| Suggested Filing Structure for MTN-023/IPM 030 Essential Documents |
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| File/Binder #1: MTN-023/IPM 030 Protocol and Current Informed Consent Forms1. MTN-023/IPM 030 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-023/IPM 030 Informed Consent Forms
 |
| File/Binder #2: Regulatory Authority Documentation (if applicable)1. 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 #3: IRB/EC Documentation 1. FWA documentation for IRB/EC
2. Roster of IRB/EC (if available)
3. Relevant IRB/EC Submission Requirements/Guidelines/SOPs
4. 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.
5. IRB approval documentation; include stamped consents if possible
 |
| File/Binder #4: Product Safety Information1. Investigator's Brochure for Dapivirine Vaginal Ring: current version and any subsequent updates
2. Product Safety Information/Reports/Memos

Notes:1. Expedited adverse event reports will be stored in participant study notebooks.
2. Documentation of IRB/EC submission of above-listed documents (if applicable) will be maintained in the IRB/EC File/Binder
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| File/Binder #5: MTN-023/IPM 030 Study-Specific Procedures (SSP) Manual1. Final version 1.0 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Notes:* For this reference copy of the SSP Manual, do not discard outdated pages or sections when updates are issued; retain all versions of all pages as a complete historical record.
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| File/Binder #6: MTN-023/IPM 030 Study-Specific Standard Operating Procedures1. Final approved version of each study-specific and/or site-specific SOPs and any subsequent updates
 |
| File/Binder #7: MTN-023/IPM 030 Staffing Documentation1. FDA Form 1572 (copy of original and dated form submitted to the DAIDS Protocol Registration Office (PRO) or Westat, and any subsequent updates)
2. Investigator of Record CV (copy of CV submitted to the DAIDS PRO or Westat; ensure that the CV is current prior to initiating the study; CVs should be signed and dated to document at least annual updating)
3. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
4. Study Staff Roster (original submitted to MTN LOC or Westat for study activation, and any subsequent updates)
5. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
6. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
7. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-023/IPM 030; it is recommended that CVs be signed and dated to document at least annual updating)
8. Study Staff Job Descriptions
9. Documentation of Study Staff Training
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| File/Binder #8: Local Laboratory Documentation 1. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
2. 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
3. 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).
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| File/Binder #9: Monitoring Visit Documentation 1. Monitoring Visit Log
2. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings
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| File/Binder #10: Documentation of Other MTN Site Visits 1. MTN LOC Site Visit Reports and Documentation of Response to Visit Findings
2. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
3. MTN Laboratory Center Site Visit Reports and Documentation of Response to Visit Findings
4. Other Site Visit Reports and Documentation of Response to Visit Findings
 |
| File/Binder #11: Study-Related Sponsor Communications 1. Study-Related Communications to and from DAIDS and/or NICHD
2. Communications to and from DAIDS RSC

**Notes**: * Communications related to individual MTN-023/IPM 030 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.
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| File/Binder #12: Other Study-Related Communications 1. Study-Related Communications to and from MTN LOC
2. Study-Related Communications to and from Westat
3. Study-Related Communications to and from MTN SDMC
4. Study-Related Communications to and from MTN Laboratory Center
5. Other Study-Related Communications

**Notes:** * Communications related to individual MTN-023/IPM 030 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.
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| File/Binder #13: Study Site Staff Meeting Documentation 1. MTN-023/IPM 030 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries
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| File/Binder #14: Conference Call Documentation 1. Protocol Team Conference Call Summaries
2. Community Working Group Conference Call Summaries
3. Summaries of Other Conference Calls
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| File/Binder #15: DAIDS and Other Reference Documentation1. DAIDS Protocol Registration Policy and Procedures Manual
2. Manual for Expedited Reporting of Adverse Events to DAIDS
3. US Regulations Applicable to Conduct of MTN-023/IPM 030 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
4. Any other relevant manuals or reference documents
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| File/Binder #16: Site-Specific Study Activation Documentation 45. Site-Specific Study Activation Notice and supporting documentation |