Section 3. Documentation Requirements

Study staff are responsible for proper collection, management, storage, quality control, and quality assurance of all study-related documentation. This section contains information on the Essential Documents that each study site must maintain throughout the study. It also contains information related to establishing adequate and accurate participant research records — commonly referred to as participant "case history records" — for HPTN 035.

NOTE: 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).

3.1 Essential Documents

The Division of AIDS (DAIDS) Standard Operating Procedure (SOP) for Essential Documents (see Section 16) specifies the essential documents that study sites must maintain for DAIDS-sponsored studies, including HPTN 035. When required documents are modified or updated, the original and all modified or updated versions must be maintained. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location.

Section Appendix 3-1 presents a suggested essential documents filing structure for HPTN 035. The suggested structure incorporates guidance received from the DAIDS Prevention Science Branch Clinical Operations Group and the DAIDS Clinical Site Monitoring Group (PPD). Study sites are not required to adopt the suggested structure, but are encouraged to consider it when developing their filing approach for HPTN 035. Study sites also are encouraged to establish an SOP to document their filing approach. Further clarifications of the suggested filing structure are as follows:

- Essential documents may be stored in files and/or in binders. The files/binders listed in Section Appendix 3-1 may be further subdivided, consolidated, and/or re-organized if desired.

- It is recommended that a contents sheet be maintained and inserted as the first page(s) of each file/binder. Within each file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).

- To preserve blinding, certain documents related to the investigational study products will be stored in site pharmacies. A listing of essential documents to be maintained in the pharmacies is provided in Section 3.3, rather than Section Appendix 3-1.

- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders (see items 26-28 in Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories.

- The suggested filing structure assumes that HPTN 035 participant case history records will be stored separately from the other essential documents listed in Section Appendix 3-1. Section 3.2 below provides information on the required contents of these records. The suggested filing structure also assumes that the HPTN 035 Screening and Enrollment Log, Participant Name-ID Number Link Log, and Clinic Randomization Envelope Tracking Record (which are described in Section 4 of this manual) will be stored in the study clinic or data management area, and not necessarily with the other essential documents listed in Section Appendix 3-1.

3.2 Participant Case History Documentation

Study sites must maintain adequate and accurate participant case history records containing all information pertinent to HPTN 035 for each study participant.

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

- Basic participant identifiers.
- Documentation that the participant provided written informed consent to screen for and participate in the study prior to the conduct of any screening or study procedures, respectively.
- Documentation that the participant met the study's selection (eligibility) criteria.
- A record of the participant's random assignment.
- A record of the participant's exposure to the investigational study products.
- A record of all contacts, and attempted contacts, with the participant.
- A record of all procedures performed by study staff during the study.
- Study-related information on the participant's condition before, during, and after the study, including:
  - Data obtained directly from the participant (e.g., interview responses and other self-reported information)
  - Data obtained by study staff (e.g., exam and lab findings)
  - Data obtained from non-study sources (e.g., non-study medical records)

In addition to the above, DAIDS requires that all protocol departures/deviations/violations be documented in participant records, along with reasons for the departures/deviations/violations and/or attempts to prevent or correct the departures/deviations/violations, if applicable. HPTN 035 study sites also must report protocol events to DAIDS and others per HPTN Operating Policy 015-00, which can be found at the following web site:

http://www.hptn.org/network_information/policies_procedures.htm

3.2.2 Concept of Source Data and Source Documentation

The International Conference on Harmonization Consolidated Guidance for Good Clinical Practice (ICH-E6) defines the terms source data and source documentation as follows:

Source data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source documents: Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies of transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the trial).

Source documents are commonly referred to as the documents —paper-based or electronic — upon which source data are first recorded. All study sites must adhere to the standards of source documentation specified in the DAIDS SOP for Source Documentation (see Section 16). The DAIDS SOP specifies both requirements and recommendations. Study sites must comply with all requirements and are encouraged, but not required, to comply with all recommendations.

