**UHL CE Marked/ Proof of Concept Medical Device studies**

**Monitoring/Audit Checklist**

**Site Information**

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

**Findings from the monitoring/audit report will be categorised as Critical, Major or Other as 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.

|  |
| --- |
| **Summary/Purpose of Visit** |
| *Complete or delete section as applicable* |

|  |
| --- |
| **Outstanding Actions from Last Monitoring Visits** |
| *Complete or delete section as applicable* |

**List of 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** | **N/A** | **Comments** |
| Is there a contacts list on file? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

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

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| Are superseded CIPs/protocols on file?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

**3. Ethics/HRA**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the signed and dated IRAS submission form on file? | ☐ | ☐ | ☐ |  |
| Is the Site Specific Assessment (SSA) form on file? | ☐ | ☐ | ☐ |  |
| 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 correspondence on file? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**4. R&I**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Is the Trust Application/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? | ☐ | ☐ | ☐ |
| Notification of trial completion on file? | ☐ | ☐ | ☐ |
| Trust correspondence on file? | ☐ | ☐ | ☐ |
| **Comments/Findings** | | | |
|  | | | |

**5. Investigator Site Personnel**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the Delegation of Authority and signature log on file and complete? | ☐ | ☐ | ☐ |  |
| Any changes in staff since last visit/audit? | ☐ | ☐ | ☐ |  |
| Are original signed and dated CVs on file? | ☐ | ☐ | ☐ |  |
| Is there evidence of appropriate training for all staff covering the duration of the study? | ☐ | ☐ | ☐ |  |
| Is there evidence of UHL consent training for all non-medics taking consent? | ☐ | ☐ | ☐ |  |
| Multicentre studies only  Has an updated copy of the delegation log been supplied to the CI in the last 4 weeks?  If no please forward copy of updated log and any relevant training records. | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**6. 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 Questionnaires, 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 Form  on file? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**7. 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** | | | | |
|  | | | | |

**8.Standard Operating Procedures**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are there current SOPs on file/staff aware of where to access most current SOPs (R&I Website)? | ☐ | ☐ | ☐ |  |
| Standard Operating Procedures read list completed as relevant for all study team members? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**9. 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 as per study protocol? | ☐ | ☐ | ☐ |  |
| Access required to the emergency code break information available (where applicable)? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**10. Informed Consent**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| 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? | ☐ | ☐ | ☐ |  |
| Where consent audit has been undertaken, is documentation of the audit on file? | ☐ | ☐ | ☐ |  |
| 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? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**11. Data Management**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is all study hard copy documentation stored in a restricted access area? | ☐ | ☐ | ☐ |  |
| Are all study related documentation 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? | ☐ | ☐ | ☐ |  |
| Where a data access/sharing agreement exists, has the data been accessed in accordance with the terms & conditions of the agreement? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**12. Medical Device/Labelling**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current manufacturer instructions/manual on file? Version and date. |  |  |  |  |
| Are any superceded versions of the manufacturer instructions/manual 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** | | | | |
|  | | | | |

**13. 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/manufacturer’s instructions/manual? |  |  |  |  |
| Are USADE reporting guidelines on file? |  |  |  |  |
| Are USADE reports and associated acknowledgement correspondence from Sponsor/ MHRA/R&D on file? |  |  |  |  |
| **Comments/Findings** | | | | |
|  | | | | |

**14. Monitoring/Audit**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Has an initiation visit taken place (Higher risk CE Marked/Proof of concept device studies only)? | ☐ | ☐ | ☐ |  |
| Is the initiation report on file? | ☐ | ☐ | ☐ |  |
| Is the study specific monitoring plan on file (Higher risk CE marked/proof of concept studies only)? | ☐ | ☐ | ☐ |  |
| Is the monitoring log template on file? | ☐ | ☐ | ☐ |  |
| Is there a completed monitoring log? | ☐ | ☐ | ☐ |  |
| Are all monitoring/audit visit reports on file? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**15. 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 on file? | ☐ | ☐ | ☐ |  |
| 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 and 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** | | | | |
|  | | | | |

**16. 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? | ☐ | ☐ | ☐ |  |
| Is financial correspondence on file? | ☐ | ☐ | ☐ |  |
| Are there records of subject expenses? | ☐ | ☐ | ☐ |  |
| **Comments/Findings** | | | | |
|  | | | | |

**17. Annual Reports**

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

**18. Publication**

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

**19. 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** | | | | |
|  | | | | |

**20. Miscellaneous**

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

**Monitoring /Audit Visit Response Document for study :**

**Visit Date: Visit report date: Date response required:**

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

**Report Completed By:**

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

**Report Responses Completed By:**

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

**Completed Responses Approved by PI:**

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

**Completed Report Approved by:**

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