**Instructions:**

*Instructional text – requires you to complete the information. Remove the italics / brackets prior to finalising the letter and ensure all text is black.*

Optional text – delete when not required as applicable to your trial.

Standard wording – not to be removed or changed without prior consultation with the Sponsor.

**There are several processes to be completed as part of site closure. The Clinical Trial Monitor/Clinical Trial Manager (or delegate) must use this Site-Level Close Out Visit Checklist to track progress of Close-Out activities at site. Close-out activities can commence prior to the formal End of Study declaration being submitted. This checklist includes activities inclusive of many different types of studies and should be edited as required for the study it is being used for.**

|  |
| --- |
| **SITE-LEVEL CLOSE OUT VISIT CHECKLIST** |
| **Site and Site Code:**  | *<Insert full name of site and site code>* |
| **Site Principal Investigator:**  | *<Insert full name>* | **Date:** *<Insert date(s) of visit>* |
| **Protocol Title:**  | *<Insert full Protocol title>* |
| **Monitor(s):**  | *<Insert full name>* |
| **Purpose of Visit:**  | *<*Early Termination *or* End of Trial Close-Out*>* | **Mode of Visit:** *<*Onsite *or* Remote (Virtual)*>* |

|  |  |
| --- | --- |
|  | **Check if Present** |
| **Site Principal Investigator:**  | *<Insert full name>* | [ ]  |
| **Research Nurse/Study Coordinator:**  | *<Insert full name>* | [ ]  |
| **Name of Pharmacist:**  | *<Insert full name and role>* | [ ]  |
| **Other Site Staff:**  | *<Insert full name and role>* | [ ]  |
| **ISF FORMAT** *<select format of ISF from options below then delete this text>* |
| Paper ISF | [ ]  |
| eISF - Florence eBinders | [ ]  |

