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 MTN-011.

3.1 Essential Documents

The Division of AIDS (DAIDS) policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* specifies the essential documents that study sites must maintain for DAIDS-sponsored studies, including MTN-011. When required documents are modified or updated, the original and all 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. In its policy on *Requirements for Manual of Operational Procedures*, DAIDS requires study sites to establish a standard operating procedure (SOP) for maintaining essential documents. This SOP should be established prior to activation of MTN-011 and should be followed for MTN-011.

Section Appendix 3-1 presents a suggested essential documents filing structure for MTN-011. The suggested structure incorporates guidance received from the DAIDS Prevention Science Program and the DAIDS Clinical Site Monitoring Group. Study sites are not required to adopt the suggested structure, but are encouraged to consider it when developing their filing approach for MTN-011. 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 ensure study integrity, 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 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 MTN-011 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 MTN-011 Screening and Enrollment Log and Participant Name-ID Number Link Log (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 MTN-011 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 and her male partner 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 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)

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 comply with the standards of source documentation specified in the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*. The DAIDS policy specifies both requirements and recommendations. Study sites must comply with all requirements and are encouraged, but not required, to comply with all recommendations.

For MTN-011, it is expected that participant case history records will consist of the following source documents:

- Narrative chart notes
- Investigational product dispensing and chain of custody records (maintained in the study site pharmacy)
- 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.

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 product dispensing documentation is provided in Sections 4, 5, and 7 of this manual. Detailed information on proper completion of DataFax and non-DataFax forms provided by the MTN SDMC is provided in Section 10 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. For field and outreach workers, participant contacts may alternatively be documented on worksheets or other forms designated for this purpose. 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 should be used to document the following:

- The screening and enrollment informed consent processes (see also Section 4)
- Procedures performed that are not recorded on other source documents
- Study-specific counseling sessions, and any associated referrals, that are not documented on other source documents
- Other pertinent data about the participant that are not recorded on other source documents
- Protocol deviations 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 Good Clinical Practice standards. Sample notes in SOAP format are available from the MTN Coordinating and Operations Center (CORE; FHI 360) upon request.

Visit Checklists: The checklists in Section 5 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 10 of this manual. The SDMC will provide these forms to each site. The SDMC also will provide study-specific non-DataFax forms to each site. See Section Appendix 3-2 for a listing of all DataFax and non-DataFax forms for this study.

The SDMC will provide each site with forms in pre-assembled packets for each protocol-specified study visit. Additionally, packets of "as needed" CRFs (for example, Adverse Experience Log forms, Concomitant Medications Log forms) will be provided to the site. Some of these forms will be available for download and printing at each site as needed via the ATLAS website.

As shown in Section Appendices 3-3 and 3-4, 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 onto 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 and enter a note on the form stating the alternate source document used
- Enter a chart note stating the relevant study visit date and the reason why an alternative source document was used

3.3 Protocol Deviations

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with efforts made to correct the deviations, and efforts made to prevent similar deviations in the future. The MTN policy on protocol deviations and the MTN Manual of Operational Procedures should be referenced for complete guidance on protocol deviations.

The Protocol Deviation Log CRF will be used to document each protocol deviation. The Protocol Deviation Log CRF is completed and faxed to the SDMC for each reportable deviation identified for female and male participants. Like all CRFs, completed Protocol Deviation Log CRFs will be filed in the participant's study binder. Missed visits are considered protocol deviations per the MTN policy, however these will *not* be captured on the Protocol Deviation Log CRF (the Missed Visit CRF will capture this information instead). Protocol deviations relating to study product adherence will also be captured via other study CRFs. Because detailed information regarding the efforts to correct the deviation and the efforts to prevent similar deviations from occurring in the future are not specifically captured on these CRFs, sites are required to document this information in the participant's study record.

If there is any question as to whether a deviation has occurred, or how it should be documented, MTN Regulatory should be contacted at mtnregulatory@mtnstopshiv.org. Once the potential protocol deviation has been confirmed by the MTN Regulatory Department, the site will be contacted with this confirmation and the 3 day reporting requirement will begin. Once the CRF is faxed, the MTN Regulatory department will follow up with the site if any clarifications or additional information on the CRF is needed. The study management team will follow up with the site regarding any next steps as needed.

3.4 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. Sites should consider including documentation of both the female participant and her male partner in the same study binder for ease of reference. 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 it is recommended that records that bear names or other personal identifiers, such as locator forms and informed consent forms, be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location — including DataFax 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 should 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, and CASI questionnaire data, 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 participant name only and separate from records identified by PTID only. When in use, documents that link PTIDs to other participant identifiers 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
- DataFax 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
- 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)
- QC/QA procedures related to the above (if not specified elsewhere)

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

The essential documents listed in Figure 3-1 below should be maintained in study site pharmacies.

