**UHL Non-CTIMP Monitoring/Audit Checklist**

**Site Information**

|  |
| --- |
| **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** |
| *Not applicable – first sponsor review* |

**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. Protocol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current approved protocol on file? |  |  |  |  |
| Is the protocol signed and dated? |  |  |  |  |
| Are superseded protocols on file? |  |  |  |  |
| Is there a protocol deviation log on file? |  |  |  |  |
| Have all 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? (where applicable) |  |  |  |  |
| Is the statement of activities/schedule of events 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? |  |  |  |  |
| **Comments/Findings** | | | | |
|  | | | | |

**4. R&I**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **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. 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** | | | | |
|  | | | | |

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

**8. 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** | | | | |
|  | | | | |

**9. Randomisation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there documentation of the randomisation process on file? |  |  |  |  |
| Where is the master randomisation list held? |  |  |  |  |
| 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? |  |  |  |  |
| 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 designed to ensure that they are 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** | | | | |
| Remove sponsor form from | | | | |

**12. 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? |  |  |  |  |
| Have all CRF data queries resolved since previous visit? |  |  |  |  |
| Has SDV been performed according to the monitoring plan (where applicable)? |  |  |  |  |
| Location of source documents |  |  |  |  |
| Is a Statistical Analysis Plan (SAP) in place? |  |  |  |  |
| **Comments/Findings** | | | | |
|  | | | | |

**13. Safety Reporting**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are SAE reporting Guidelines/SOP and Pharmacovigilance/Governance contact on file? |  |  |  |  |
| Is there a current SAE form template on file? |  |  |  |  |
| Are SAE reports and associated acknowledgement correspondence from Sponsor/R&I on file? |  |  |  |  |
| **Comments/Findings** | | | | |
|  | | | | |

**14. Monitoring**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Has an initiation visit taken place (Higher risk Non CTIMPs only)? |  |  |  |  |
| Is the Initiation report on file? |  |  |  |  |
| Is the study specific monitoring plan on file (Higher risk Non CTIMPs only)? |  |  |  |  |
| Is the monitoring log template on file? |  |  |  |  |
| Is there a completed monitoring log? |  |  |  |  |
| Are all monitoring visit reports on file? |  |  |  |  |
| **Comments/Findings** | | | | |
|  | | | | |

**15. Clinical Laboratory/Specimen Collections**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are central labs being used? |  |  |  | Not applicable |
| 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. Study Related Supplies**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are shipment and delivery records on file? |  |  |  |  |
| Is collection and return of equipment documented and on file? |  |  |  |  |
| Are supply reorder form templates on file? |  |  |  |  |
| Are completed supply request forms on file? |  |  |  |  |
| Are records kept and retained for maintenance, calibration and validation of all equipment used as part of the study? |  |  |  |  |
| **Comments/Findings** | | | | |
|  | | | | |

**18. Annual/Final Reports**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are annual progress and where applicable safety reports to the Ethics committee on file? |  |  |  |  |
| Are Sponsor confirmations of annual report receipt on file? |  |  |  |  |
| Is their evidence of notification of trial completion to Sponsor, REC, Competent Authority and R&I? |  |  |  |  |
| **Comments/Findings** | | | | |
|  | | | | |

**19. Publication**

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

**20. 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** | | | | |
|  | | | | |

**21. Other**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Report Completed By:**   |  | | --- | | Monitor : | | Telephone: | | e-mail: | | Signature: | | Date: | | **Completed Responses Approved by PI:**   |  | | --- | | PI Name: | | PI Signature: | | Date: | |
| **Report Responses Completed By:**   |  | | --- | | Name : | | Telephone: | | e-mail: | | Signature: | | Date: | | **Completed Report Approved by:**   |  | | --- | | Monitor : | | Signature: | | Date Monitoring Report Closed: | |