For HPTN 035, it is expected that participant case history records will consist of the following source documents:

- Narrative chart notes
- Clinic randomization envelopes and prescriptions documenting participants' random assignments
- Pharmacy randomization envelopes and investigational product dispensing and chain of custody records
- Visit checklists and/or other site-specific flowsheets
- Local laboratory testing logs and result reports
- DataFax and Non-DataFax forms provided by the MTN Statistical and Data Management Center (SDMC)
- Other source documents (e.g., site-specific worksheets, non-study medical records)

As a condition for study activation, each study site must establish an SOP for source documentation that specifies the use of the above-listed documents as source documents. Although it is the responsibility of each site to determine the most appropriate source document for each required case history element, Section Appendix 3-2 provides a guide that sites may follow for this study. Supplemental information on the use of chart notes, visit checklists, and forms provided by the MTN SDMC is provided below. Detailed information on proper completion, maintenance, and storage of participant randomization and product dispensing documentation is provided in Sections 4, 6, and 9 of this manual. Detailed information on proper completion of DataFax and Non-DataFax forms provided by the MTN SDMC is provided in Section 13 of this manual.

Chart Notes: Study staff must document every contact with a study participant in a signed and dated chart note specifying the date, type, purpose, and location of the contact, and the general status of the participant. The time at which a contact takes place, or at which particular procedures take place, also should be specified when necessary to document adherence to protocol requirements. Chart notes also must be used to document the following:

- The screening and enrollment informed consent processes (see also Section 5)
- Procedures performed that are not recorded on other source documents
- Pertinent data about the participant that are not recorded on other source documents
- Protocol departures/deviations/violations that are not otherwise captured on other source documents

Study sites are strongly encouraged to adopt a common format — such as the Subjective-Objective-Assessment-Plan (SOAP) format — for all chart notes, to help ensure adequacy and consistency of note content and maximize adherence to GCP standards. Further information on the SOAP note format can be found in Appendix 11 of the HPTN Manual of Operations. Several sample notes in SOAP format are provided in Section Appendix 3-3.

Visit Checklists: The checklists in Section 7 of this manual represent convenient tools to fulfill the requirement of documenting all study procedures performed with each study participant. Note, however, that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to document procedures performed at unscheduled study visits, and/or to explain why procedures in addition to those listed on a checklist may have been performed or why procedures listed on a checklist were not performed. Chart notes also may be required to document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements).

DataFax and Non-DataFax Forms Provided by the MTN SDMC: The case report forms for this study are designed for use with the DataFax data management system described in Section 13 of this manual. The SDMC will provide these forms to each site. The SDMC also will provide several study-specific non-DataFax forms to each site. See Section Appendix 3-4 for a listing of all DataFax and non-DataFax forms to be provided for this study.

The SDMC will provide all forms in pre-assembled packets for each protocol-specified study visit (i.e., Screening Part 1 packet, Screening Part 2 packet, Enrollment packet, Monthly and Quarterly Follow-up packets, Study Exit packet). A packet of other "as needed" forms also will be provided. The packets will be produced at a US-based printing company, and will be shipped from the printing company to each study site. For non-US sites, forms will be printed on A4 paper and four-hole punched. For the US site, forms will be printed on letter size paper and three-hole punched. For all sites, forms that are administered directly to participants will be available in local languages relevant to the site.

As shown in Section Appendices 3-5 and 3-6, many of the DataFax and non-DataFax forms provided by the SDMC have been designed to serve as source documents. Each study site must document the forms that routinely will be used as source documents in its SOP for source documentation, and must follow the specifications of this SOP consistently for all study participants. In the event that study staff are not able to record data directly forms designated as source documents, the following procedures should be undertaken:

- Record the data onto an alternative source document
- Enter the alternative source document into the participant's study chart
- Transcribe the data from the alternative source document onto the appropriate form
- Enter a chart note stating the relevant study visit date and the reason why an alternative source document was used

3.2.3 Document Organization

Study staff must make every effort to store all study records securely and confidentially. Case history records must be stored in the same manner for all participants, in areas with access limited to authorized study staff only. Study staff are responsible for purchasing file folders, binders, storage cabinets, and any other equipment or supplies needed to properly store all records.

Study-related documentation collected during the screening process should be stored in file folders or thin notebooks for each potential participant. All screening documentation — for potential participants who eventually enroll in the study as well as for those who do not enroll — must be maintained and available for monitoring throughout the study. This documentation also must be available for reference should participants present to the site for re-screening. For participants who enroll in the study, screening documentation should be transferred into large ring binders that will serve as participants' study notebooks for the duration of their participation in the study.

