**Site Closedown Checklist for**

**UHL Sponsored CE Marked Medical Device Studies**

**Site Information**

|  |
| --- |
| **Sponsor Number:** |
| **Study Name:** |
| **Study Site:** |
| **Chief /Principal Investigator name:** |
| **Date of Visit:** |

**List of site and monitoring personnel in attendance (if applicable)**

|  |  |
| --- | --- |
| **Name** | **Position** |
|  |  |
|  |  |
|  |  |

**Study Status**

|  |  |
| --- | --- |
| Planned patient number |  |
| Number of patients randomised |  |
| Number of patients completed |  |
| Number of patients withdrawn |  |
| Number of patients lost to follow up |  |
| **Comments:** |  |

**1. Contacts List**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed /verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there a current contact list on file? |  |  |  |  |
| Are there superseded contact lists on file |  |  |  |  |

**2. Protocol** **/Clinical Investigation Plan**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current approved protocol/  Clinical Investigation Plan on file? |  |  |  |  |
| Is the protocol / Clinical Investigation Plan signed and dated? |  |  |  |  |
| Are signed and dated superseded protocols  Clinical Investigation Plans on file? |  |  |  |  |
| Is there a protocol deviation log on file? |  |  |  |  |
| Have protocol / Clinical Investigation Plan deviations been reported / reviewed by the PI? |  |  |  |  |
| **Comments/Findings** | | | | |

**3. Ethics/HRA**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all original applications/authorisations on file? |  |  |  |  |
| Are all substantial amendment/s complete and on file? |  |  |  |  |
| Are all non-substantial amendment/s complete and on file? |  |  |  |  |
| Is the notification of trial completion (end of study declaration) on file? |  |  |  |  |
| Is Ethics/HRA correspondence on file? |  |  |  |  |
| Is the REC acknowledgement of end of study declaration on file? |  |  |  |  |
| **Comments/Findings** | | | | |

**4. R&I/R&D/Research Office**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all original copies of relevant applications/ authorisations on file? |  |  |  |  |
| Are all substantial amendment/s complete and on file? |  |  |  |  |
| Are all non-substantial amendment/s complete and on file? |  |  |  |  |
| Is all Research Office correspondence on file? |  |  |  |  |
| **Comments/Findings** | | | | |

**5. Investigator Site Personnel**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Have the end dates been updated for all research personnel named on the Delegation of Authority Log? |  |  |  |  |
| Has the Principal Investigator signed off the Delegation of Authority Log? |  |  |  |  |
| Confirm that all CVs/GCP/training records are up to date and on file |  |  |  |  |
| **Comments/Findings** | | | | |

**6. Standard Operating Procedures**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are details of where to access current Sponsor SOPs on file |  |  |  |  |
| Standard Operating Procedures read logs completed for all study team members? (where applicable) |  |  |  |  |
| **Comments/Findings** | | | | |

**7. Study Documentation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current approved subject documentation on file? |  |  |  |  |
| Are all superseded subject documents on file? |  |  |  |  |
| Are previous versions of study documentation marked as superseded? |  |  |  |  |
| Is there a copy of the current Case Report Form on file? |  |  |  |  |
| Are all superseded Case Report Forms on file? |  |  |  |  |
| **Comments/Findings** | | | | |

**8. Subject Documentation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there a current screening log template on file? |  |  |  |  |
| Is the subject screening log complete? |  |  |  |  |
| Is there a current enrolment log template on file? |  |  |  |  |
| Is the enrolment log complete and up to date to indicate that all patients have completed or withdrawn from the study? |  |  |  |  |
| **Comments/Findings** | | | | |

**9. Randomisation (if not applicable )**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there documentation of the randomisation process on file? |  |  |  |  |
| Are details of where the master randomisation list held on file? |  |  |  |  |
| IS there evidence of correct blinding as per study protocol? |  |  |  |  |
| **Comments/Findings** | | | | |

**10. Informed Consent**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all consent forms present and correctly completed? |  |  |  |  |
| Is the informed consent process properly documented in the medical/trial records |  |  |  |  |
| **Comments/Findings** | | | | |

**11. Data Management**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are computer records and files containing identifiable data stored on a remote and secure server? |  |  |  |  |
| Is the emergency recovery procedure for retrieving data available |  |  |  |  |
| Is access to electronic study records and files password protected? |  |  |  |  |
| Are electronic data files for analysis anonymised? |  |  |  |  |
| Confirmation that all personnel data will be removed according to the timespan stated within the ethical application? |  |  |  |  |
| Is there provision in place for suitable archiving? If yes are details logged with the Sponsor office? |  |  |  |  |
| **Comments/Findings** | | | | |

**12. Source Data Verification**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all CRFs complete and all data queries resolved? |  |  |  |  |
| Has all patient identifiable data been removed? |  |  |  |  |
| Confirmation that Data Lock point has been achieved? |  |  |  |  |
| Confirmation that a Statistical Analysis Plan (SAP) is in place? |  |  |  |  |
| **Comments/Findings** | | | | |