Pharmacy staff will document the receipt, dispensing, return, and final disposition of each investigational product used in the study. Separate accountability records must be maintained for product, per instructions provided in the *MTN-011 Pharmacist Study Product Management Procedures Manual* available from the MTN Pharmacist.

Pharmacy staff also will maintain in the study pharmacies product dispensing records for all participants, per instructions in the *MTN-011 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, 5, and 7 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.

Figure 3-1
MTN-011 Essential Documents Maintained in Study Site Pharmacies

- Current MTN-011 protocol
- Current Investigator's Brochure for Tenofovir Gel
- Current MTN-011 FDA Form 1572
- Current list of authorized prescribers to sign MTN-011 prescriptions
- MTN Pharmacy Establishment Plan
- MTN-011 pharmacy and product-related SOPs
- MTN-011 PTID list
- MTN-011 product shipping and receipt documentation
- MTN-011 product storage temperature logs
- MTN-011 investigational product accountability records
- MTN-011 participant-specific and site-specific records (including prescriptions, documentation of product dispensing)
- MTN-011 monitoring visit reports
- MTN-011 communications with site clinic staff
- MTN-011 communications with the MTN CORE (PITT), including the MTN Pharmacist
- MTN-011 communications with the MTN CORE (FHI 360)
- MTN-011 communications with the MTN SDMC
- Other MTN-011 communications
- Other locally-required administrative, operational, and/or regulatory documentation

3.6 Record Retention Requirements

All study records must be maintained for at least two years following the date of marketing approval for the study product for the indication in which it was studied. If no marketing application is filed, or if the application is not approved, records must be retained for two years after the US Food and Drug Administration is notified that the Investigational New Drug application for the product(s) is discontinued.

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 site 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. Study records should not be re-located to an off-site location or destroyed without prior approval from DAIDS.

Section Appendix 3-1
Suggested Filing Structure for MTN-011 Essential Documents

File/Binder #1: MTN-011 Protocol and Current Informed Consent Forms

1. MTN-011 Protocol (including signed and dated protocol signature page): Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments
2. Currently-approved (blank) MTN-011 informed consent forms

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

3. Regulatory Authority Correspondence/Authorization/Approval/Notification of the MTN-011 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 #3: IRB/EC Documentation

4. FWA documentation for IRB/EC
5. Roster of IRB/EC (if available)
6. Relevant IRB/EC Submission Requirements/Guidelines/SOPs
7. IRB Correspondence for IRB/EC: 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

8. Investigator's Brochure for Tenofovir Gel: current version and any subsequent updates
9. 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 #3).

File/Binder #5: MTN-011 Study-Specific Procedures (SSP) Manual

10. Version 1.0 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: MTN-011 Study-Specific Standard Operating Procedures

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

File/Binder #7: MTN-011 Staffing Documentation

12. FDA Form 1572 (copy of original form submitted to the DAIDS Protocol Registration Office (PRO), and any subsequent updates)
13. MTN-011 Investigator of Record CV (copy of CV submitted to the DAIDS PRO; ensure that the CV is current prior to initiating MTN-011; it is recommended that CVs be signed and dated to document at least annual updating)
14. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
15. Study Staff Roster (copy of original submitted to FHI 360 for study activation, and any subsequent updates)
16. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
17. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
18. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-011; it is recommended that CVs be signed and dated to document at least annual updating)
19. Study Staff Job Descriptions
20. Documentation of Study Staff Training

Section Appendix 3-1
Suggested Filing Structure for MTN-011 Essential Documents

File/Binder #8: Local Laboratory Documentation

21. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
22. 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
23. 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

24. Monitoring Visit Log
25. Monitoring Visit Reports and Documentation of Response to Visit Findings

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

26. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings
27. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
28. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
29. Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #11: Study-Related Sponsor Communications

30. Study-Related Communications to and from DAIDS
31. Communications to and from DAIDS Regulatory Support Center (includes copies of all submissions to the DAIDS PRO)

Notes:

- Communications should be filed beginning from the date of DAIDS Protocol Registration
- Communications related to individual MTN-011 study participants will be filed in individual participant study records.

File/Binder #12: Other Study-Related Communications

32. Study-Related Communications to and from MTN CORE
33. Study-Related Communications to and from MTN SDMC
34. Study-Related Communications to and from MTN Network Lab
35. Other Study-Related Communications

Notes:

- Communications related to individual MTN-011 study participants will be filed in individual participant study records.

