Site Close Out Checklist

*Instructions For Use – please delete before sending to site*

*This is a template – please make study specific as appropriate. Please attach ISF checklist prior to sending to site for completion. The sections can be separated into different documents if they require completion by different parts of the Site team, for example Pharmacy section 3 can be used as a standalone document and sent direct to a pharmacy contact.*

*This checklist is to be completed by the Site Team if the close out visit is performed remotely. Where possible a final checklist (or draft) will be returned and at this point a close out telephone call will be arranged (unless no participants have been consented at site, in which case, the checklist is sufficient). Please note the checklist does not need to be fully completed and signed off prior to the close out call however sites should be at a stage where they can answer the close out requirements highlighted below during the call. The close out telephone call can be used to discuss any outstanding issues that have been identified. If checklist completion is delaying the site close out visit telephone call – please escalate to the Clinical Trials Monitor for discussion.*

*Please note that those actions highlighted below must be completed prior to database lock.*

|  |  |
| --- | --- |
| Study Name |  |
| Site Name |  |
| Lothian R&D Ref |  | Principal Investigator |  |
| Date of last participant last visit (LPLV) at site |  |

|  |
| --- |
| Final Site Recruitment Figures |
| Screened |  |
| Consented |  |
| Screen fails |  |
| Randomised |  |
| Completed |  |
| Withdrawn |  |

*If action cannot be completed at this stage of close out, please complete “Date completed” field with the phrase “Action Required” and add any additional information into the “Comments/Actions” field to confirm what needs to be done. This can be discussed during the close out telephone call where appropriate and raised as a close out action. Where the site has not recruited and checks are not applicable please state N/A in the date completed field.*

*Please note that those actions highlighted below should be completed as fully as possible prior to the close out call and must be completed prior to database lock.*

|  |  |  |
| --- | --- | --- |
| SECTION 1: Research Team Close Out Checks | Date Completed | Comments/Actions |
| Pharmacovigilance |
| Confirm all AEs and SAEs at site followed up as per protocol |  |  |
| Total number of SAEs reported in ISF |  | # of SAEs: |
| All AEs/SAEs in ISF confirmed as entered in eCRF/database |  |  |
| Deviations and Violations |
| Deviation logs completed and filed in ISF* Please state total number of deviations listed in ISF
 |  | # of deviations in total: |
| Violations reported to Sponsor and filed in the ISF* Please state total number of violations filed in ISF
 |  | # of violations in total: |
| Monitoring  |
| Confirm all monitoring visit action logs completed and all findings resolved*If any action logs are pending completion, please note in the “comments/actions” field* |  |  |
| Data  |
| Pre-screening log and Consent and subject status log complete and filed |  |  |
| Confirm data entry complete |  |  |
| Confirm site level data queries resolved*If any data queries are pending, please note the total number of queries open at site*  |  | *# of open data queries:* |
| Confirm data in CRF signed off by PI or designee*If pending, please state in “comments/action” field* |  |  |
| Essential Documentation  |
| Original signed Consent forms filed for all participants consented at site |  |  |
| End dates added to delegation log and PI sign off completed (*if all study activities have been completed at site)* |  |  |
| Confirm the following documents have been provided for filing in the TMF* Final copy of delegation log (with PI signature)
* CVs and GCP certificates
* Final training logs
* Monitoring visit log

*If some documents are still to be provided, please list in the “comments/actions” field* |  |  |
| Confirm where ISF will be archived and who is named contact during archiving period – please state address and contact details |  | Address:Name:Role: Tel:Email: |
| Results Reporting |
| Local R&D department informed that recruitment complete (including total # of participants recruited) and site for closure |  |  |

|  |
| --- |
| **SECTION 1 Checks Completed By:** |
| To the best of my knowledge the above checks are complete and information documented accurate. |
| **NAME** |  | **STUDY ROLE** |  |
| **SIGNATURE** |  | **DATE** |  |

|  |
| --- |
| SECTION 2: Investigator Site File |
| Please use provided ISF checklist to confirm documents are present in the ISF |
|  | Date completed | Comments/Actions |
| ISF review complete using essential document checklist and all documents filed or location file noted (*or, if ISF not complete, please list missing documents identified in the “comments/actions” field)* |  |  |
| PI Declaration For Essential Documentation *(Complete for remote close out only)* |
| I confirm that all essential documentation is present in the ISF and the ISF will be archived in compliance with the requirements of the protocol and ACCORD SOP CR009. |
| PI Signature: |  | Date: |  |

**Pharmacy**

|  |  |  |
| --- | --- | --- |
| SECTION 3 | Date Completed  | Comments/Actions |
| Pharmacy Close Out Checks |
| Pharmacy Site File (PSF) complete and ready for archiving(*or, if PSF not complete, please list missing documents identified in the “comments/actions” field)* |  |  |
| If PSF will **not** be archived alongside the ISF, please state where this will be archived and who is contact during archiving |  | Address:Name:Role:Tel:Email: |
| Documents required for final site level accountability provided for TMF:* Master accountability log
* Destruction records

*If some documents are still to be provided, please list in the “comments/actions” field* |  |  |
| Temperature records complete and reviewed for period of storage  |  |  |
| Emergency unblinding tools intact and ready for archive |  | If emergency unblinding has occurred at site please document participant number here: |

|  |
| --- |
| **SECTION 3 Checks Completed By:** |
| To the best of my knowledge the above checks are complete and information documented accurate. |
| **NAME** |  | **STUDY ROLE** |  |
| **SIGNATURE** |  | **DATE** |  |

**Laboratory**

|  |  |  |
| --- | --- | --- |
| SECTION 4: | Date Completed  | Comments/Actions |
|  |  |  |
| Laboratory Close Out Checks |
|  |
| Lab sample accountability complete – all samples sent for analysis |  |  |
| Lab accreditation certificates filed in the ISF |  |  |
| Lab normal reference rangers filed in the ISF |  |  |
| Temperature records complete and reviewed for period of sample storage |  |  |

|  |
| --- |
| **SECTION 4 Checks Completed By:** |
| To the best of my knowledge the above checks are complete and information documented accurate. |
| **NAME** |  | **STUDY ROLE** |  |
| **SIGNATURE** |  | **DATE** |  |

*When checklist is completed as fully as possible (and signed), please send to the Clinical Trials Monitor, or designee/ Trial Manager, and file the original in the ISF. Once the close out process is complete and all close out actions are resolved, a final letter confirming site closure will be issued. Please file this in the ISF. Please do not proceed with archiving until this letter is received.*