**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:  |