**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: |