Suggested Filing Structure for MTN-017 Essential Documents

File/Binder #1: MTN-017 Protocol and Current Informed Consent Forms

1. MTN-017 Protocol (including copy of signed and dated protocol signature page): Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments issued after Version 1.0
2. Currently-approved (blank) MTN-017 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; #3B: IRB/EC Documentation for each applicable IRB [IRB/EC A]; [IRB/EC B]

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.
8. IRB approval documentation; include stamped consents if possible

File/Binder #4: Product Safety Information

9. Investigator's Brochure for Tenofovir Gel (GS-1278): current version and any subsequent updates
10. Package Insert for Truvada: current version and any subsequent updates
11. Product Safety Information/Reports/Memos

Notes:

12. Expedited adverse event reports will be stored in participant study notebooks.
13. 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: MTN-017 Study-Specific Procedures (SSP) Manual

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

Notes:

- For this reference copy of the SSP Manual, do not discard outdated pages or sections when updates are issued; retain all versions of all pages as a complete historical record.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-017 Study-Specific Standard Operating Procedures

15. Final approved version of each site specific SOP, and any subsequent updates to each

File/Binder #7: MTN-017 Staffing Documentation

16. FDA Form 1572 (copy of original and dated form submitted to the DAIDS Protocol Registration Office (PRO), and any subsequent updates)
17. Investigator of Record CV (copy of CV submitted to the DAIDS PRO; ensure that the CV is current prior to initiating the study; CVs should be signed and dated to document at least annual updating)
18. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
19. Study Staff Roster (original submitted to MTN CORE for study activation, and any subsequent updates)
20. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
21. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
22. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-013; it is recommended that CVs be signed and dated to document at least annual updating)
23. Study Staff Job Descriptions
24. Documentation of Study Staff Training

Suggested Filing Structure for MTN-017 Essential Documents

File/Binder #8: Local Laboratory Documentation

25. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
26. 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
27. 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

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

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

30. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings
31. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
32. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
33. Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #11: Study-Related Sponsor Communications

34. Study-Related Communications to and from DAIDS
35. Communications to and from DAIDS RSC (includes copies of all submissions to the DAIDS PRO)

Notes:

- Communications related to individual MTN-017 study participants will be filed in individual participant study records.
- Product-related communications with MTN Pharmacist (and its contractors) will be stored in the study pharmacy.

File/Binder #12: Other Study-Related Communications

36. Study-Related Communications to and from MTN CORE
37. Study-Related Communications to and from MTN SDMC
38. Study-Related Communications to and from MTN Network Lab
39. Other Study-Related Communications

Notes:

- Communications related to individual MTN-017 study participants will be filed in individual participant study records.
- Product-related communications with MTN Pharmacist (and its contractors) will be stored in the study pharmacy.

File/Binder #13: Study Site Staff Meeting Documentation

40. MTN-017 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

File/Binder #14: Conference Call Documentation

41. Protocol Team Conference Call Summaries
42. Community Working Group Conference Call Summaries
43. Summaries of Other Conference Calls

File/Binder #15: DAIDS and Other Reference Documentation

44. DAIDS Protocol Registration Policy and Procedures Manual
45. Manual for Expedited Reporting of Adverse Events to DAIDS
46. US Regulations Applicable to Conduct of MTN-017 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
47. Any other relevant manuals or reference documents

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

45. Site-Specific Study Activation Notice and supporting documentation