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| --- | --- | --- |
| **Task** | **Date Completed** | **Comments** |
| **Completion of participant visits and contacts:**  |
| 1  | Complete and document all remaining study visits, including any final contacts to provide outstanding test results, counseling, referrals and treatment. Note guidance in Sections 6.10 and 11.7 of the SSP manual for Study Exit Considerations. See also HOPE Operational Guidance #3 and #5. |  |  |
| 2  | Complete contact log(s) for study results dissemination and permission to contact for future studies for all participants. File with appropriate study essential documents.  |  |  |
| 3 | Complete follow-up for all SAEs/AEs that require re-assessment after study end per SSP Section 11.7. *Note: Re-assess these AEs at least once within 30-60 days after the study end date. Send an informational query regarding any such cases to the PSRT at the time of reassessment. The MTN-025 PSRT also may advise on whether any additional follow-up is indicated on a case by case basis.* |  |  |
| 4 | Complete final contacts to assess pregnancy outcomes for all pregnant participants. For pregnancy outcomes that were previously documented as ‘outcome unobtainable,’ determine if further information is available and whether the outcome can be updated. |  |  |
| 5 | As directed by the MTN LC, complete any outstanding HIV testing per the protocol specified testing algorithm. |  |  |
| 6 | Notify local IRBs/ECs of completion of participant follow up. Complete study close-out reporting requirements per local IRBs/ECs guidelines. File final report by investigator to IRBs/IECs and local drug regulatory authorities, where applicable. |  |  |
| 7 | Complete protocol de-registration with the DAIDS Protocol Registration Office, per the DAIDS RSC de-registration guidance, located here: <http://rsc.tech-res.com/protocolregistration/> |  |  |
| **File review, data submission, and verification:** |
| *Perform final participant file review, by completing all tasks listed in items 8-11.* |
| 8 | Review of all AEs that meet safety endpoint definitions (related G2, all G3/G4 AEs, and all SAEs) to confirm they were evaluated by qualified and designated staff, and that the relationship status, AE grade, and outcome are accurately documented in the participant record. |  |  |
| 9 | Conduct 100% check of clinic product accountability log in each PTID binder to ensure all product provided to each participant is accounted for.  |  |  |
| 10 | Ensure all CRFs are complete and accurate to the best of sites’ knowledge. Per your site’s Forms Not Touched Report, this includes completion of Y/N admin forms and log forms within Medidata. |  |  |
| 11 | Any other reviews as determined necessary by the IoR (e.g. informed consent review, eligibility review, etc.) or as requested by MTN-025 study management. Note any reviews conducted in comments. |  |  |
| 12 | Ensure all ACASI surveys have been uploaded to SCHARP Atlas portal, including all ACASI surveys marked as ‘duplicate’. |  |  |
| 13 | Complete prescreening reconciliation process with SCHARP and FHI 360 to document an outcome for all former ASPIRE participants. |  |  |
| 14 | Resolve all outstanding Medidata queries. Confirm with SCHARP that there are no outstanding queries (includes System, DM, Safety, Coder, Monitor queries). Note: *Data cleaning will continue until database lock, and new queries may be identified as part of intensified data cleaning efforts during close-out.* |  |  |
| 15 | Resolve all outstanding discrepancies and errors on the LDMS Specimen Monitoring Reports. Confirm with the LC that discrepancies and errors have been resolved. |  |  |
| 16 | Once all queries have been resolved and when instructed by SCHARP, complete IoR sign-off in Medidata on all participant casebooks to attest that the data has been reviewed and is deemed to be accurate. |  |  |
| **Qualitative data submission and other considerations (N/A for sites not participating in HOPE Qualitative):** |
| 17 | Ensure accurate completion and submission of all debrief reports, tools, and transcripts for the qualitative component. |  |  |
| 18  | Resolve any outstanding qualitative component queries on debrief reports, tools, or transcripts. |  |  |
| 19  | Ensure all transcripts are certified, printed, and saved in participant files along with debrief reports and tools. |  |  |
| 20  | Review the Qualitative Participation Log and assemble with other documents outlined in item 33 of this checklist for long term storage. |  |  |
| 21  | Ensure all audio recordings of in-depth interviews have been saved onto CDs and prepare them for long term storage, either together with participant charts or in a separate secured location, as specified in the site’s written inventory (see item 30 of this checklist). After notification from RTI, audio files saved on the site computers should be deleted. |  |  |
| **Specimen management and laboratory considerations:**  |
| 22  | Destroy any specimens collected during failed screening attempts. This includes participants who did not enroll and participants that required a new screening attempt before being enrolled. This does not require prior notification from the LC or SCHARP. |  |  |
| 23 | **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.* |  |  |
| 24 | **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.* |  |  |
