**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 study closure. The Clinical Trial Monitor/Clinical Trial Manager (or delegate) must use this Study Closure Checklist to track progress of Close-Out activities. 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.**

|  |  |
| --- | --- |
| **STUDY-LEVEL CLOSE OUT CHECKLIST** | |
| **Protocol Name:** | *<Insert full protocol title>* |
| **Protocol Acronym:** | *<Insert protocol acronym, if applicable>* |
| **Sponsor:** | *<Insert full name of Sponsor>* |
| **ClinicalTrials.gov NCT# / ANZCTR Registry No.** | *<Insert Registry No.>* |
| **Sponsor Investigator Name:** | *<Insert full name>* |
| **Clinical Trial Manager Name / Trial Coordinator:** | *<Insert full name>* |
| **Trial Monitor(s):** | *<Insert full name>* |
| **Data Manager(s):** | *<Insert full name/s>* |
| **Statistician(s):** | *<Insert full name/s>* |
| **Date of Close-Out Report:** | *<Insert date this checklist was completed>* |
| **Purpose of Visit:** | *<Select* Early Termination *or* End of Trial Study Close-Out*>* |

|  |  |
| --- | --- |
| **ISF FORMAT** *<select format of ISF from options below then delete this text>* | |
| Paper ISF |  |
| eISF - Florence eBinders |  |