**Part 1: Participating Site COV Checklist**

|  |
| --- |
| **SECTION A: FINAL SITE RECRUITMENT DATA** |
| **No. of participants Planned:** |  |
| **No. of participants Screened:** |  |
| **No. of participants Consented:** |  |
| **No. of participants Randomised/Enrolled:** |  |
| **No. of participants Withdrawn:** |  |
| **Deceased: Only if applicable to study** |  |
| **No. of participants Lost to Follow Up:** |  |
| **No. of participants that Completed the study:** |  |
| **Date Last Participant Last Visit (LPLV) at the site:** | Click to choose a date. |
| **Comments:** *e.g. For example, state reason for high number of withdrawals, lost to follow-up, etc.* |  |
| **SECTION B: SAFETY** | **Yes** | **No** | **Comments** |
| *Have all AEs and SAEs <add other required safety events> at site been followed up as per protocol?* | [ ]  | [ ]  | ***Total Number of AEs/SAEs*** *<add other required safety events>:*  |  |
| *Have all SAE <add other required safety events> Report Forms submitted to the Sponsor been filed in the ISF?** *Including copies of SAE Review Forms?*
 | [ ]  | [ ]  |  |
| *Was the last annual safety report sent to the site’s RGO?* | [ ]  | [ ]  | ***Date sent****:*  | Click to choose a date. |
| **SECTION C: DATABASE & DATA MANAGEMENT** | **Yes** | **No** | **Comments** |
| *Is all data entry complete in Trial Database/s?* | [ ]  | [ ]  |  |
| *Is all source data and/or source documents filed appropriately, and where necessary, redacted accordingly?* | [ ]  | [ ]  |  |
| *Is all remote Source Data Verification (SDV) completed as stipulated by the Data Validation Plan?* | [ ]  | [ ]  |  |
| *Are all data queries resolved?* | [ ]  | [ ]  | ***If pending, please note total number open queries:*** |  |
| *Has the data been signed-off by Site PI or delegate?* | [ ]  | [ ]  |  |
| *Have all user-permissions to IT study systems (e.g. database, randomisation system, participant questionnaires, Participant Apps etc) been revoked from trial site personnel?* | [ ]  | [ ]  | ***If no, confirm date when user-permissions will be revoked/stripped:*** |  |
| *Has locking of database been performed/discussed with the site?* | [ ]  | [ ]  |  |
| **SECTION D: INVESTIGATIONAL MEDICINAL PRODUCT (IMP)**  | **Yes** | **No** | **Comments** |
| *Is all documentation in the pharmacy file is present and complete and that all current and previous versions of documents used at this site are present.* *\*This includes cross checking the contents of the Pharmacy Folder (PF) with the PF Table of Contents. Request any missing documentation from the site team.* | [ ]  | [ ]  |  |
| *Is the Pharmacy Site training log complete and fully signed?* | [ ]  | [ ]  |  |
| *Are IMP accountability records complete, accurate, and signed/dated by the Site PI or delegate?* | [ ]  | [ ]  |  |
| *Are IMP storage temperature logs complete?* | [ ]  | [ ]  |  |
| *Are IMP returns and/or destruction completed?* | [ ]  | [ ]  | ***Details:*** |
| *Have arrangements been made for IMP return or destruction?* | [ ]  | [ ]  | ***Details:*** |
| *Have excess Randomisation Envelopes been returned to the Central Trial Team, if applicable?* | [ ]  | [ ]  |  |
| *Are unblinding envelopes intact (unless opened for planned unblinding) and re-turned to the Central Trial Team?* | [ ]  | [ ]  |  |
| **SECTION E: INVESTIGATIONAL MEDICAL DEVICE (IMD)**  | **Yes** | **No** | **Comments** |
| *Are IMD accountability records complete, accurate, and signed/dated by the Site PI or delegate?* | [ ]  | [ ]  |  |
| *Are IMD returns and/or destruction completed?* | [ ]  | [ ]  | ***Details:***       |
| *Have arrangements been made for IMD return or destruction?* | [ ]  | [ ]  | ***Details:***       |
| **SECTION F: BIOLOGICAL SUB-STUDIES / FACILITIES / EQUIPMENT / STUDY MATERIALS** | **Yes** | **No** | **Comments** |
| *Have all biological/research samples been sent to the designated laboratory/central laboratory or arrangements made for final shipment?* | [ ]  | [ ]  |  |
| *Are Freezer (-200/-800/LN2) storage temperature logs complete?* | [ ]  | [ ]  |  |
| *Has all study material and/or equipment needing to be returned to the Sponsor at the end of the trial been returned or have arrangements been made for their return?* | [ ]  | [ ]  | ***Details:***       |
| *Have all study material and/or equipment requiring destruction at the end of the trial been destroyed or have arrangements been made for their destruction?* | [ ]  | [ ]  | ***Details:***       |
| **SECTION G: FINANCE**  | **Yes** | **No** | **Comments** |
| *Has the final Invoice been received from the site?* | [ ]  | [ ]  | ***Date received:***Click to choose a date. |
| *Has the final Invoice been submitted to finance for payment?* | [ ]  | [ ]  | ***Date sent to finance:***Click to choose a date. |
| **SECTION H: INVESTIGATOR SITE FILE**  | **Yes** | **No** | **Comments** |
| *Was a final ISF review performed and were all essential documents present and missing documents noted?**\*This includes cross checking the contents of the ISF with the ISF Table of Contents. Request any missing documentation from the site team.* | [ ]  | [ ]  |  |
| *Have there been any investigator/sub-investigator changes since the final monitoring visit?** *If yes, ensure CV & GCP Certificate filed in ISF*
 | [ ]  | [ ]  |  |
| *Were all applicable CVs and GCP Training Certificates present, current and filed appropriately in the ISF?* | [ ]  | [ ]  |  |
| ***Protocol*** | **Yes** | **No** | **Comments** |
| *Is the Site Protocol Tracker is complete?* | [ ]  | [ ]  |  |
| *Care all versions of the approved protocol are filed accordingly?* | [ ]  | [ ]  |  |
| *Have the Protocol Signature Page/s have been signed and dated by the Site Principal Investigator, and any superseded signed protocol signature pages are present and filed accordingly?* | [ ]  | [ ]  |  |
| ***Informed Consent*** |
| *Is the Site PICF Tracker/s is/are complete?* | [ ]  | [ ]  |  |
| *Are all versions of the approved PICF/s and other forms of participant information are filed accordingly?* | [ ]  | [ ]  |  |
| *Are all copies of (signed and dated) consent forms for all participants recruited into the trial are present in the ISF?* | [ ]  | [ ]  |  |
| ***Essential Documents*** |
| *Is the Pre-Screening Log complete, legible, paginated and filed in the ISF?* | [ ]  | [ ]  |  |
| *Is the Screening Log complete, legible, paginated and filed in the ISF?* | [ ]  | [ ]  |  |
| *Is the Participant Randomisation and Enrolment Log complete, legible, paginated and filed in the ISF?* | [ ]  | [ ]  |  |
| *Have end dates been added for all staff to Delegation Log and signed off by Site PI?* | [ ]  | [ ]  |  |
| *Is a final copy of Delegation Log provided to Trial Monitor/Trial Coordinator for filing in the TMF/SIF?* | [ ]  | [ ]  |  |
| *Is the Training Log complete and fully signed?**Was a final copy of Training Log provided to Trial Monitor/Trial Coordinator for filing in the TMF/SIF?* | [ ]  | [ ]  | *\*If Training Logs are not applicable a file note to state this should be present.* |
| *Is the Non-Compliance Log complete, legible, paginated and filed in the ISF?* | [ ]  | [ ]  | *\*If Non-Compliance Logs are not applicable a file note to state this should be present.* |
| *Is the Biospecimen Tracking Log complete, legible, paginated and filed in the ISF?* | [ ]  | [ ]  | *\*If Biospecimen Tracking Logs are not applicable a file note to state this should be present.* |
| *Were Freezer/Refrigerator Temperature Logs complete, legible, paginated and filed in the ISF?*  | [ ]  | [ ]  | *\*If Freezer/Refrigerator Temperature Logs are not applicable a file note to state this should be present.* |
| *Is the Unblinding Log complete, legible, paginated and filed in the ISF?* | [ ]  | [ ]  | *\*If Unblinding Logs are not applicable a file note to state this should be present.* |
| ***Monitoring*** |
| *Haver all monitoring findings/action items resolved with none remaining outstanding for the site to address?* | [ ]  | [ ]  | ***If no, please provide details of outstanding actions:***  |  |
| *Is the Monitoring Log complete, legible, paginated and filed in the ISF?* | [ ]  | [ ]  |  |
| ***Site Archiving Obligations*** |
| *Has the Site PI been reminded of their obligation to keep all study documents (including electronic/paper records) in accordance with regulatory requirements?* | [ ]  | [ ]  |  |
| *Has the Site PI been reminded of obligation to inform trial sponsor of any change to local archiving location?* | [ ]  | [ ]  |  |
| *Was the following ISF Archiving information provided during the COV?* | [ ]  | [ ]  | ***Archiving period:*** |       |
| ***Contact during archiving period:***  |       |
| ***Name:***  |       |
| ***Role:***  |       |
| ***Contact number:***  |       |
| ***Email:***  |       |
| ***Site End of Trial Obligations*** | **Yes** | **No** | **Comments** |
| *Was the Site PI reminded of their obligation to submit the Ethically approved End of Trial Notification to their RGO as soon as it is available?** *International sites must submit End of Trial Notifications to their ethics committee and any relevant regulatory body as required.*
 | [ ]  | [ ]  |  |
| *Was the Site PI reminded of their obligation to disseminate a Final Letter to Participants as soon as it becomes available from the Sponsor?* | [ ]  | [ ]  | *\*\* Sites must first obtain ethics and/or governance approval for disseminating the Final Letter to Participants.* |
| *Remind the Site PI that audits/inspections could still occur for this trial and that archiving of the Site and Pharmacy Files is their responsibility.* | [ ]  | [ ]  |  |
| *Explain that the ‘End of Trial Notification’ and the ‘Clinical Trial Summary Report’ will be forwarded from MCRI (the Sponsor) when available. Remind the PI that it is their responsibility that these documents are filed appropriately in the Site File.* | [ ]  | [ ]  |  |