| 25  | Create a PDF sample disposition record that includes a sample identification and final location/disposition, at minimum. Send an electronic version of the document to the LC. Print a final, hardcopy sample disposition record for storage and file with other study records. Each page of the printout should be initialed/dated by the person printing it, testifying that it is accurate and complete to the best of their knowledge. |  |  |
| 26 | Organize and/or archive any lab documentation (log sheets, QC records, maintenance records, personnel records etc.) to be available for potential audits. |  |  |
| **Study product and pharmacy considerations:** |
| 27 | Conduct final reconciliation of study product accountability records in the pharmacy |  |  |
| 28  | Quarantine all remaining MTN-025 study product in accordance with the CTA. After receiving notification from the MTN Pharmacist, follow instructions for “Study Product Destruction” in the HOPE Pharmacist Study Product Management Procedures Manual. This includes providing a copy of the destruction certificate to the MTN pharmacist. |  |  |
| 29  | Confirm with MTN Pharmacist the destruction of all unused dispensing records, prescriptions and request slips. |  |  |
| **Essential documents:**  |
| 30 | Complete internal review of essential document files, focusing on completeness and organization of records. All aspects of the MTN-025 Closeout Regulatory File Review Checklist should be completed during this review. Note that this checklist should also be used as an inventory for study essential documents. If moved to an offsite location, inform LOC (FHI 360) of storage locations of files and inventory list.  |  |  |
| 31  | Scan and email final screening and enrollment logs for enrolled and decliner populations to FHI 360. |  |  |
| 32  | Complete end of study Financial Disclosure form for all investigators/sub-investigators and submit to DAIDS PRO and MTN Regulatory. Ideally this should occur on the last day of participant follow-up at the site, but no later than 30 days following that date. |  |  |
| 33  | To the extent possible, organize and categorize all study documentation according to ICH E6: GCP guidelines and prepare for long term storage. This includes all study essential documents as outlined in the MTN-025 Close Out Regulatory Review Checklist, as well as all study documents bearing participant names or PTIDs, all study-specific laboratory documentation, and all study product receipt, dispensing, accountability, and final disposition documentation. Documents maintained on-site must be stored with adequate protection of participant confidentiality and per all applicable IRB/EC policies. Refer to MTN MOP Section 18.2.2 and Protocol Section 11.2 for further guidance record retention requirements. Note:* Verify with your IRBs/ECs and follow the strictest of any applicable laws, regulations, policies or other requirements for record retention. Study records will not be destroyed prior to receiving approval for record destruction from DAIDS.
* If off-site storage becomes necessary, approval must be obtained from the DAIDS.
* Pharmacy source documents (e.g. accountability records or any other record that captures dispensing data) must be kept in the pharmacy until the study has reached the DAIDS Enterprise System status of *Concluded*. Once this occurs, participant specific dispensing records and other participant specific pharmacy documents should be archived in a folder or envelope marked as “pharmacy records” and stored together in the front of the participant binder. These pharmacy documents must be placed in a folder or envelope marked “pharmacy records”.
* Pharmacy documents including order forms, receipts for transfers and returns (if applicable), communications, packing slips and destruction documentation MUST BE RETAINED IN THE PHARMACY until the trial is completed (see MTN Pharmacy Guidelines and Instructions for Clinical Trials). After study closeout, the records should be stored in the pharmacy or with other records from the clinic
 |  |  |
| **Other tasks:** |
| 34 | Verify that all audio recordings of adherence counseling sessions have been uploaded to the HOPE ATLAS website. In consultation with the HOPE Options Counseling team, destroy all audio files once uploaded to ATLAS by ensuring that they have been deleted from both the audio recorders and the computers onto which they were downloaded and emptying the “Trash can” on the computers. |  |  |
| 35 | Develop draft plan for release of study results to study staff, participants, and participant communities to suit local needs in consultation with site staff and community representatives. Timelines and parameters for these plans will be developed in coordination with MTN LOC (FHI 360 and Pitt), DAIDS, and IPM. |  |  |
| 36  | Resolve any outstanding assessment visit findings/queries, and confirm with the appropriate FHI 360 CRM that all have been resolved/completed. |  |  |
| 37  | Resolve any outstanding monitoring findings and/or action items identified by DAIDS Clinical Site Monitoring Group, and confirm with the appropriate OCSO PO that all have been resolved/completed. |  |  |
| 38  | Confirm with MTN Regulatory that all necessary documentation is in place at LOC-Pitt. This includes, but is not limited to financial disclosures and investigator documentation. |  |  |
| 39 | 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 |  |  |

# 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)