**Study Close-Out Checklist**

| **Protocol <#> SITE CLOSE-OUT VISIT READINESS CHECKLIST** |
| --- |
| **<PROJECT TITLE>** |
| **Site Name:** |  | **Site PI:** |  |
| **Final Protocol Version**  |  | **Date:** | Click or tap to enter a date. |
| **No.** | **Task** | **Owner** | **Date Completed** | **Comments** |
| **Case Report Forms (CRFs)/Source Documents** |
| 1 | Confirm that appropriate source documentation is present for all site participants |        |        |        |
| 2 | Paper Studies: Confirm that all CRFs have been completed, collected, and the proper legible copies are present in study filesElectronic Data Capture (EDC) Studies: Confirm that all electronic CRFs have been completed and entered into the EDC |        |        |        |
| 3 | Paper Studies: Confirm that all data clarification forms (DCFs) and queries issued to date have been addressed and appropriately resolved, signed and dated by the Site PI, and that signed and dated queries are filed with the corresponding CRF page or participant study file.EDC Studies: Confirm that all electronic queries issued to date have been appropriately resolved, reviewed by the CRA/SC/DM as appropriate, and closed, where applicable |        |        |        |
| 4 | EDC Studies: Ensure that all CRF pages requiring signature have been electronically signed and dated by the Site PI |        |        |        |
| **Data Management** |
| *Note: For trials using an external data manager (EDM) you will need to ensure tasks 5-8 occurs, some will be owned by the EDM.* |
| 5 | Confirm all data is entered into the database  |  |  |  |
| 6 | Ensure all queries have been issued, returned, and resolved |  |  |  |
| 7 | Once all queries have been resolved, clean and QC the database |  |  |  |
| 8 | Perform database lock  |  |  |  |
| **Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting/Reconciliation** |
| 9 | Ensure that all AEs, UPs, and SAEs have been captured, followed, and resolved per protocol, and reported to the appropriate parties (Sponsor, HREC, RGO, and TGA, if applicable) according to protocol reporting requirements |        |        |        |
| 10 | Confirm that all required follow-up documentation has been retrieved, communicated to appropriate parties, and is present in the study files |        |        |        |
| **Investigator Site Files** |
| 11 | Confirm that signed consent forms are on file for all participants |        |        |        |
| 12 | Reconcile study files with Trial Master File (TMF) list. For studies where the TMF is maintained at the lead site or by the CRG/Sponsor, ensure all required documents are present, including collection of all required documents from all Investigator Site Files, where appropriate. These can include, but are not limited to: * protocols and amendments
* approved consent document templates
* HREC approvals
* study team licenses
* study certification documentation and CVs
* laboratory documentation
* Manual of Procedures (MOP)
* Standard Operating Procedures (SOPs)
 |        |        |        |
| 13 | Ensure reporting of study closure to the HREC and receipt/filing of study closure confirmation in the investigator site files |        |        |        |
| 14 | If study was terminated early, confirm notification of study termination has been sent to all enrolled participants as appropriate\*and the RGO |        |        |        |
| 15 | Confirm that all protocol deviations have been noted in source documentation and reported to the HREC as appropriate |       |       |       |
| 16 | Consider appropriate storage of Quality Management (QM) reports / metrics |       |       |       |
| 17 | Confirm sponsor requirements for record retention and notify sponsor when study files will be transferred to long term off-site storage |       |       |       |
| ***Ensure the completeness of the following logs:*** |
| 18 | Pre-Screening Log (*if applicable)* |        |        |        |
| 19 | Participant Screening and Enrollment Log |       |       |       |
| 20 | Monitoring Visit Log *(if applicable)* |       |       |       |
| 21 | Delegation of Responsibilities Log |       |       |       |
| 22 | Telephone Log |       |       |       |
| 23 | Training Log |       |       |       |
| 24 | Participant Code List |       |       |       |
| 25 | Randomisation Log *(if applicable)* |       |       |       |
| 26 | Investigational Product Accountability Log: Stock Record *(if applicable)* |       |       |       |
| 27 | Investigational Product Accountability Log: Subject Record *(if applicable)* |       |       |       |
| 28 | Specimen Tracking Log *(if applicable)* |       |       |       |
| 29 | Freezer/Refrigerator Temperature Logs *(if applicable)* |       |       |       |
| **Investigational Product** |
| 30 | Confirm that investigational product disposition forms and accountability records are complete and present for all participants receiving study drug |       |       |       |
| 31 | Confirm final disposition of investigational product was completed per MOP, site pharmacy protocol, supplier, and sponsor requirements |       |       |       |
| 32 | If applicable ensure that the CTN status is changed to completed |       |       |       |
| **Collected Laboratory Specimens (Samples)** |
| 33 | Confirm that all specimens have either been analysed or stored for future use |       |       |       |
| 34 | Ensure that specimens collected for future use have been adequately processed, labeled/de-identified, and stored |       |       |       |
| 35 | Confirm site process for identification and disposition of future use specimens connected to participants who withdraw consent or do not consent for their specimens to be saved |       |       |       |
| 36 | Confirm destruction, per institutional policies, of specimens not identified for future analysis |       |       |       |
| **Analysis, Manuscripts, and Submissions/Publications** |
| 37 | Data analysis complete  |       |       |       |
| 38 | Ensure Non NT Health researchers access to ICT system is revoked |       |       |       |
| 39 | Primary manuscript finalised |       |       |       |
| 40 | Send through details of any publications to HREC and RGO office |       |       |       |
| 41 | Confirm that the appropriate party has updated the clinical trials registry with the update in study status |       |       |       |
| 42 | Ensure data sharing statement is updated and relevant on the clinical trial registration |       |       |       |
| 43 | Confirm final disposition of study supplies and any equipment provided for the study: <insert study-specific items> |       |       |       |

\* Note: If the study is closing early, contact the RGO office for additional guidance.