**UHL Site Initiation Checklist**

**for studies NOT involving Investigational Medicinal Products**

**Site Information**

|  |  |
| --- | --- |
| **Site** | **Initiation Visit Method** |
| Sponsor Reference Number: | On Site 🞏 |
| Study Name: | Teleconference 🞏 |
| Investigator: | Other (specify) 🞏 |
| Study Site: |  |
| Date of Initiation |  |
| Conducted by: |  |

**Personnel in Attendance/Completing Report**

|  |  |
| --- | --- |
| Name | Title |
|  |  |
|  |  |

**Study Overview/Protocol Overview**

|  |  |
| --- | --- |
| **Items discussed/verified** | Comments |
| Background and purpose of study |  |

**1. Training and Regulatory Compliance**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Investigator obligations |  |  |  |
| Sponsor obligations |  |  |  |
| Standard Operating Procedures |  |  |  |
| Regulatory Authority reporting requirements |  |  |  |
| Sponsor reporting requirements |  |  |  |
| Amendments |  |  |  |
| Annual progress reports |  |  |  |
| Data Protection/ GDPR |  |  |  |
| Study record storage requirements |  |  |  |

**2. Trial Master File/Investigator Site File**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| TMF/ISF created and complete |  |  |  |
| Delegated individual for TMF/ISF maintenance |  |  |  |
| Secure location/limited access |  |  |  |

**3. Study Approval Status/Essential Documents**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Version/ Comments |
| REC Favourable opinion/HRA approval |  |  |  |
| R&D/R&I/Host organisation approval/authorisation/ Capability & Capacity |  |  |  |
| Signed Sponsor/CI agreement |  |  |  |
| Signed financial agreement/ contract |  |  |  |
| Protocol - Confirm protocol signed and dated by the PI |  |  |  |
| Protocol deviation/Serious breach reporting |  |  |  |
| Patient Information Leaflet  (document version no and date) |  |  |  |
| Are the contact numbers on the PIS correct/ been checked? |  |  |  |
| Consent  (document version no and date) |  |  |  |
| Patient Invitation  (document version and date) |  |  |  |
| GP Letter  (document version and date) |  |  |  |
| Advertisement  (document version and date) |  |  |  |
| CRF  (document version and date) |  |  |  |
| Other |  |  |  |

**4. Investigator Site Personnel**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Adequate site staff to conduct the study |  |  |  |
| All study team members listed on delegation of authorities log/ all entries signed and dated by PI |  |  |  |
| Signed and dated CVs for all study team members |  |  |  |
| Documented evidence of research training / consent/study specific training |  |  |  |

**5. Recruitment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | Yes | No | Comments |
| Planned number of trial subjects |  |  |  |
| Methods for identifying subjects |  |  |  |
| Requirement to complete subject logs |  |  |  |
| Requirement to complete subject enrolment logs |  |  |  |
| Procedure for withdrawn subjects/Lost to follow-up |  |  |  |

**6. Informed Consent/Enrolment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Informed consent/ procedures/documentation requirements |  |  |  |
| Eligibility criteria confirmed |  |  |  |

**7. Randomisation/Blinding**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | Yes | No | Comments |
| Unblinding procedure/code break envelopes |  |  |  |
| Randomisation procedures |  |  |  |
| Blinded/ unblinded team members |  |  |  |

**8. Safety Reporting** (Check box if N/A  )

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| AE / SAE reporting procedures |  |  |  |
| Sponsor notification process |  |  |  |

**9. Data** Management

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Format and timelines |  |  |  |
| CRF completion guidelines |  |  |  |
| Are all study related documentation designed to ensure that they are anonymised by the use of study patient identifier |  |  |  |
| Is all study hard copy documentation stored in a restricted access area |  |  |  |
| Is access to electronic study records and files password protected? |  |  |  |
| Are computer records and files containing identifiable data stored on a remote and secure server? Are emergency recovery processes in place? |  |  |  |
| Requirements for Queries and corrections resolution |  |  |  |
| eDC training (for electronic case report forms) |  |  |  |
| Are electronic data files for analysis anonymised? |  |  |  |
| Data Management plan in place (If applicable) |  |  |  |
| Statistical analysis plan requirements |  |  |  |

**10. Source Documentation**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Source Data agreement/ schedule in place? |  |  |  |
| CRFs as source |  |  |  |
| Document retention requirements |  |  |  |
| Archiving requirements/ responsibilities |  |  |  |

**11. Equipment List** (Check box if N/A  )

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Equipment list |  |  |  |
| Calibration of equipment |  |  |  |
| Maintenance/service record requirements |  |  |  |

**12. Specimen collection** (Check box if all N/A  )

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Specimen collection |  |  |  |
| Sample result verification. CS/NCS status and required actions |  |  |  |
| Specimens to be obtained |  |  |  |
| Specimen storage |  |  |  |
| Specimen storage and tracking logs |  |  |  |
| Temperature monitoring |  |  |  |
| Sample shipment |  |  |  |
| Laboratory training/manual/SOPs |  |  |  |
| Lab kits |  |  |  |
| Lab accreditation |  |  |  |
| Lab reference ranges |  |  |  |

**13. Communication**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | Yes | No | Comments |
| Format and frequency |  |  |  |
| Site contacts |  |  |  |
| Recruitment updates to Sponsor |  |  |  |

**14. Monitoring/Audit**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | Yes | No | Comments |
| Site Monitoring/Audit/ response requirements |  |  |  |

**15. SOP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | Yes | No | Comments |
| Do all members of the study team know how to access the Sponsor SOPs via the webpages? |  |  |  |
| CI/PI confirmation of review and compliance with all Sponsor Standard Operating Procedures. |  |  |  |
| UHL Sponsor SOPs: http://www.leicestersresearch.nhs.uk/sops/sop-downloads-sponsor/ | | | |

**Additional Comments/ Visit Overview**

**Study commencement must not occur until Sponsor Green Light process has been completed**

UHL Site Initiation Outstanding Issues Report

**Sponsor Reference and Short Title:**

**Date of Visit: Date of Report: Date Responses Due Back:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No** | **Outstanding Issue** | **Action required** | **Action Taken** | **Signature & Date** |
|  |  |  |  |  |
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|  |  |  |  |  |

**SIV Report Completed By:**

|  |
| --- |
| Name:: |
| Role: |
| 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 SIV Report Approved By:**

|  |
| --- |
| Name: |
| Role: |
| Signature: |
| Date: |