**13. Investigational Medicinal Device**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current signed and dated investigation brochure on file? |  |  |  |  |
| Are all superceded versions of the investigator brochure on file |  |  |  |  |
| Are all safety alerts on file (where applicable)? |  |  |  |  |
| Are copies of all electrical testing certificates on file? |  |  |  |  |
| Is there a complete equipment list, including components on file) |  |  |  |  |
| Are calibration records on file for all equipment? |  |  |  |  |
| Are maintenance/service records on file for all equipment? |  |  |  |  |
| Are sterilisation records on file(if applicable) |  |  |  |  |
| Are software use/licencing records on file(if applicable) |  |  |  |  |
| Are there copies of all labelling utilised on file |  |  |  |  |
| **Comments/Findings** | | | | |

**14. Safety Reporting**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are SAE/SADE reporting Guidelines on file? |  |  |  |  |
| Is there a current SAE form template on file? |  |  |  |  |
| Is there a Current SADE form Template on file? |  |  |  |  |
| Are SAE/SADE reports and associated acknowledgement correspondence from Sponsor/R&I on file? |  |  |  |  |
| Are all device deficiency forms complete and on file? |  |  |  |  |
| Have all SADEs been reviewed against Investigator Brochure? |  |  |  |  |
| Are USADE reporting guidelines on file |  |  |  |  |
| Are USADE reports and associated acknowledgement correspondence from Sponsor/ HRA/REC and R&I(Multicentre only) on file? |  |  |  |  |

|  |
| --- |
| **Comments/Findings** |

**15. Monitoring / Audit**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are the study’s monitoring / audit visit documentation and responses on file? |  |  |  |  |
| Is the monitoring log complete and on file? (where applicable) |  |  |  |  |
| Is the study specific monitoring plan on file? (where applicable) |  |  |  |  |
| **Comments/findings** | | | | |

**16. Clinical Laboratory (if not applicable □)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are current and superseded certificates of accreditation/laboratory SOPs on file? |  |  |  |  |
| Are current and superseded normal reference ranges on file? |  |  |  |  |
| Are current and superseded sampling and sample handling procedures documented/ is there a lab manual on file? |  |  |  |  |
| Are completed sample logs on file? |  |  |  |  |
| Are all specimen results reviewed and signed and dated by PI? (where applicable) |  |  |  |  |
| Are all specimen results that are out of range marked as clinically significant or not clinically significant? (where applicable) |  |  |  |  |
| Are freezer temperature monitoring records for duration of sample storage/study on file? |  |  |  |  |
| Are all sample shipment receipt/tracking records on file? |  |  |  |  |
| Is there clear evidence that all specimens/samples which are not being retained under the original REC application following study closure have been destroyed as per relevant laboratory SOP? |  |  |  |  |
| Are details of where samples are to be held for future research complete and on file together with the relevant contact details of personnel responsible for sample/specimen maintenance?  Copy of document to be provided for sponsor records.  Please be aware that once specimens /samples are not covered by this ethical application, they must be stored in a HTA licensed area. |  |  |  |  |
| **Comments/Findings** | | | | |

**17. Study Related Supplies if N/A □**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all study related supplies documents completed and on file? |  |  |  |  |
| Are all maintenance and calibration records completed and on file? |  |  |  |  |
| **Comments/Findings** | | | | |

**18. Financial/Legal agreements**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all completed documents relating to contracts, finance, funding, indemnity and sponsorship on file? |  |  |  |  |
| **Comments/Findings** | | | | |

**19. Annual Reports**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are annual progress reports to the Ethics Committee on file? |  |  |  |  |
| Are Sponsor confirmations of annual report receipt on file? |  |  |  |  |
| **Comments/Findings** | | | | |

**20. End of Study Declaration/Final Study Report/Publication**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are copies of all interim study analysis publications on file? |  |  |  |  |
| Is a copy of the End of study Declaration/ final study report t on file |  |  |  |  |
| Is an acknowledgement of receipt by HRA on file? |  |  |  |  |
| Discuss the requirement to submit final study report and study publication(s) to be submitted to the REC |  |  |  |  |
| Discuss the requirement for copies of the final report and study publication(s) |  |  |  |  |
| **Comments/Findings** | | | | |

**21. Correspondence**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is all study related correspondence on file? |  |  |  |  |
| **Comments/Finding** | | | | |

**22. Other/Miscellaneous**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** | |
|  |  |  |  |  | |
| **Comments/Findings** | | | | | **Category** |
|  | | | | |  |

UHL Site close down Final Outstanding Issue Sign Off

**Date of Visit: Study Title:   
Sponsor Reference: UHL/CLRN:   
Principal Investigator:   
Date Responses Due Back:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Finding**  **Number** | **Outstanding Issue** | **Action required** | **Action Taken** | **Principal Investigator/ delegate Signature** |
|  |  |  |  |  |
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|  |  |  |  |  |

Principal Investigators Name (Print)…………………………………………

Signature…………………………………………………………………………………

Date ………………………………………………………………………………………..

Confirmation by Sponsor/Sponsors delegate that study ready for closure.

Name (Print) …………………………………………………………..

Signature …………………………………………………………..