All documents contained in participant case history records must bear a participant identifier, which generally will consist of either the participant identification number (PTID) or the participant name. To maximize participant confidentiality, the PTID should be used whenever possible, and records that bear names or other personal identifiers, such as locator forms and informed consent forms, should be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location — including DataFax forms and Expedited Adverse Event Forms — must be identified by PTID only.

Regardless of whether the identifier on a particular document consists of the participant name or PTID, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated on copies of original source documents. For example, if medical records obtained from a non-study health care provider bear the participant's name, the original documents bearing the name must be stored unaltered with other study documents bearing the name. However, a copy of the original documents could be made, the PTID could be entered onto the copies, and then the participant name could be obliterated from the copies. Copies handled in this way could then be stored in participants' study notebooks and/or transferred or transmitted to non-study site locations.

All on-site databases must be secured with password-protected access systems. Any lists, logbooks, appointment books, or other documents that link PTIDs to other participant identifiers should be stored securely in a location separate from records identified by either participant name or PITD. When in use, these documents should not be left unattended or otherwise accessible to study participants, other study clinic patients, or any other unauthorized persons.

As a condition for study activation, each study site must establish an SOP for data management. This SOP minimally should contain the following elements:

- Procedures for assigning PTIDs, linking PTIDs to participant names, and storing the name-PTID link log
- Procedures for establishing participant files/charts/notebooks
- During-visit participant chart and case report form review procedures
- Post-visit participant chart and case report form review procedures and timeframes
- Data transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted
- Procedures for resolving data quality control notes from the SDMC
- Procedures for handling and filing field workers' logs, worksheets, etc.
- Storage locations for blank case report forms
- Storage locations for documents identified by participant names or other personal identifiers
- Storage locations for documents identified by PTID
- Procedures for back up of electronic study data (if applicable)
- Handling of participant study records for off-site contacts and visits
- Confidentiality protections
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements (if not specified elsewhere)
- QC/QA procedures related to the above (if not specified elsewhere)

3.3 Study Product Accountability, Chain of Custody, and Dispensing Documentation

The following essential documents should be maintained in study site pharmacies:

- Current HPTN 035 protocol
- Current Investigator's Brochures for BufferGel and PRO 2000/5 Gel (P) (if brochures on file in the clinic essential document files are not easily accessible to pharmacy staff)
- Current HPTN 035 FDA Form 1572
- Current list of authorized prescribers and staff authorized to sign HPTN 035 Study Product Request Slips (names and signatures)
- Pharmacy Establishment Plan
- HPTN 035 pharmacy and product-related SOPs
- HPTN 035 pharmacy randomization envelopes
- HPTN 035 pharmacy randomization envelope tracking record
- HPTN 035 PTID list (provided by the HPTN SDMC)
- HPTN 035 product import documentation
- HPTN 035 product shipping and receipt documentation
- HPTN 035 product storage temperature logs
- HPTN 035 investigational agent accountability records
- HPTN 035 participant-specific records (including prescriptions, product re-supply slips, pharmacy randomization envelopes, dispensing records, and DataFax forms as applicable)
- HPTN 035 monitoring visit reports
- HPTN 035 communications with site clinic staff
- HPTN 035 communications with the DAIDS Pharmaceutical Affairs Branch (PAB) and the NIAID Clinical Research Product Management Center
- HPTN 035 communications with the MTN Coordinating and Operations Center (CORE)
- HPTN 035 communications with the MTN SDMC
- Other HPTN 035 communications
- Other locally-required administrative, operational, and/or regulatory documentation

Pharmacy staff will document the receipt, dispensing, and final disposition of the investigational products used in the study, i.e., BufferGel, PRO 2000/5 Gel (P), and placebo gel. Separate accountability records must be maintained for each gel, per instructions provided in the HPTN 035 Pharmacist Study Product Management Procedures Manual available from the DAIDS PAB.

Pharmacy staff also will maintain in the study pharmacies randomization materials for all enrolled study participants and product dispensing records for all participant assigned to a study gel group, per instructions in the HPTN 035 Pharmacist Study Product Management Procedures Manual. Study clinic staff will contribute to the documentation of product dispensation and chain of custody as described in Sections 4, 6, and 9 of this manual.

The specifications related to document security and participant confidentiality described in Section 3.2 also apply to records maintained in the study pharmacies. All records must be stored securely in the pharmacies with access limited to authorized study pharmacy staff only.

