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| Study Title |  |
| Lothian R&D Reference |  | Principal Investigator |  |
| Location of Trial Master File (TMF) |  | Trial Manager |  |

*This is a template – please make study specific as appropriate. To be completed by the local PI, or designee, prior to archiving. If sections below are not relevant to the study mark as ‘NA’ and add a comment to document why N/A.*

|  |  |  |
| --- | --- | --- |
|  | Date Completed  | Comments/Actions |
| Essential Documentation |
| ISF review performed with essential document checklist completed (please file alongside this checklist) |  |  |
| Original signed consent forms filed for all participants consented at site |  |  |
| End dates added to delegation log and PI sign off as completed (*once 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
* Site Visit Log (if applicable)
 |  |  |
| Confirm where the ISF will be archived and who is the named contact during the 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 |  |  |
| Summary of study results filed in the ISF– *If not available, file note present to confirm this will be added when available* |  |  |
| Pharmacovigilance |
| Confirm all AEs and SAEs at site followed up as per protocol |  |  |
| Total number of SAEs reported in ISF |  | # 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 |  |  |
| Data |
| Participant logs complete and filed in ISF |  |  |
| Confirm data entry/collection complete |  |  |
| Confirm site level data queries resolved |  |  |
| Confirm data in CRF is complete and accurate |  |  |
| Site access to eCRF/database deactivated |  |  |
| Pharmacy (if applicable) |
| Pharmacy Site File (PSF) complete and ready for archiving with ISF |  |  |
| 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 complete, filed and provided for TMF:* Master accountability log
* Destruction records
 |  |  |
| 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: |

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| **Study Closure Checklist Completion** |
| Checklist completed by: |  | Role: |  |
| Signature: |  | Date: |  |

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| **PI Declaration for Essential Documentation**  |
| 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. |
| Signature: |  | Date: |  |