancy outcome.
21c.____ If applicable, schedule clinically indicated follow-up for unresolved SAEs/EAEs and previously reported AEs found to have increased severity at this visit.
21d.____ Inform the participant of planned methods and timeframes for unblinding and dissemination of study results.
21e. ____Determine and document whether participant is willing to be contacted about future studies for which she may be eligible.
21f.____ Reinforce site contact information, update participant locator information, and determine participant preferences for post-study contact.

Record information and plans related to 21a-f on the Study Exit Worksheet as applicable.

22._____ Complete the **Monthly or Quarterly Visit** form (or Interim Visit form if applicable per SSP Section 6.12.3).

Study Exit Visit – US
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PTID:	Visit Date:

23.____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:

- ❒ Follow-up Medical History
- ❒ Pelvic Exam Diagrams (only if pelvic exam performed)
- ❒ Genital Bleeding Assessment (only if genital bleeding/blood reported or observed at this visit)
- ❒ LDMS Specimen Tracking Sheet
- ❒ [sites may list alternative/additional local source documents here if desired]

24.____ Fax all required DataFax forms to SCHARP DataFax:

- ❒ Monthly or Quarterly Visit (or Interim Visit form if applicable per SSP Section 6.12.3)
- ❒ Follow-up Behavioral Assessment
- ❒ Study Exit Acceptability Assessment
- ❒ Product Hold/Discontinuation (only for participants in a gel group)
- ❒ Follow-up Laboratory Results (when all results available)
- ❒ Safety Laboratory Results (when all results available)
- ❒ End of Study Inventory

Optional:

- ❒ Concomitant Medications Log (required for updated or new pages)
- ❒ Pelvic Exam (required if pelvic exam performed)
- ❒ Pelvic Laboratory Results (required if pelvic exam performed)
- ❒ HIV Test Results (required if rapid HIV test is positive)
- ❒ Adverse Experience Log (required if any AEs identified or updated at this visit)
- ❒ Pregnancy Report and History (required if pregnancy identified at this visit)
- ❒ Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)