**UHL Monitoring Visit Report**

 **for UHL Sponsored Non CE Marked Medical Device Studies**

**Site Information**

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| --- |
| **Site:** |
| **Study Title:** |
| **Sponsor Reference Number/EDGE ID:** |
| **Investigator Name:** |
| **Date of Visit:** |
| **Date of Report:** |
| **Date Responses Due Back:**  |

**Findings from the monitoring report will be categorised as Critical, Major or Other as per SOP S-1016 UHL, Procedure in the event of non-compliance in clinical research. Response to all findings will be required in the format of a CAPA Corrective Action Preventative Action plan. A summary of all findings will be entered into a plan and submitted to the Principal Investigator for action. The CAPA must be returned to the Sponsor within 4 weeks of issue. This requires the CI / PI to explain what action they will take, not necessarily take the action at that point in time. The CAPA will be followed up by the Sponsor until completion/closure.**

**Critical**

Where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that:

The rights, safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and/or the clinical trial data are unreliable and/or

There are a number of Major non-compliances across areas of responsibility, indicating a systematic quality assurance failure and/or

Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances

Where provision of the TMF does not comply with regulatory requirements and/or as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection.

**Major**

A non-critical finding where evidence exists that a significant and unjustified departure from applicable legislative requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed,

Where evidence exists that a number of departures from applicable legislative requirements and/or established GCP guidelines have occurred within a single area of responsibility, indicating a systematic quality assurance failure.

**Other**

Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither Critical nor Major.

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| --- |
| **Summary/Purpose of Visit** |
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|  |
| --- |
| **Outstanding Actions from Last Monitoring Visits** |
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 **List of Site and Monitoring Personnel in Attendance**

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

**Study Status**

|  |  |
| --- | --- |
| Planned patient number |  |
| Planned recruitment timescale |  |
| Number of patients randomised |  |
| Number of patients on going |  |
| Number of patients completed |  |
| Number of patients withdrawn |  |
| Number of patients ineligible |  |
| Number of patients lost to follow up |  |
| Comments: |  |

**1. Study Team Contacts**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is there a contacts list on file? |[ ] [ ]   |

**2. Clinical Investigation Plan**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the current approved clinical investigation plan on file? |[ ] [ ]   |
| Is the clinical investigation plan signed and dated? |[ ] [ ]   |
| Are superseded clinical investigation plan(s) on file? |[ ] [ ]   |
| Is there a clinical investigation plan deviation log on file? |[ ] [ ]   |
| Have clinical investigation plan deviations been reported/reviewed by PI? |[ ] [ ]   |

**3. Ethics/HRA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the signed and dated IRAS submission form on file? |[ ] [ ]   |
| Is the Site Specific Assessment (SSA) form on file? (where applicable) |[ ] [ ]   |
| Is the statement of activities/schedule of events on file? (where applicable) |[ ] [ ]   |
| Is the HRA initial assessment letter on file? (where applicable) |[ ] [ ]   |
| Is the Favourable Opinion Letter/HRA Approval on file/ details of Ethics committee constitution? |[ ] [ ]   |
| Are substantial amendments on file? |[ ] [ ]   |
| Are non-substantial amendments on file? |[ ] [ ]   |
| Ethics/HRA correspondence on file? |[ ] [ ]   |

**4. Competent Authority**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the CTA application on file? |[ ] [ ]   |
| Is the CTA acceptance letter on file? |[ ] [ ]   |
| Are CTA amendment/submission forms on file? |[ ] [ ]   |
| Is there CTA acknowledgement of amendment letter/s on file? |[ ] [ ]   |
| MHRA correspondence on file? |[ ] [ ]   |

**5. R&I**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the Trust application/confirmation of capability assessment on file? |[ ] [ ]   |
| Is the Trust approval/authorisation on file? |[ ] [ ]   |
| Are there substantial amendment/s on file? |[ ] [ ]   |
| Are there non-substantial amendment/s on file? |[ ] [ ]   |
| Trust correspondence on file? |[ ] [ ]   |

**6. Investigator Site Personnel**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the Delegation of Authority and signature log on file and complete? |[ ] [ ]   |
| Any changes in staff since last visit? |[ ] [ ]   |
| Are original signed and dated CVs on file? |[ ] [ ]   |
| Is there evidence of GCP training/ device training for all staff covering the duration of the study? |[ ] [ ]   |
| Is there evidence of UHL consent training for all non medics taking consent? (where applicable) |[ ] [ ]   |

**7. Standard Operating Procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Are all staff aware of where to access most current versions of sponsor SOPs (R&I Website)? |[ ] [ ]   |
| Are staff aware of where to access all study specific standard operating procedures/guidelines |[ ] [ ]   |
| Is the Standard Operating Procedures read list completed for all study team members? |[ ] [ ]   |