To preserve the double blinding of participants' random assignments, neither study clinic staff nor study participants will be provided access to product-related documentation maintained in the study pharmacies. Pharmacy staff may provide copies of some participant-specific documentation maintained in the study pharmacies (e.g., chart notes) to clinic staff for purposes of communication and operational coordination. However, decisions to provide such documentation to clinic staff will be made by pharmacy staff only, and under no circumstances will documentation released from the pharmacy include participants' product dispensing records or other information related to participants' random assignments (see also Section 9.1 of this manual).

3.4 Record Retention Requirements

All study records must be maintained for at least two years following the date of marketing approval for each of the two study products for the indication in which they were studied. If no marketing application is to be filed, or if the application is not approved, the records must be retained until two years after the investigation is discontinued and the US Food and Drug Administration (FDA) is notified. All records must be retained on-site throughout the study's period of performance, and for at least three years after completion or termination of the study. Study product records must be stored in the study pharmacies, with access limited to authorized study pharmacy staff only, until the study is unblinded. DAIDS will provide further instructions for long-term storage of study records after the study is completed.

Section Appendix 3-1
Suggested Filing Structure for HPTN 035 Essential Documents

File/Binder #1: HPTN 035 Protocol and Current Informed Consent Forms

1. HPTN 035 Protocol (including copy of signed and dated protocol signature page): Version 1.0, Version 2.0, Clarification Memo #1, and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments issued after Version 2.0
2. Currently-approved HPTN 035 informed consent forms

File/Binder #2: Regulatory Authority Documentation (if applicable)

3. Regulatory Authority Correspondence/Authorization/Approval/Notification of Protocol (if applicable; if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)

File/Binder #3A: IRB/EC Documentation for [IRB/EC A]

4. FWA documentation for IRB/EC A
5. Roster of IRB/EC A (if available)
6. Relevant IRB/EC A Submission Requirements/Guidelines/SOPs
7. IRB Correspondence for IRB/EC A: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.

File/Binder #3B: IRB/EC Documentation for [IRB/EC B]

8. FWA documentation for IRB/EC B
9. Roster of IRB/EC B (if available)
10. Relevant IRB/EC B Submission Requirements/Guidelines/SOPs
11. IRB Correspondence for IRB/EC B: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.

File/Binder #4: Product Safety Information

12. Investigator's Brochure for BufferGel: current version and any subsequent updates
13. Investigator's Brochure for PRO 2000/5 (P): current version and any subsequent updates
14. Product Safety Information/Reports/Memos

Notes:

- It is assumed that expedited adverse event reports will be stored in participant study notebooks.
- It is assumed that documentation of IRB/EC submission of above-listed documents (if applicable) will be maintained in the relevant IRB/EC Files/Binders (i.e., File/Binder #3A and #3B).

File/Binder #5: HPTN 035 Study-Specific Procedures (SSP) Manual

15. Final version 1.0 (when available) and any subsequent updates

Notes:

- For this reference copy of the SSP Manual, do not discard out-dated pages or sections when updates are issued; retain all versions of all pages as a complete historical record.
- The SSP Manual contains reference versions of all study case report forms, therefore additional (blank) copies of the case report forms need not be stored elsewhere in the essential document files.

File/Binder #6: HPTN 035 Study-Specific Standard Operating Procedures

16. Final approved version of each SOP, and any subsequent updates to each

Section Appendix 3-1
Suggested Filing Structure for HPTN 035 Essential Documents

File/Binder #7: HPTN 035 Staffing Documentation

17. FDA Form 1572 (copy of original and dated form submitted to the MTN CORE for Protocol Registration, and any subsequent updates)
18. HPTN 035 Investigator of Record CV (copy of CV submitted to the MTN CORE for Protocol Registration; ensure that the CV is current prior to initiating HPTN 035; it is recommended that CVs be signed and dated to document at least annual updating)
19. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
20. Study Staff Roster (original submitted to MTN CORE for study activation, and any subsequent updates)
21. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
22. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
23. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating HPTN 035; it is recommended that CVs be signed and dated to document at least annual updating)
24. Study Staff Job Descriptions
25. Documentation of Study Staff Training

File/Binder #8: Local Laboratory Documentation

26. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
27. Local Laboratory Normal Ranges: file documentation of relevant normal ranges for all protocol-specified tests current at time of study activation and all subsequent updates
28. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7)

Note:

- It is recommended that a cross-reference be included in this file/binder specifying the storage location(s) of other lab-related essential documents filed in the local lab(s).

