|  |  |  |  |
| --- | --- | --- | --- |
| *Task* | | *Initial/Date Completed* | *Comments* |
| Case Report Forms (CRF)/Source Documents[[1]](#footnote-1) | | | |
|  | Confirm appropriate source documentation is completed and filed for all participants |  |  |
|  | Resolve all pending queries from monitoring/audit reviews |  |  |
|  | Confirm all data is entered in the CRF and all queries have been resolved |  |  |
|  | Ensure all CRF pages are signed by Investigator prior to data lock |  |  |
| Unexpected AE, Unanticipated Problem, and SAE Reporting/Reconciliation | | | |
|  | Confirm all AE and SAE follow-up and documentation is completed, and all AEs and SAEs have been captured and reported, as required, to Sponsor, IRB, and/or other regulatory agencies |  |  |
|  | Confirm all required follow-up documentation has been completed, reported to appropriate parties, and is filed with study documents |  |  |
| Investigator Site Files1 | | | |
|  | Confirm receipt of close-out letter from sponsor (as applicable) and notify the following: PI, coordinator(s), regulatory coordinator, pharmacy, lab and any other pertinent study staff |  |  |
|  | Ensure reporting of study closure to the IRB (see IRB Final Project Policy, here: <https://irb.utah.edu/submit-application/final-project-reports.php>) and filing of study closure confirmation is in the investigator site files |  |  |
|  | Ensure all essential documents (e.g., CV, CITI, GCP, HIPAA) are available for duration of study |  |  |
|  | Ensure end dates on the Delegation of Authority (DOA) are completed with a final PI signature, after close-out visit is completed and prior to archiving |  |  |
|  | If study was terminated early, confirm notification of study termination has been communicated and documented for all enrolled participants, as appropriate |  |  |
|  | Confirm signed consent forms are on file for all participants |  |  |
|  | Confirm all protocol deviations have been documented in source, signed off by the PI and reported to the IRB, as appropriate |  |  |
| *Ensure the completeness of the following logs:* | | | |
|  | Pre-Screening/Screening Log |  |  |
|  | Subject Enrollment Log |  |  |
|  | Site Monitoring Visit Log |  |  |
|  | Delegation of Authority Log |  |  |
|  | Site Training Log |  |  |
|  | Other Misc. Logs (Communication, Temperature, Calibration Logs etc.) |  |  |
| Investigational Product (IP) | | | |
|  | Confirm IP disposition forms and accountability records are complete and present for all participants |  |  |
|  | Confirm final disposition of IP was completed per site protocol |  |  |
|  | Return/destroy IP/supplies according to sponsor/protocol instructions and maintain all required documentation |  |  |
| Collected Laboratory Specimens, Laboratory Kits, and Study Equipment | | | |
|  | Confirm all samples have been shipped, analyzed, and/or stored for future use, per protocol |  |  |
|  | Ensure samples collected for future use have been adequately processed, labeled/de-identified, and stored |  |  |
|  | Confirm site process for identification and disposition of future use samples connected to participants who withdrew consent |  |  |
|  | Confirm destruction of samples not identified for future analysis, per institutional policies |  |  |
|  | Return/destroy study labs kits, study equipment, and study materials, per site guidelines, and maintain required documentation |  |  |
| MISC. | | | |
|  | Securely store records for the period of time required by the clinical trial agreement, funding agency requirement, or University record retention schedule. |  |  |
|  | Ensure all notes-to-file (NTF) are completed and filed |  |  |
|  | *Ensure this Checklist is filed in the Regulatory Binder when archiving documents. This will be the last document to be completed and filed when completing closeout.* |  |  |

1. For a list of possible study documents to consider for inclusion in the final study record, see [UU SOP-6-A: STUDY RECORDS MANAGEMENT - SUPPLEMENT A](https://qualitycompliance.research.utah.edu/clinical-research-sops.php). Supplement A is not an exhaustive list. Individual studies may have other individual and significant records that should also be filed. [↑](#footnote-ref-1)