**APPENDIX 3a
Site Closedown Checklist for**

**UHL Sponsored UKCA/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| Number of patients withdrawn |   |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** | **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| Are there superseded contact lists on file |[ ] [ ]   |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** | **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| Are signed and dated superseded protocols Clinical Investigation Plans on file?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? |[ ] [ ]   |

**3. Ethics/HRA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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? |[ ] [ ]   |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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? |[ ] [ ]   |

**5. Investigator Site Personnel**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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 |[ ] [ ]   |

**6. Standard Operating Procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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) |[ ] [ ]   |

**7. Study Documentation**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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? |[ ] [ ]   |

**8. Subject Documentation**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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?  |[ ] [ ]   |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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? |[ ] [ ]   |

**10. Informed Consent**

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

**11. Data Management**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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? |[ ] [ ]   |

**12. Source Data Verification**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **Comments** |
| Are all CRFs complete and all data queries resolved? |[ ] [ ]   |
| Confirm that CRF documents have been reviewed to ensure no patient identifiable data held.?  |[ ] [ ]   |
| Confirmation that Data Lock point has been achieved? |[ ] [ ]   |
| Confirmation that a Statistical Analysis Plan (SAP) is in place? This may form part of the protocol |[ ] [ ]   |

**13. Investigational Medicinal Device**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **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  |  |  |  |

**14. Safety Reporting**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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? |[ ] [ ]   |

**15. Monitoring / Audit**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **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) |[ ] [ ]   |

**16. Clinical Laboratory Tick if not applicable □**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **Comments** |
| 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 sample shipment receipt/tracking records on file? |[ ] [ ]   |
| Are records of sample destruction/method complete as per relevant laboratory SOP and 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 as part of End of Sponsor Green Light process.Please be aware that once specimens /samples are not covered by this ethical application, they must be stored in a HTA licensed area. |[ ] [ ]   |

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

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

**18. Financial/Legal agreements**

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

**19. Annual Reports**

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **Comments** |
| Are copies of all interim study analysis publications on file? |[ ] [ ]   |
| The Investigator understands the sponsor/regulatory requirements with regards to submission of the end of study declaration.The end of study declaration will be submitted to the Sponsor for processing.Acknowledgements from the sponsor and REC will be filed with the end of study declaration in the Trial Masterfile/Investigator site file. |[ ] [ ]   |
| The Investigator understands the process for submitting the final report to the HRA, within 12 months of end of study declaration.The Investigator will provide a copy of the acknowledgement email from the HRA (which includes details of the final report) to the sponsor and a copy filed in the Trial Master File/Site file.  |[ ] [ ]   |
| The Investigator understands the requirement to update relevant public research databases as required.The Investigator will provide copies of all publications to the sponsor.  |[ ] [ ]   |
| The Investigator understands that archiving of both paper and electronic records including the TMF/ISF must be undertaken as per the sponsor SOP S-1029 |[ ] [ ]   |

**21. Correspondence**

|  |
| --- |
| **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 …………………………………………………………..