**8. Study Documentation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there a copy of the current approved Patient Information Leaflet on file? |[ ] [ ] [ ]   |
| Is there a copy of the current approved Patient Consent Form on file? |[ ] [ ] [ ]   |
| Is there a copy of the current approved Letter of Invitation on file? |[ ] [ ] [ ]   |
| Is there a copy of the current approved GP Letter on file? |[ ] [ ] [ ]   |
| Is there a copy of the current approved Questionnaire, if applicable? |[ ] [ ] [ ]   |
| Is there a copy of the current approved Advert if applicable? |[ ] [ ] [ ]   |
| Other study specific documents reviewed and documented? |[ ] [ ] [ ]   |
| Are previous versions of study documentation marked as superseded? |[ ] [ ] [ ]   |
| Is there a copy of the current Case Report Formon file? |[ ] [ ] [ ]   |
| **Comments/Findings** |
|  |

**9. Subject Documentation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there a current master copy of the screening log template on file? |[ ] [ ] [ ]   |
| Is the subject screening log complete and up to date? |[ ] [ ] [ ]   |
| Is there a current master copy of the enrolment log template on file? |[ ] [ ] [ ]   |
| Is the enrolment log complete and up to date? |[ ] [ ] [ ]   |
| **Comments/Findings** |
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**10. Randomisation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there documentation of the randomisation/ decoding process on file? |[ ] [ ] [ ]   |
| Where is the master randomisation list held? |[ ] [ ] [ ]   |
| Evidence of correct blinding (where applicable) as per study protocol? |[ ] [ ] [ ]   |
| **Comments/Findings** |
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**11. Informed Consent**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **Comments** |
| Are study staff aware of the correct ethics approved recruitment and consent process? |[ ] [ ]   |
| Are all consent forms present and correctly completed? |[ ] [ ]   |
| Have the correct versions of the PIL and consent been used according to the timelines of ethics and R&I approval? |[ ] [ ]   |
| Have study participants been re consented on new PIL information if applicable? |[ ] [ ]   |
| Has 100% consent audit been undertaken? |[ ] [ ]   |
| Are copies of the patient information sheet and consent present in the medical records and TMF/ISF? |[ ] [ ]   |
| Is informed consent process properly documented in the medical/trial records? |[ ] [ ]   |

**12. Data Management**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Confirmation a Data Management Plan is in place |[ ] [ ] [ ]   |
| Has the Data Management plan been revised following protocol amendment ? |[ ] [ ] [ ]   |
| Is all study hard copy documentation stored in a restricted access area? |[ ] [ ] [ ]   |
| Are all study related documents anonymised by the use of study patient identifier? |[ ] [ ] [ ]   |
| 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? |[ ] [ ] [ ]   |
| Will any documentation be archived off site? If yes are details logged with the Sponsor? |[ ] [ ] [ ]   |
| **Comments/Findings** |

**13. Source Data Verification**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all source documents available to verify the data in the Case Report Form? |[ ] [ ] [ ]   |
| Is the CRF completion timely and accurate? |[ ] [ ] [ ]   |
| Has the CRF been revised in response to protocol amendment where applicable? |[ ] [ ] [ ]   |
| Have all CRF data queries resolved since previous visit? |[ ] [ ] [ ]   |
| Has SDV been performed according to the monitoring plan? |[ ] [ ] [ ]   |
| Location of source documents |[ ] [ ] [ ]   |
| Confirmation that a Statistical Analysis Plan (SAP) is in place |[ ] [ ] [ ]   |
| **Comments/Findings** |
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**14. Medical Device/Labelling**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current Investigator brochure and/ or Manufacturer Instructions on file? Version and date.  |[ ] [ ] [ ]   |
| Is the IB signed and dated by the CI/PI? |[ ] [ ] [ ]   |
| Are any superceded versions of IB/ Manufacturer instructions on file? |[ ] [ ] [ ]   |
| Are shipping/receipt records on file for all medical devices and components? |[ ] [ ] [ ]   |
| Is there a copy of the current device label on file? |[ ] [ ] [ ]   |
| Is there correct labelling in place for all devices and components? |[ ] [ ] [ ]   |
| Is there a master copy of the device accountability log on file? |[ ] [ ] [ ]   |
| Are device accountability logs on file? |[ ] [ ] [ ]   |
| Are equipment maintenance and calibration records on file? |[ ] [ ] [ ]   |
| Are storage area temperature logs on file? (where applicable) |[ ] [ ] [ ]   |
| **Comments/Findings** |
|  |