File/Binder #13: Study Site Staff Meeting Documentation

36. MTN-011 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

Note: Meeting documentation should be filed beginning from the date of Version 1.0 of the protocol

File/Binder #14: Conference Call Documentation

37. MTN-011 Protocol Team Conference Call Summaries
38. Summaries of Other MTN-011 Conference Calls

Note: Conference call summaries will be filed beginning from the date of Version 1.0 of the protocol

File/Binder #15: DAIDS and Other Reference Documentation

39. DAIDS Protocol Registration Policy and Procedures Manual
40. Manual for Expedited Reporting of Adverse Events to DAIDS
41. DAIDS Adverse Experience Reporting System Reference Guide for Site Reporters and Study Physicians
42. US Regulations Applicable to Conduct of MTN-011 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
43. Any other relevant manuals or reference documents

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

45. Site-Specific Study Activation Notice and supporting documentation

Section Appendix 3-2
MTN-011 DataFax and Non-DataFax Forms

MTN-011 DataFax Forms	MTN-011 Non-DataFax Forms
Adverse Experience Log	Baseline Medical History Questions
Concomitant Medications Log	Pre-Existing Conditions Resolution Tracker (Male)
Demographics	Genital Exam – Male
End of Study Inventory	Pelvic Exam Diagrams
Enrollment	Physical Exam – Male
Family Planning	Screening Menstrual History
Group 2 – Participant-reported Dosing	
HIV Test Results	
Laboratory Results	
Male Practices – Group 1	
Male Practices – Group 2	
Missed Visit	
Pelvic Exam	
Pelvic Exam – Clinically-indicated	
Pharmacokinetics	
Physical Exam	
Pre-existing Conditions	
Pregnancy Outcome	
Pregnancy Report and History	
Product Hold/Discontinuation Log	
Protocol Deviation Log	
STI Test Results	
Study Exit CASI Tracking	
Study Product Accountability	
Termination	
Visit Summary	

Section Appendix 3-3
Use of MTN-011 DataFax Forms as Source Documents

MTN-011 DataFax Forms	Source?	Comments
Adverse Experience Log	Yes	Form may be source for all items.
Concomitant Medications Log	Yes	Form may be source for all items.
Demographics	Yes	Form may be source for all items
End of Study Inventory	No	All items should be completed based on source data recorded on other source documents.
Enrollment	Mixed	Source for Item 1 are the male and female Eligibility Checklists. Source for Items 2and 6 is Screening and Enrollment Informed Consent Form. Form or visit checklists may be source for all other items – site to choose.
Family Planning	Yes	Form may be source for all items.
Group 2 – Participant-reported Dosing	No	The participant's home dosing log should be source for all items; however if participant does not complete log, form may be source.
HIV Test Results	Mixed	Form is source for Item 3. All other items should be completed based on laboratory source documents.
Laboratory Results	No	All items should be completed based on laboratory source documents.
Male Practices – Group 1	No	Self-administered Male Practices Questionnaire – Group 1 is source.
Male Practices – Group 2	No	Self-administered Male Practices Questionnaire – Group 2 is source.
Missed Visit	Yes	Form may be source for all items.
Pelvic Exam	Mixed	Form may be source for items 2 and 3. Other items should be based on non-DataFax Pelvic Exam Diagrams form
Pelvic Exam – Clinically Indicated	Mixed	Form may be source for items 2 and 3. Other items should be based on non-DataFax Pelvic Exam Diagrams form
Pharmacokinetics	Mixed	Form may be source for all items; however Physical Exam CRF may be source for weight and height (Items 1 and 2). Sites to note what is source for these items.
Physical Exam	Yes	Form may be source for all items.
Pre-existing Conditions	No	All items should be completed based on source data recorded on other source documents.
Pregnancy Outcome	Yes	Form may be source for all items. If medical records are obtained, then they will be source for as many items as possible.
Pregnancy Report and History	Yes	Form may be source for all items.
Product Hold/Discontinuation Log	Yes	Form may be source for all items.
Protocol Deviation Log	Yes	Form may be source for all items.
STI Test Results	Mixed	Form may be source for items 1a, 1b, 1c, 5, and 6. All other items should be completed based on laboratory source documents.
Study Product Accountability	Yes	Form may be source for all items.
Study Exit CASI Tracking	Yes	Form may be source for all items. Visit checklists may also be source – site to choose.

Section Appendix 3-3
Use of MTN-011 DataFax Forms as Source Documents

MTN-011 DataFax Forms	Source?	Comments
Termination	No	All items should be completed based on source data recorded on other source documents.
Visit Summary	Mixed	Form may be source for items 7, 8, and 9. All other items should be completed based on source data recorded on other study documents.

Section Appendix 3-4
Use of MTN-011 Non-DataFax Forms as Source Documents

MTN-011 Non-DataFax Forms	Source?	Comments
Baseline Medical History Questions	Yes	Form may be source for all items.
Pre-Existing Conditions Resolution Tracker (Male)	No	All items should be completed based on source data recorded on other source documents.
Genital Exam – Male	Yes	Form may be source for all items.
Pelvic Exam Diagrams	Yes	Form may be source for all items.
Physical Exam – Male	Yes	Form may be source for all items.
Screening Menstrual History	Yes	Form may be source for all items.