**Part 1: Study Close-Out Report**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SECTION A: OVERALL PARTICIPATING TRIAL SITE DATA** | | | | | |
| **No. of planned participating trial sites:** |  | | | | |
| **No. of participating trial sites activated to recruitment:** |  | | | | |
| **No. of actively\* enrolling participating trial sites at the end of recruitment:**  *\*actively enrolling means the participating trial site has enrolled at least 1 participant into the trial during the recruitment period.* |  | | | | |
| **No. of participating trial sites withdrawn from the trial after activation:** |  | | | | |
| **Comments:**  *e.g. For example, state reason/s why target number of Participating Sites was not met, reason/s why sites did not open, and/or reason why sites may have withdrawn from the trial.* |  | | | | |
| **SECTION B: OVERALL TOTAL RECRUITMENT DATA** | | | | | |
| **No. of total participants Planned:** |  | | | | |
| **No. of total participants Screened:** |  | | | | |
| **No. of total participants Consented:** |  | | | | |
| **No. of total Screening Fails:** |  | | | | |
| **No. of participants Randomised/Enrolled/Registered:** |  | | | | |
| **No. of participants Withdrawn:** |  | | | | |
| **No. of participants Deceased:** |  | | | | |
| **No. of participants Lost to Follow Up:** |  | | | | |
| **No. of participants that Completed the study:** |  | | | | |
| **Comments:**  *e.g. State reason for high number of withdrawals, lost to follow-up, etc.* |  | | | | |
| **SECTION C: SAFETY** | **Yes** | **No** | **Comments** | | |
| *Have all AEs and SAEs <add other required safety events> across all sites been reconciled with study eCRF/database?* |  |  | ***Total Number of AEs/SAEs*** *<add other required safety events>:* | |  |
| *Confirm copies of all expedited SAE Report Forms and any associated documentation has been filed in each site’s Safety Section of their SIF?* |  |  |  | | |
| *Has the last Annual Safety Report been completed and submitted to the lead HREC, if applicable?* |  |  |  | | |
| **SECTION D: DATABASE & DATA MANAGEMENT** | **Yes** | **No** | **Comments** | | |
| *Has the Statistical Analysis Plan (SAP) been finalised?* |  |  |  | | |
| *Is all data entry complete in the Trial Database/s, including participant questionnaires?* |  |  |  | | |
| *Are all data cleaning activities completed as stipulated by the Data Validation Plan?* |  |  |  | | |
| *Are all data queries resolved?* |  |  | ***If pending, please note total number open queries****:* | |  |
| *Has all external independent medical review of endpoint data been completed?* |  |  |  | | |
| *Have all Principal Investigator’s provided sign-off on their data?* |  |  |  | | |
| *Have participating trial site been provided copies of their complete dataset?* |  |  | *See MCTC/CRDO for further guidance on this requirement.* | | |
| *Has locking of database been performed?* |  |  |  | | |
| **SECTION E: INVESTIGATIONAL MEDICINAL PRODUCT (IMP) / INVESTIGATIONAL MEDICAL DEVICE (IMD)** | **Yes** | **No** | **Comments** | | |
| *Have all IMP/IIMD held outside participating trial sites been destroyed or returned as appropriate?* |  |  | ***If no, please provide details of outstanding IMP/IMD:*** | |  |
| *Have drug accountability reports been completed as appropriate?* |  |  |  | | |
| *If required, are arrangements in place for post-trial IMP/IMD supply to participants (i.e. compassionate access)* |  |  |  | | |
| **SECTION F: BIOLOGICAL SUB-STUDIES / FACILITIES / EQUIPMENT / STUDY MATERIALS** | **Yes** | **No** | **Comments** | | |
| *Have all biological/research samples been received by designated laboratory/central laboratory or arrangements made for final shipment?* |  |  |  | | |
| *Has all study material and/or equipment needing to be returned to the Sponsor by the trial sites been received?* |  |  | ***If no, please provide details of study material and/or equipment outstanding****:* | |  |
| *Is that Sample Tracking Tool complete (if applicable)?* |  |  |  | | |
| **SECTION G: SITE MONITORING & SITE CLOSURE** | **Yes** | **No** | **Comments** | | |
| *Was a Site-Level Close Out visit performed for each participating trial site, including completion of a Site-Level Close Out Checklist (MCTC207)?* |  |  | ***If no, please provide details of why COV were not completed****:* | |  |
| *Are all site level close out actions resolved?* |  |  | ***If no, please provide details of outstanding actions****:* | |  |
| *Are all participating trial sites closed?* |  |  | ***If no, please provide details of sites which remain open and plans for closure****:* | |  |
| **SECTION H: END OF TRIAL NOTIFICATIONS** | **Yes** | **No** | **Comments** | | |
| *Has an End of Trial Notification been submitted to the lead Human Research Ethics Committee?* |  |  |  | | |
| *Has an End of Trial Notification been submitted to all other international Ethics Committee’s/Institutional Review Boards (IRB), as applicable?* |  |  |  | | |
| *Has an End of Trial Notification been submitted to all applicable Research Governance Offices (RGOs)?* |  |  |  | | |
| *Has an End of Trial Notification been submitted to all other international Research Governance Offices (or similar e.g. UK R&D Offices), as applicable?* |  |  |  | | |
| *Has the CTA Clinical Trial Completion Advice notification been submitted to the TGA?* |  |  |  | | |
| *Has an End of Trial Notification been submitted to all other international Regulatory Bodies, as applicable? E.g. FDA, MHRA, Health Canada etc* |  |  |  | | |
| *Has the Clinical Trial Registry entry (e.g. Clinicaltrials.gov/ ANZCTR) been updated to reflect study closure?*  *\*A requirement of HREC approval is that all clinical trials be registered on a public trial register. The registry should now be updated to indicate study (or site) closure.* |  |  |  | | |
| *Has the IMP/IMD supplier been notified of study closure?* |  |  |  | | |
| *Has the TSC/DSMC members been notified of study closure?* |  |  |  | | |
| *Have other parties been notified as appropriate regarding study closure, e.g. funder, external vendors/third-party services providers, central laboratory etc.* |  |  |  | | |
| *Have Research Participants been informed of the trial results by way of Final Letter to Participants?* |  |  | ***If no, please provide details of how research results are going to be disseminated to Participants:*** | |  |
| *Central Trial Team aware to submit Clinical Study Report/Statistical Report/Publication as required.*  *\*Teams should complete and file a Note to File in this section of the TMF confirming that a copy of the Clinical Study Report/Statistical Report/Publication be filed within TMF when available.* |  |  |  | | |
| *Central Trial Team is aware to contact MCRI Sponsorship with end of trial reporting requirements within 6 months of end of trial date.* |  |  |  | | |
| **SECTION I: ESSENTIAL DOCUMENTS & TMF** | **Yes** | **No** | **Comments** | | |
| *Was a final TMF review performed?*  *\*This includes cross checking the contents of the TMF with the TMF Table of Contents.* |  |  |  | | |
| *Have end dates been added to the Signature & Delegation Log and signed off by Sponsor-Investigator?*  *\*The Signature & Delegation log should cover the entire period of the trial, and a signed copy should be present in the TMF.* |  |  |  | | |
| *Is the final Training Log, complete, up to date and signed off by Sponsor-Investigator?* |  |  |  | | |
| *Are all CVs from Central Trial Team members present in the TMF for the duration of the trial?*  *\*If previously filed centrally during trial conduct, copies must now be filed in the TMF.* |  |  |  | | |
| *Are all GCP Training Certificates from Central Trial Team members present in the TMF for the duration of the trial?*  *\*If previously filed centrally during trial conduct, copies must now be filed in the TMF.* |  |  |  | | |
| *Is the Statistics section of the TMF up to date and have all statistical documents and/or reports that have been temporarily filed outside of the TMF, been moved and filed within the TMF?* |  |  |  | | |
| *Is the Data Management section of the TMF up to date and has all data management, cleaning and validation documents and/or reports that have been temporarily filed outside of the TMF, been moved and filed within the TMF?* |  |  |  | | |
| *Is the IMP/IMD section of the TMF up to date and have all relevant documents that have been temporarily filed outside of the TMF, been moved and filed within the TMF?* |  |  |  | | |
| *Have all other documents that are temporarily filed outside of the TMF, been moved and filed within the TMF?*  *e.g. Study documents and/or files which may be temporarily filed in Microsoft Teams, Sharepoint or OneDrive.* |  |  |  | | |
| *Are all TMF review actions followed up, essential documents filed appropriately and TMF ready for archiving?* |  |  |  | | |
| *Archiving details and location where the TMF is to be archived by Sponsor:* |  |  | ***Archiving period:*** |  | |
| ***Contact during archiving period:*** |  | |
| ***Name:*** |  | |
| ***Role:*** |  | |
| ***Contact number:*** |  | |
| ***Email:*** |  | |
| **SECTION J: GENERAL** | **Yes** | **No** | **Comments** | | |
| *Have all significant emails and correspondence (e.g. received and sent emails) been filed and organised into logical folders within the TMF?* |  |  |  | | |
| *If a generic MCRI Trial email account was used during trial conduct, e.g.* [*trialname@mcri.edu.au*](mailto:trialname@mcri.edu.au)*, has an ‘Out of Office’ reply set up (e.g. This trial is now closed, please contact [insert appropriate email address] for further details)?* |  |  |  | | |
| *[Insert trial-specific check, as appropriate]* |  |  |  | | |
| *[Insert trial-specific check, as appropriate]* |  |  |  | | |