**15. Safety Reporting**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are SAE, SADE and USADE reporting guidelines on file? |[ ] [ ] [ ]   |
| Have any device deficiencies been reported? |[ ] [ ] [ ]   |
| Is there a current SAE/SADE form template on file? |[ ] [ ] [ ]   |
| Are SAE/SADE reports and associated acknowledgement correspondence from Sponsor/R&I on file? |[ ] [ ] [ ]   |
| Have all SAEs/SADEs /device deficiencies been reviewed against the current Investigator brochure/manufacturers instructions/ manual ? |[ ] [ ] [ ]   |
| Are USADE reporting guidelines on file? |[ ] [ ] [ ]   |
| Are USADE reports and associated acknowledgement correspondence from Sponsor/ MHRA/R&D on file? |[ ] [ ] [ ]   |
| **Comments/Findings** |
|  |

**16. Monitoring/Audit**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **Comments** |
| Has an initiation visit taken place? |[ ] [ ]   |
| Is the initiation report on file? |[ ] [ ]   |
| Is the study specific monitoring plan on file? |[ ] [ ]   |
| Is the monitoring log template on file? |[ ] [ ]   |
| Is there a completed monitoring log? |[ ] [ ]   |
| Are all completed monitoring visit /audit reports on file? |[ ] [ ]   |
| Has the monitoring plan been reviewed/revised? |[ ] [ ]   |
| **Comments/Findings** |
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**17. Clinical Laboratory/Specimen Collections (**check box if N/A[ ] )

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are central labs being used? |[ ] [ ] [ ]   |
| Are the current and previous central lab accreditations on file? |[ ] [ ] [ ]   |
| Is central lab normal reference ranges on file? |[ ] [ ] [ ]   |
| Are local labs being used? |[ ] [ ] [ ]   |
| Are the local laboratory current and previous accreditation certificates on file? |[ ] [ ] [ ]   |
| Local lab normal reference ranges |[ ] [ ] [ ]   |
| Are there signed and dated copies of CVs of heads of departments? |[ ] [ ] [ ]   |
| Are sampling and sample handling procedures documented? Is there a lab manual on file? |[ ] [ ] [ ]   |
| Are specimen results reviewed and signed and dated by PI? |[ ] [ ] [ ]   |
| Are specimen results that are out of range marked as clinically significant or not clinically significant? |[ ] [ ] [ ]   |
| Are all samples correctly stored in a suitable secure environment? |[ ] [ ] [ ]   |
| Are sample logs/records held? |[ ] [ ] [ ]   |
| Are lab kits available and in date? |[ ] [ ] [ ]   |
| Are sample shipment/receipt tracking available? |[ ] [ ] [ ]   |
| Are storage conditions monitored and recorded? |[ ] [ ] [ ]   |
| Is there a contingency plan in place for storage facility failure? |[ ] [ ] [ ]   |
| **Comments/Findings** |
|  |

**18. Financial/Legal agreements**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are contracts in place with all Investigators and sub-contractors? Clinical Agreements etc.? |[ ] [ ] [ ]   |
| Is confirmation of sponsorship on file? |[ ] [ ] [ ]   |
| Is funding documentation on file? |[ ] [ ] [ ]   |
| Are insurance/indemnity statements on file? |[ ] [ ] [ ]   |
| Is financial correspondence on file? |[ ] [ ] [ ]   |
| Are there records of subject expenses? |[ ] [ ] [ ]   |
| **Comments/Findings** |
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**19. Annual Reports**

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| --- | --- | --- | --- | --- |
| **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. Publication**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are copies of interim study analysis publications on file? |[ ] [ ] [ ]   |
| **Comments/Findings** |
|  |

**21. Correspondence**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are meeting agendas and minutes on file? |[ ] [ ] [ ]   |
| Are copies of study newsletters on file? |[ ] [ ] [ ]   |
| Are copies of all correspondence between the Chief Investigator and collaborating centres on file? (multicentre studies only) |[ ] [ ] [ ]   |
| Is general study related correspondence on file? |[ ] [ ] [ ]   |
| **Comments/Findings** |
|  |

**22. Miscellaneous**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
|  |[ ] [ ] [ ]   |
| **Comments/Findings** |
|  |

**Monitoring Visit Response Document for UHL Study No:**

**Monitoring visit Date: Monitoring visit report date: Date response required:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No** | **Category** | **Finding** | **Immediate/ Corrective Action** | **Preventative Action**  | **Completed by Initials & Date****Completed** |
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**Monitoring Report Completed By:**

|  |
| --- |
| Name:  |
| Telephone: |
| e-mail:  |
| Signature:  |
| Date:  |

**Report Response Completed By:**

|  |
| --- |
| Name:  |
| Telephone: |
| e-mail:  |
| Signature:  |
| Date:  |

**Completed Responses Approved by PI:**

|  |
| --- |
| PI Name: |
| PI Signature: |
| Date: |

**Completed Monitoring Report Approved by:**

|  |
| --- |
| Name :  |
| Role: |
| Signature:  |
| Date Monitoring Report Closed:  |