**UHL Site Initiation Checklist**

**For CE Marked or Proof of Concept Medical Device Studies**

**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 |
|  |  |
|  |  |
|  |  |
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**Study Overview/Protocol Overview**

|  |  |
| --- | --- |
| **Items discussed/verified** | Comments |
| Background and purpose of study |  |
| Investigational Medicinal Device/Software |  |

**1. GCP 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 reports/DSUR requirements |[ ] [ ]   |
| Data Protection |[ ] [ ]   |
| Study record storage requirements |[ ] [ ]   |
| Archiving arrangements |[ ] [ ]   |

**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 |
| EC Favourable opinion/HRA approval |[ ] [ ]   |
| R&D/R&I/Host organisation approval/authorisation |[ ] [ ]   |
| Signed Sponsor/CI agreement |[ ] [ ]   |
| Signed financial agreement |[ ] [ ]   |
| Protocol/CIP - Confirm protocol/CIP signed and dated by the CI/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 authority log/ all entries signed and dated by PI |[ ] [ ]   |
| Signed and dated CVs for all study team members |[ ] [ ]   |
| Documented evidence of GCP/ consent/device/study specific training |[ ] [ ]   |

**5. Recruitment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | Yes | No | Comments |
| Planned number of trial subjects |[ ] [ ]   |
| Methods for identifying subjects |[ ] [ ]   |
| Research team aware of inclusion/exclusion criteria? |[ ] [ ]   |
| Requirement to complete subject screening and 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. Medical Device/Software**

|  |  |  |  |
| --- | --- | --- | --- |
| Items discussed/verified | Yes | No | Comments |
| Medical Device Investigation Brochure/ Manufacturer Instructions on file |[ ] [ ]   |
| Electrical safety testing completed |[ ] [ ]   |
| Equipment List: Batch No/Lot No/Device No are entered on device accountability log |[ ] [ ]   |
| Calibration of equipment has occurred/processes are in place. |[ ] [ ]   |
| Sterilisation process(s) if applicable |[ ] [ ]   |
| Software use/licensing (If applicable) |[ ] [ ]   |
| Maintenance/service record requirements |[ ] [ ]   |

**8. Labelling (Check box if N/A ☐ )**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | Yes | No | Comments |
| Does the label include the name or trade name and address of the manufacturer? |[ ] [ ]   |
| Does the label indicate exclusively for clinical investigation? |[ ] [ ]   |
| Does packaging identify the device and the contents of the packaging? |[ ] [ ]   |
| Where appropriate is the product marked as sterile? |[ ] [ ]   |
| Is the batch No/Lot No or serial number on the label |[ ] [ ]   |
| Where appropriate does the label indicate the date by which the device should be used? |[ ] [ ]   |
| Where appropriate is there an indication that the device is for single use only? |[ ] [ ]   |
| Does the label contain special operating instructions/warnings and/or precautions to take? |[ ] [ ]   |

**9. Randomisation/Blinding** (check box if N/A[ ] )

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | Yes | No | Comments |
| Is a blinded evaluator being utilised |[ ] [ ]   |
| Randomisation procedures |[ ] [ ]   |
| Decoding procedure/code break envelopes where applicable |[ ] [ ]   |

**10. Safety Reporting**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comments |
| AE / SAE reporting procedures |[ ] [ ]   |
| Device deficiency reporting/ quarantine procedures |[ ] [ ]   |
| ADE/SADE reporting procedures |[ ] [ ]   |
| USADE reporting procedures |[ ] [ ]   |
| Notification process |[ ] [ ]   |
| Data safety monitoring board/committee reporting requirements |[ ] [ ]   |

**11. Data Collection**

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |[ ] [ ]   |

**12. Source Documentation**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Source data agreement in place? |[ ] [ ]   |
| CRFs as source |[ ] [ ]   |
| Document retention requirements/procedures |[ ] [ ]   |

**13. Specimen collection (Check box if 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 |[ ] [ ]   |

**14. Communication**

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

**15. Monitoring/Audit**

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

**16. 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. |[ ] [ ]   |

**17. Archiving**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No |  |
| Site Archiving at end of study discussed? |[ ] [ ]   |
| Will any documentation be archived off site? If yes, Sponsor archiving requirements discussed.  |[ ] [ ]   |

**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: Site:**

**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:  |