File/Binder #9: Monitoring Visit Documentation

29. Monitoring Visit Log
30. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings

File/Binder #10: Documentation of Other HPTN/MTN Site Visits

31. (Non-Monitoring) Site Visit Log
32. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings
33. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
34. HPTN/MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
35. Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #11: Study-Related Sponsor Communications

36. Study-Related Communications to and from DAIDS
37. Communications to and from DAIDS RCC (includes copies of all submissions to the DAIDS Protocol Registration Office, which will be prepared and copies provided by the HPTN CORE, as well as the current monthly DAIDS IB/PI listing and year-end and current monthly DAIDS Comprehensive Safety Distribution Report)

Notes:

- Communications should be filed beginning from the date of the HPTN 035 Central Investigators Meeting.
- Communications related to individual HPTN 035 study participants will be filed in individual participant study records.
- As needed to preserve blinding, product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.

Section Appendix 3-1
Suggested Filing Structure for HPTN 035 Essential Documents

File/Binder #12: Other Study-Related Communications

38. Study-Related Communications to and from MTN CORE
39. Study-Related Communications to and from MTN SDMC
40. Study-Related Communications to and from HPTN/MTN Network Lab
41. Other Study-Related Communications

Notes:

- Communications should be filed beginning from the date of the HPTN 035 Central Investigators Meeting.
- Communications related to individual HPTN 035 study participants will be filed in individual participant study records.
- As needed to preserve blinding, product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.

File/Binder #13: Study Site Staff Meeting Documentation

42. HPTN 035 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

Note:

- Meeting documentation should be filed beginning from the date of the HPTN 035 Central Investigators Meeting.

File/Binder #14: Conference Call Documentation

43. HPTN 035 Protocol Team and Protocol Co-Chairs Conference Call Summaries
44. HPTN 035 Study Coordinators Group Conference Call Summaries
45. HPTN 035 Laboratory Group Conference Call Summaries
46. HPTN 035 Community Educators Group Conference Call Summaries
47. Summaries of Other HPTN 035 Conference Calls

Note:

- Conference call summaries will be filed beginning from the date of the HPTN 035 Central Investigators Meeting.

File/Binder #15: DAIDS and Other Reference Documentation

48. DAIDS SOP for Source Documentation (Version 2.0 and any subsequent updates)
49. DAIDS SOP for Essential Documents (Version 2.0 and any subsequent updates)
50. DAIDS Protocol Registration Policy and Procedures Manual (August 2004 and any subsequent updates)
51. Manual for Expedited Reporting of Adverse Events to DAIDS
52. US Regulations Applicable to Conduct of HPTN 035 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
53. Any other relevant manuals or reference documents

File/Binder #16: Site-Specific Study Activation Documentation

54. Site-Specific Study Activation Documents

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for HPTN 035

Required Case History Element	Source Documents*
Basic participant identifiers.	Locator form; Demographics forms.
Documentation that the participant provided written informed consent to screen for and participate in the study.	Signed and dated informed consent forms; signed and dated chart notes stating that informed consent was obtained prior to initiating study procedures.
Documentation that the participant met the study selection (eligibility) criteria.	Demographics form, locator form; Screening Part 1 Eligibility form; Screening Part 2 Eligibility form; Screening Safety Laboratory Results form; Baseline Medical History form, Concomitant Medications Log form, Physical Exam form, (Repeat) Screening Pelvic Exam form; Pelvic Exam Diagrams; Screening Part 2 Laboratory Results form; local lab logs and result reports[§]; signed and dated chart notes.
A record of the participant's random assignment.	HPTN 035 clinic randomization envelope tracking records; HPTN 035 clinic randomization envelope; HPTN 035 prescription; HPTN 035 pharmacy randomization envelope tracking records; HPTN 035 pharmacy randomization envelope; HPTN 035 participant-specific pharmacy dispensing record.
A record of the participant's exposure to the investigational study products.	HPTN 035 Gel Re-Supply Worksheet, HPTN 035 Study Product Request Slip, HPTN 035 participant-specific pharmacy dispensing record; dispensed gel chain of custody logs, visit checklists.
A record of all contacts, and all attempted contacts, with the participant.	Signed and dated chart notes, and/or other worksheets or site-specific documents if designated in site SOPs.
A record of all procedures performed by study staff.	Completed visit checklists; signed and dated chart notes detailing (i) procedures performed in addition to those contained on the checklist and/or (ii) the reason why procedures contained on the checklist were not performed.
Information on the participant's condition before, during, and after the study.	All documents listed above; Enrollment Behavior Assessment form, Follow-up Behavior Assessment form; Acceptability Assessment form; Study Exit Acceptability Assessment form; Follow-up Medical History form; Genital Bleeding Assessment form; Pelvic Exam form; Pelvic Laboratory Results form; Safety Laboratory Results form; Adverse Experience Log form; HIV Test Results form; Product Hold/Discontinuation form; Pregnancy Report and History form; Pregnancy Outcome form; Missed Visit form; Participant Transfer form; Participant Receipt form; End of Study Inventory form; local lab logs and result reports from the local lab[§]; results of information pertinent to the study obtained from non-study sources; signed and dated chart notes.

