|  |  |  |
| --- | --- | --- |
| **Task** | **Date Completed** | **Comments** |
| **Completion of participant visits and contacts:**  |
| 1  | Complete and document all remaining study visits |  |  |
| 2  | At all termination visits, review/update participant contact information. Document participant consent to be contacted for study results. |  |  |
| 3 | Establish a clinically appropriate follow-up plan for participants with on-going medical conditions; see MTN-015 SSP Manual, Section 5.9.2.  |  |  |
| 4 | Notify local IRB/EC of study closure of accrual and participant follow up. Complete study close-out reporting requirements per local IRB/EC guidelines. |  |  |
| 5 | Complete protocol de-registration with the DAIDS Protocol Registration Office via DPRS when applicable. Protocol de-registration may take place after all responsible IRB/ECs are informed that all participant study visits and data collection have been completed. Regardless of when protocol de-registration is completed, all sites must maintain continuing review until the study is considered completed/closed per IRB/EC policies. |  |  |
| **File review, data submission, and verification:** |
| 6 | Perform final participant file review of clinic records. Ensure all documents are properly filed and up to date. |  |  |
| 7 | Complete and submit all required DataFax case report forms and submit to SCHARP. A Termination CRF and End of Study Inventory CRF must be completed for each enrolled participant, even if the participant did not complete the study exit/termination visit. |  |  |
| 8 | Resolve all outstanding data QC notes. Confirm with SCHARP that there are no outstanding data QC notes. |  |  |
| **Specimen management and laboratory considerations:**  |
| 9 | Resolve all outstanding discrepancies and errors on the LDMS Specimen Monitoring Reports. Confirm with the LC that discrepancies and errors have been resolved.  |  |  |
| 10 | **After** receiving notification from the MTN LC, ship all requested biological specimens to designated laboratories for protocol testing. Confirm with LC that all required samples have been shipped. *All other samples will remain on site indefinitely; samples will be requested when additional testing is approved.* |  |  |
| 11 | **After** receiving notification from SCHARP and written approval from the MTN LC, destroy all remaining specimens for participants who did **not** provide informed consent for long term specimen storage and future research testing (a list of PTIDs will be provided by SCHARP).  Document destruction using destruction logs and within LDMS.  If all specimens have been shipped to the LC and none remain on site, the LC will be responsible for archival or destruction and documentation.Note: *The LC authorization memo, dated \_\_\_\_\_\_\_\_\_\_\_ (sites to insert date DD/MMM/YYYY) instructs the site to complete study closeout before sample destruction due to delay in protocol required testing.  Prepare a written inventory of all samples and storage locations; submit copy to LC and DAIDS OCSO Program Officer.* |  |  |
| 12  | Organize and/or archive any lab documentation (log sheets, QC records, maintenance records, personnel records etc.) to be available for potential audits. |  |  |
| **Essential documents:**  |
| 13 | IoR to review and complete final sign off of Delegation of Authority Log. Prior to filing for long term storage, scan and email all final signed Delegation of Authority log(s)to FHI 360 (maintain originals on site). |  |  |
| 14 | Scan and email final screening and enrollment logs to FHI 360 (maintain originals on site). |  |  |
| 15 | Review and assemble for long term storage all required study documents, including:• Delegation of Authority Log • Logs that link participants’ names and ID numbers (which also serve as the completed participant identification code lists required by International Conference on Harmonization (ICH/GCP guidelines)• All study documents bearing participants’ names• All study documents bearing participants’ ID numbers • Final report by investigator to IRBs/IECs • Any other key communication/correspondence with the site |  |  |
| 16 | Prepare a written inventory of all documentation and storage locations; inform FHI 360 if documents are moved to an offsite location. |  |  |
| 17  | Store all documents on-site with adequate protection of participant confidentiality and per all applicable IRB/EC policies:* 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.
 |  |  |
| 18 | Resolve any outstanding monitoring findings and/or action items and confirm with the appropriate OCSO Program Officer that all have been resolved/completed. Scan and email copies of all monitoring visit logs to FHI 360 (maintain originals on site). |  |  |

# Investigator of Record Sign Off

**Instructions:** Once all items on this checklist are completed, notify your FHI 360 CRM. After verification with FHI 360 that the checklist can be finalized, the IoR should print, sign, and date where indicated below. File original signed checklist with study essential documents, scan and email a copy to FHI 360.

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Investigator of Record Signature Date

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Investigator of Record Name (Print)