**APPENDIX 1a**

**UHL Site Close Down Report**

**UHL Non UKCA/CE Marked Medical Device Studies**

**Site Information**

|  |
| --- |
| **Sponsor Number [EDGE number]:** |
| **Study Name:** |
| **Study Site** |
| **Investigator name:** |
| **Date of visit:** |

**List of site and monitoring personnel in attendance**

|  |  |
| --- | --- |
| **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| Number of patients withdrawn |  |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: |

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| Are there superseded contact lists on file |  |  |  |

**1. Contacts List**

**2. Clinical Investigation Plan (CIP) /Protocol**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the current approved CIP/ protocol on file? |  |  |  |
| Is the CIP/protocol signed and dated? |  |  |  |
| Are superseded CIP/protocols on file? |  |  |  |
| Is there a completed CIP/protocol deviation log(s) on file? |  |  |  |
| Have all CIP/protocol deviations been reported and reviewed by PI? |  |  |  |

**3. Ethics/HRA/MHRA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Are all original applications/submissions/approvals on file? |  |  |  |
| Are all Substantial Amendments complete and on file? |  |  |  |
| Are all Non substantial amendments complete and on file? |  |  |  |
| Is there REC/HRA/MHRA correspondence on file? |  |  |  |
| Notification of trial completion (end of study declaration) on file? |  |  |  |
| Is the REC acknowledgement of end of study declaration on file? |  |  |  |

**4. R&I**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Are all original copies of relevant applications/ authorizations on file |  |  |  |
| Are all substantial amendment/s complete and on file? |  |  |  |
| Are all non-substantial amendment/s complete and on file? |  |  |  |
| Is there R&I correspondence on file? |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the Delegation of Authority and signature log updated to reflect end of study |  |  |  |
| Confirm that all CVs/GCP/training records are up to date and on file |  |  |  |

**5. Investigator Site Personnel**

**6. Standard Operating Procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Standard operating procedures read log completed for all Study team members? |  |  |  |

**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** | **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, including an outcome for all subjects? |  |  |  | |

**9. Randomisation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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** | **Comments** |
| Are all consent forms present and correctly completed? |  |  |  |
| Has consent audit been undertaken and documentation of the audit on file? |  |  |  |
| Is informed consent process properly documented in the medical/trial records for all subjects? |  |  |  |

**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** | **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. 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 all complete SAE/SADE reports and associated acknowledgement correspondence from Sponsor on file? |  |  |  |
| Are all device deficiency forms complete and on file? |  |  |  |
| Have all SAEs been reviewed against the current Reference Safety Information (where applicable) |  |  |  |
| Have all SAE/SADEs been reviewed against Investigator Brochure? |  |  |  |
| Are USADE reporting guidelines on file |  |  |  |
| Are all USADE reports and associated acknowledgement correspondence from Sponsor/ MHRA/REC and R&I (Multicentre only) on file? |  |  |  |

**14. Investigational Medicinal Device**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the current signed and dated investigation brochure on file? |  |  |  |
| Are all superseded 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 |  |  |  |

**15. Reference Safety Information (where medical device studies include Investigational medicinal products) Tick if Not Applicable**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **Comments** |
| Have there been any changes to the Reference Safety Information? |  |  |  |
| If changes have been made to the reference safety information are all relevant substantial amendments on file? |  |  |  |
| Is there a current Signed and dated Investigator Brochure (IB) on file? |  |  |  |
| Are all superseded IB brochures on file? |  |  |  |
| Is there a current signed and dated Summary of Product Characteristics (SmPC) on file? |  |  |  |
| Are all Superseded SPCs on file? |  |  |  |
| Are all Safety alert updates on file? |  |  |  |

**16. Monitoring**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is study initiation and all subsequent monitoring/audit visit documentation on file? |  |  |  |  |
| Are all versions of the study specific monitoring plan on file? |  |  |  |  |
| Is the monitoring visit log complete and on file? |  |  |  |  |
| **Comments/findings** | | | | |

**17. Clinical Laboratory/Specimen Collections Tick if not applicable**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Have central labs been used? |  |  |  |
| Are the current and previous central lab accreditations on file? |  |  |  |
| Are current and superseded central lab normal reference ranges on file? |  |  |  |
| Have local Labs been used? |  |  |  |
| Are the local laboratories current and superseded accreditation certificates on file? |  |  |  |
| Are current and superseded local lab normal reference ranges on file? |  |  |  |
| Are current and superseded versions of the sampling and sample handling procedures documents/ lab manuals on file? |  |  |  |
| Are all specimen results reviewed and signed and dated by PI? |  |  |  |
| Are all specimen results that are out of range marked as clinically significant or not clinically significant? |  |  |  |
| Are all sample logs/records complete and on file? |  |  |  |
| Is there on going storage of samples for future research? |  |  |  |
| If yes; Are storage conditions monitored and recorded? |  |  |  |
| 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. |  |  |  |
| If yes; Has the sponsor been notified as to storage location? |  |  |  |
| 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? |  |  |  |

**18. Pharmacy (where medical device studies include Investigational medicinal products) Tick if Not Applicable ☐**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Are pharmacy staff GCP and CVs up to date and on file? |  |  |  |
| Is the delegation of authority and signature log updated to reflect end of study? |  |  |  |
| Are instructions in place with regards to handling trial medication and trial related materials. Dispensing procedure  Randomisation/resupply/returns and destruction?  IMP packaging samples |  |  |  |
| Is there a pharmacy approved prescription template on file? |  |  |  |
| Records of drug dispensing on file and has the drug been correctly dispensed with all completed prescriptions on file? |  |  |  |
| Have drug accountability records been completed? |  |  |  |
| Are their adequate collection, recording and maintenance of temperature monitoring records for all locations storing IMPs? |  |  |  |
| Have any drug excursions been recorded? |  |  |  |
| Have any drug been quarantined? |  |  |  |
| Are all required GMP, certificate of analysis and QP release documents on file? |  |  |  |

**19. Financial/Legal agreements**

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

**21. Annual Reports**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Are all annual progress and safety reports to the Ethics Committee and acknowledgements on file? |  |  |  |
| Are Sponsor confirmations of annual report receipt on file? |  |  |  |

**22. Final Study Report/ Publication**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** | |
| Are copies of all interim study analysis publications on file? |  |  |  | |
| The Investigator understands the process for submitting the final report to the HRA and will provide a copy of the acknowledgement email from the HRA, which includes details of the final report, to the sponsor. A copy of the report will be filed in the Trial Master File/Investigator Site File. |  |  |  |
| The Investigator understands the requirement to update the relevant public research database and upload report/publications as required.  The investigator will confirm with the sponsor when this has been completed. |  |  |  | |
| 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 |  |  |  | |

**23. Correspondence**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is all study related correspondence on file? |  |  |  |

**Additional Comments/Overview**

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

**Name (Print) …………………………………………………………..**

**Signature …………………………………………………………..**

**Role …………………………………………………………..**

**Date: …………………………………………………………..**

UHL Site close down Final Outstanding Findings Sign Off

**Date of Visit: Study Title:**

**Sponsor Reference: Principal Investigator: Date Responses Due Back:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Finding**  **Number** | **Outstanding findings** | **Action required** | **Action Taken** | **Principal Investigator/ delegate Signature** |
|  |  |  |  |  |
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**Chief Investigator Signature ………………………………………. Date ………………………………………………….**