*Other site-specific source documents also may be used.

[§]A clinician must review all local laboratory reports and document this review by signing and dating all reports.

Section Appendix 3-3
Sample Chart Notes for HPTN 035 in Subjective-Objective-Assessment-Plan (SOAP) Format

Sample Chart Note for Screening Part 1:

15 NOV 2004: Participant presented for HPTN 035 screening. Obtained written informed consent for screening before initiating any procedures. Procedures were completed per protocol, visit checklist and SOPs.

S: Participant reported no current health problems.

O: Pregnancy test negative, participant behaviorally eligible per the Screening Part 1 Eligibility form, tested HIV negative.

A: Participant is eligible for the study thus far.

P: Screening Part 2/Enrollment scheduled for 25 NOV 2004.

{staff signature}

Sample Chart Note for Screening Part 1:

15 NOV 2004: Participant presented for HPTN 035 screening. Obtained written informed consent for screening before initiating any procedures. Procedures were completed per protocol, SOPs and visit checklist, with the additions listed here.

S: Participant complained of current genital itching and yellowish discharge, no other current health problems.

O: Participant behaviorally eligible per the Screening Part 1 Eligibility form, tested negative for pregnancy and HIV.

A: Other than genital symptoms, participant appears eligible for the study thus far. Syndromic treatment provided [insert details here], participant must be symptom free at next visit in order to enroll in study.

P: Screening Part 2/Enrollment scheduled for 27 NOV 2004, participant counseled to contact site if symptoms do not resolve in 5-7 days.

{staff signature}

Sample Chart Note for a Screening Part 1:

15 NOV 2004: Participant presented for HPTN 035 screening. Obtained written informed consent for screening before initiating any procedures. Procedures were completed per protocol, SOPs and the visit checklist, with the additions listed here.

S: Participant complained of current genital itching and yellowish discharge.

O: Participant behaviorally eligible per the Screening Part 1 Eligibility form, tested negative for pregnancy and HIV. Pelvic exam completed to assess genital symptoms. Discharge noted, but no abdominal tenderness or other signs present. Wet prep was positive for trichomonads, negative for whiff test, clue cells, and yeast.

A: Participant appears eligible for the study thus far, but trich must be treated and symptoms resolved before enrollment. Treatment provided [insert details here].

P: Screening Part 2/Enrollment scheduled for 27 NOV 2004, participant counseled to contact site if symptoms do not resolve in 5-7 days.

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Sample Chart Note for Screening Part 2/Enrollment:

3 DEC 2004: Participant presented for HPTN 035 Screening Part 2. Procedures completed per protocol, visit checklist and SOPs. Participant was confirmed eligible and willing to take part in study. Written informed consent obtained for enrollment before initiating any study procedures. Participant was not willing to consent to specimen storage for possible future research.

S: Participant reported that itching and discharge reported at Screening Part 1 resolved 3-4 days after treatment given at last visit. No current genital symptoms reported today.

O: Screening GC and CT tests were negative. Today's pregnancy test was negative. Pelvic exam and wet mount were normal (see findings on DataFax forms). Participant behaviorally eligible per Screening Part 2 Eligibility form. Screening documentation reviewed and eligibility confirmed by [insert name]. {counter-signature}

A: Participant is eligible for the study.