**Part 2: Site Data Receipt & Revocation of User Permissions**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Site Data Receipt***  | **Yes** | **No** | **Comments** |
| *Document details of how individual trial site dataset will be transferred:* |  |  | *\*NA if no participants were recruited at site.* |
| Florence eBinders | [ ]  | [ ]  |  |
| Sharepoint (*via unique individual link)* | [ ]  | [ ]  |  |
| Other MCRI approved data sharing platform | [ ]  | [ ]  |  |
| ***Revocation of User Permissions*** | **Yes** | **No** | **Comments** |
| *Has site access to all IT systems has been disabled and user permissions revoked?* | [ ]  | [ ]  |  |

**Part 3: Findings from COV**

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| **Items Identified by Trial Monitor/Trial Coordinator/Trial Manager during Close Out Visit***Summarise issues identified during the COV that are outstanding and require follow up in the table below*  |
| **Item/Title** | **Action Required by Site** | **Task Owner** (Initials) | **Target Completion Date** |
|  |  |  | Click to choose a date. |
|  |  |  | Click to choose a date. |

|  |
| --- |
| **Items Addressed by Trial Monitor/Trial Coordinator/Trial Manager during Close Out Visit:***Summarise issues identified during the COV that were addressed by the Monitor and hence require no further action in the table below*  |
| **Item/Title** | **Task Owner** (Initials) | **Target Completion Date** |
|  | Monitor | NA – Addressed during MV |
|  | Monitor | NA – Addressed during MV |

**Part 4: Declaration, Approval and Sign-Off**

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| --- |
| **Site Close-Out Visit Signatures:** |
| I confirm that all the above checks are complete, and information documented accurately. I also confirm that the monitoring plan for this study has been followed and that all aspects of the Data Validation Plan have been met. Where deviations from the monitoring plan have occurred or where aspects of the plan have not been met the MCRI Sponsorship Committee have been informed. |
| **COV Checklist Completion** |
| **Checklist completed by:** |  | **Role:** |  |
| **Signature:** |  | **Date:** | Click here to enter a date. |
| **COV Checklist Review and Sign-Off**  |
| **Name:** |  | **Role:** | *Trial Coordinator/Clinical Trial Manager* |
| **Signature:** |  | **Date:** | Click here to enter a date. |
| **COV Checklist Approval and Sign-Off** |
| **Name:** |  | **Role:** | Sponsor-Investigator |
| **Signature:** |  | **Date:** | Click here to enter a date. |

*When the Close Out Visit (COV) is complete, please complete and sign this report and file a copy of the report in the SIF.*