| **Study Closure Requirements** | **Completion/****Approval Date** | **Comments/Status** |
| --- | --- | --- |
| **Data Requirements** |
| 1 | Ensure all required DataFax forms are completed and faxed to DF Net |  |  |
| 2 | Resolve all outstanding data QC notes and clinical queries. Confirm with SCHARP that there are no outstanding data QC notes or clinical queries. |  | Note: Data cleaning will continue until database lock, and new QCs may be identified as part of intensified data cleaning efforts during closeout. Sign off on this item cannot occur until the database is locked. |
| **Pharmacy Requirements** |
| 3 | Reconcile study product accountability records. |  |  |
| 4 | In consultation with the MTN Pharmacist, destroy unused ring return bags, unused Intravaginal Ring Request Slips and Prescriptions, and unused participant specific pharmacy dispensing records  |  |  |
| 5 | In consultation with the MTN Pharmacist, destroy or return remaining unused study product per the instructions for “Study Product Destruction” in the Pharmacy Study Product Management Procedures Manual. |  |  |
| **Laboratory Requirements** |
| 6 | In consultation with the MTN LC, resolve all outstanding errors/discrepancies on the LDMS Specimen Monitoring Report. Confirm with MTN LC that there are no outstanding errors or discrepancies. |  |  |
| 7 | In consultation with the MTN LC, ship all pending biological specimens to the designated laboratories (MTN LC, Merck Laboratories, and/or Colorado Antiviral Pharmacology Laboratory [CAVP]). |  |  |
| 8 | In consultation with SCHARP and the MTN LC, after all protocol-specified laboratory testing is complete, archive or destroy all remaining stored specimens. ***Note:*** *Specimens obtained from participants who did not provide informed consent for post-study specimen storage and possible future research testing must be destroyed once protocol testing is complete. In addition, any samples at the conclusion of a study that are deemed worthless to any further investigation will be destroyed with consent of study team. Lab Center will ensure that the samples will be destroyed, a Sample Destruction Form completed, and a DSR (Destroyed) code placed in the condition field of the specimen details section in LDMS.*  |  | Primary testing can take many years to conclude; therefore this is checked off as an acknowledgement that MTN LC will remove applicable samples from storage and destroy at the appropriate time. |
| **Regulatory Requirements** |
| 9 | In consultation with MTN Regulatory, ensure all regulatory documentation requests have been resolved/completed. ***Note****: This includes, but is not limited to, financial disclosures and investigator qualifications.* |  |  |
| 10 | Notify all responsible IRBs/ECs of completion of participant accrual and follow up. Complete necessary study closure reporting requirements. |  |  |
| 11 | Complete protocol deregistration with the DAIDS Protocol Registration Office, when applicable. ***Note****: Study closure/termination with a site’s IRB/EC is not required for a CRS to deregister with DAIDS. If a site plans to complete the DAIDS deregistration process for a study but will not be closing/terminating the study at their IRB/EC, the site should consult their IRB/EC to confirm any requirements and/or standard operating procedures that must be met prior to deregistering with DAIDS. A site’s IRB/EC may require the continued submission of safety information and/or other data (e.g., from data queries) for the study. In this case, deregistration with DAIDS cannot be done until the study has been completed and closed out with the IRB/EC. Regardless of when protocol deregistration is completed, all sites must maintain continuing review until the study is considered completed/closed per IRB/EC policies.* |  |  |
| **General/Data Storage Requirements** |
| 12 | Document follow-up plans for the monitoring of any ongoing unresolved AE(s)/EAE(s) at the end of the study (see protocol section 4.6 and SSP section 8.15) and any other relevant study exit considerations including pending test results. |  |  |
| 13 | Resolve any outstanding PPD monitoring and assessment visit findings and/or action items. Confirm with the appropriate monitor(s) or representatives that all findings and/or action items have been resolved/completed. |  |  |
| 14 | Review all termination visit documentation. Review/update participant contact information. Compile a list of participants who consented to be contacted for study results and/or participation in future studies. |  |  |
| 15 | Review and assemble all required essential documents for long-term secured storage, focusing on completeness and organization of records.* + - * Administrative and regulatory documentation
* All study documents bearing or linking participant names and/or PTID (including the PTID Linkage Log and Screening and Enrollment Log)
* All study drug/product receipt, dispensing, accountability, and final disposition documentation
	+ ***Note****: The site Pharmacist of Record should place all pharmacy source documents in its own folder or envelope and must clearly mark the location as ‘Pharmacy Records’.*
* All study-specific laboratory documentation
* Updated financial disclosure forms (reflecting any relevant changes that occur during the course of the study, at study completion [i.e. date of last follow up at the site]
 |  |  |

[ ]  Once all of the above requirements are met, staff should prepare a written inventory of all documentation and storage locations and forward a copy of

this documentation to FHI 360, MTN Regulatory, and designated OCSO Program Officer.

[ ]  Following CRF Database Lock, store all documents on-site for long-term storage with adequate protection of participant confidentiality and per all applicable IRB policies.

***Note****: In accordance with US regulations, all records must be stored for at least two years after the investigation is discontinued (see Protocol Section 11.2). Study records will not be destroyed prior to receiving approval for record destruction from DAIDS. Applicable records include source documents, site registration documents and reports, correspondence, informed consent forms, and notations of all contacts with the participant. If off-site storage becomes necessary, approval must be obtained from the DAIDS.*

**Once all requirements have been completed, the site Investigator of Record must sign, and date this checklist. File original with other study documentation and provide a copy to FHI 360 and MTN Regulatory.**

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Investigator of Record Signature Date

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Investigator of Record Name (Print) Date