P: Participant was enrolled in study. Month 1 visit scheduled for 4 JAN 2005.

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Section Appendix 3-3
Sample Chart Notes for HPTN 035 in Subjective-Objective-Assessment-Plan (SOAP) Format

Sample Chart Note for Screening Part 2/Enrollment:

3 DEC 2004: Participant presented for HPTN 035 enrollment visit. Procedures completed per protocol, SOPs and visit checklist. Screening was discontinued at this visit due to ineligibility.

S: Participant reported no current health problems.

O: Screening GC and CT lab tests were negative, but today's pregnancy test was positive. Screening discontinued upon finding this result.

A: Participant is pregnant — not eligible for study.

P: Participant informed that she is pregnant and referred to [clinic name] for antenatal care. Participant informed that she can return to find out about study participation when she is no longer pregnant.

{staff signature}

Sample Chart Note for Monthly Follow-up (Phase IIb):

7 March 2005: Participant presented for HPTN 035 Month 2 visit. Procedures completed per protocol, visit checklist and SOPs.

S: No issues/problems reported since last visit.

O: Pregnancy test negative.

A: No issues of concern.

P: Month 3 visit scheduled for 7 APRIL 2005.

{staff signature}

Sample Chart Note for Quarterly Follow-up:

10 May 2005: Participant presented for HPTN 035 Month 3 visit. Procedures completed per protocol, visit checklist and SOPs.

S: No issues/problems reported since last visit.

O: Participant tested negative for pregnancy and for HIV. Pelvic exam and wet mount normal (see test results and exam findings on DataFax forms).

A: No issues of concern.

P: Month 4 visit scheduled for 11 JUNE 2005.

{staff signature}

Section Appendix 3-4
HPTN 035 DataFax and Non-DataFax Forms

HPTN 035 DataFax Forms
Screening Consent
Demographics
Site-Specific Demographics
Screening Part 1 Laboratory Results
Screening Safety Laboratory Results
Concomitant Medications Log
Screening Pelvic Exam
Repeat Screening Pelvic Exam
Screening Part 2 Laboratory Results
Enrollment
Pre-existing Conditions
Enrollment Behavior Assessment
Pharmacy Randomization
Pap Test Result
Monthly or Quarterly Visit
Interim Visit
Missed Visit
Pelvic Exam
Pelvic Laboratory Results
Follow-up Laboratory Results
Safety Laboratory Results
Follow-up Behavior Assessment
Acceptability Assessment
Adverse Experience Log
Product Hold/Discontinuation
Pregnancy Report and History
Pregnancy Outcome
HIV Test Results
Enrollment Specimen HIV Status
HSV-2 Test Result
Study Exit Acceptability Assessment
Participant Transfer
Participant Receipt
Termination
End of Study Inventory

HPTN 035 Non-DataFax Forms
Screening Part 1 Eligibility
Screening Part 2 Eligibility
Baseline Medical History
Physical Exam
Pelvic Exam Diagrams
Clinical Eligibility
Screening Summary
Follow-up Medical History
Genital Bleeding Assessment

Section Appendix 3-5
Use of HPTN 035 DataFax Forms as Source Documents

HPTN 035 DataFax Forms	Source?	Comments
Screening Consent	Mixed	May be source for item 1. All other items are based on source data recorded in participant chart notes and on participant informed consent forms.
Demographics	Yes	Form is interviewer-administered; participant responses are recorded directly onto the form.
Demographics – Site-Specific	Mixed	Form may be source for all items. Items 1-6 are interviewer-administered; participant responses are recorded directly onto the form. Other records may be used as source for item 7.
Screening Part 1 Laboratory Results	Mixed	Form may be source for item 2a only at sites where pregnancy tests are performed in-clinic by clinic staff. All other items require local lab documentation as source.
Screening Safety Laboratory Results	Mixed	Form may be source for Severity Grade. All other items require local lab documentation as source.
Concomitant Medications Log	Yes	Form may be source for all items.
Screening Pelvic Exam	Mixed	Form may be source for all items except items 4, 5, and 7, which are based on source data recorded on visit checklists.
Repeat Screening Pelvic Exam	Mixed	Form may be source for all items except items 5 and 6, which are based on source data recorded on visit checklists. Form may be source for item 4 only at sites where pregnancy tests are performed in-clinic by clinic staff.
Screening Part 2 Laboratory Results	Mixed	Form may be source for items 3a and 3b at all sites. Form may be source for item 2a at sites where pregnancy tests are performed in-clinic by clinic staff. Form may be source for items 3c-3f at sites where wet preps are read in-clinic by clinic staff. All other items require local lab documentation as source.
Enrollment	No	Items 1 and 2 are based on source data recorded in participant chart notes and on participant informed consent forms. Item 3 is based on participant randomization documentation as source.
Pre-Existing Conditions	No	All items are based on data recorded on other source documents.
Enrollment Behavior Assessment	Yes	Form is interviewer-administered; participant responses are recorded directly onto the form.
Pharmacy Randomization	No	All items are based on participant randomization and product dispensation documentation as source.
Pap Test Result	No	All items require local lab documentation as source.
Monthly or Quarterly Visit	Mixed	Form may be source for item 1 at sites where pregnancy tests are performed in-clinic by clinic staff. All other items are based on data recorded on other source documents.