**Part 2: Findings from Study Close Out**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Identified by Trial Monitor/Trial Coordinator/Trial Manager during Study Close Out:**  *Summarise issues identified during study close out and if any actions are required in the table below.* | | | |
| **Item/Title** | **Action Required** | **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 Study Close Out:**  *Summarise issues identified during study close out that were addressed by the Monitor and hence require no further action in the table below.* | | |
| **Item/Title** | **Task Owner** (Initials) | **Target Completion Date** |
|  |  | NA – Addressed during MV |
|  |  | NA – Addressed during MV |

**Part 3: Declaration, Approval and Sign-Off**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study Close Out 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. | | | | |
| **Report Completion** | | | | |
| **Checklist completed by:** |  | | **Role:** |  |
| **Signature:** |  | | **Date:** | Click here to enter a date. |
| **Checklist Review and Sign-Off** | | | | |
| **Name:** | |  | **Role:** | Trial Coordinator/Clinical Trial Manager |
| **Signature:** | |  | **Date:** | Click here to enter a date. |
| **Checklist Approval and Sign-Off** | | | | |
| **Name:** | |  | **Role:** | Sponsor-Investigator |
| **Signature:** | |  | **Date:** | Click here to enter a date. |

*When Study Close Out is complete, please complete and sign this report and file a copy of report in the TMF.*