Section Appendix 3-5
Use of HPTN 035 DataFax Forms as Source Documents

HPTN 035 DataFax Forms	Source?	Comments
Interim Visit	Mixed	Form may be source for item 2 at sites where pregnancy tests are performed in-clinic by clinic staff. All other items are based on data recorded on other source documents.
Missed Visit	Yes	Form may be source for the fact that the visit was missed; source data on the reason why the visit was missed also may be recorded on this form.
Pelvic Exam	Yes	Form may be source for all items except items 4-6, which are based on source data recorded on visit checklists.
Pelvic Laboratory Results	Mixed	Form may be source for items 1a and 1b at all sites. Form may be source for all other items only at sites where wet preps are read in-clinic by clinic staff.
Follow-up Laboratory Results	No	All items require local lab documentation as source.
Safety Laboratory Results	Mixed	Form may be source for Severity Grade. All other items require local lab documentation as source.
Follow-up Behavior Assessment	Yes	Form is interviewer-administered; participant responses are recorded directly onto the form.
Acceptability Assessment	Yes	Form is interviewer-administered; participant responses are recorded directly onto the form.
Adverse Experience Log	Yes	Form may be source for all items.
Product Hold/Discontinuation	Mixed	Form may be source for all items except items 2 and 3b. Item 3b is based on product receipt documentation maintained in the study pharmacy as source.
Pregnancy Report and History	Mixed	Form may be source for item 2; all other items are based on data recorded on the Baseline and Follow-Up Medical History form as source.
Pregnancy Outcome	Yes	Form may be source for all items, if medical records are not available and therefore the data recorded are based on participant self-report.
HIV Test Results	Mixed	Items 1-4 require local lab documentation as source. Form may be source for the interpretation of test results recorded in Item 5.
Enrollment Specimen HIV Status	No	All items require local lab documentation as source.
HSV-2 Test Result	No	All items require local lab documentation as source.
Study Exit Acceptability Assessment	Yes	Form is interviewer-administered; participant responses are recorded directly onto the form.
Participant Transfer	Mixed	Form may be source for items 1, 2, and 4.
Participant Receipt	Mixed	Form may be source for items 1 and 2.
Termination	No	All items are based on data recorded on other documents as source.
End of Study Inventory	Mixed	Form is source for item 4 only.

Section Appendix 3-6
Use of HPTN 035 Non-DataFax Forms as Source Documents

HPTN 035 DataFax Forms	Source?	Comments
Screening Part 1 Eligibility	Yes	Form is interviewer-administered; participant responses are recorded directly onto the form.
Screening Part 2 Eligibility	Mixed	Form may be source for items 6-7, which are interviewer-administered; participant responses are recorded directly onto the form. Form also may be source for item 8. All other items are based on data recorded on other documents as source.
Baseline Medical History	Yes	Form may be source for all items. Data recorded on this form based on participant self-report may also be supplemented with data recorded on other source documents (e.g., non-study medical records).
Physical Exam	Yes	Form may be source for all items.
Pelvic Exam Diagrams	Yes	Form may be source for all items.
Clinical Eligibility	No	All items are based on data recorded on other documents as source.
Screening Summary	No	All items are based on data recorded on other documents as source.
Follow-up Medical History	Yes	Form may be source for all items.
Genital Bleeding Assessment	Mixed	Form may be source for item 5-14, 15a-15b, 16a-16b, and 17-18.