**Study Monitoring Plan Template**

**Non CE/CE Marked Medical Device Studies**

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| **Issue Number and Date :** |  |
| **Sponsor / EDGE ID Reference Number:** |  |
| **IRAS Reference Number:** |  |
| **Study Title:**  |  |
| **Chief / Principal Investigator:** |  |
| **Study Site:** |  |



The Sponsor risk assessment SOP S-1003 UHL and the trial risk based monitoring strategy, appendix 2 to SOP S- 1007, will inform the development of the monitoring plan. The type of monitoring undertaken, either onsite, remote or central, and the frequency and focus of monitoring visits will be determined by the risk rating allocated. The intervals for monitoring visits may be revised dependent on subject enrolment rate, quality issues, site compliance or other trial issues. All aspects will be undertaken in accordance with the Sponsor Standard Operating Procedures.

Any significant deviation from the planned monitoring timelines will be explained and documented in the monitoring visit report and the plan amended if appropriate.

If the site does not enroll any participants or enrolment is stopped, regular monitoring visits will not be scheduled. If there is an extended gap in trial activities the monitor will confirm with the CI or PI that site staff are appropriately trained when trial activities recommence.

**Type of Monitoring to be undertaken**

*Detail Type/s of monitoring to be utilised.*

**Frequency of monitoring visits**

**I**nitiation

*Document site initiation date*

First monitoring visit

*Detail expected timescale.*

Interim monitoring visits

*Consider the timing of interim monitoring visits for dose escalation studies and/or data monitoring committee review of data.*

Close out visits

*Ensure all aspects of study closure are completed as per Sponsor Standard Operating Procedure S-1024.*

**Contact with the Principal Investigator**

The monitor will communicate with relevant study personnel discuss study progress and issues.

**Monitoring**

The monitor should complete and sign the Trial Monitoring Visit Log (Appendix 3 SOP 1007) at each visit

Recruitment

*The study specific recruitment plan and recruitment timeframe as per specific*

*clinical investigator plan/protocol*

Eligibility

The following inclusion and exclusion criteria should be checked in full:

Inclusion criteria

*As per clinical investigator plan/protocol*

Exclusion criteria

*As per clinical investigator plan/protocol*

All subjects participating in the study should meet ALL of the inclusion criteria and NONE of the exclusion criteria. Any deviations from the inclusion/exclusion criteria should be documented as a *clinical investigator plan/protocol* breach/deviation.

Primary /Secondary endpoints

*As per clinical investigator plan/protocol*

**Consent**

*Informed consent is fundamental to research and must have been given prior to ANY study related procedures. The monitor will ensure that the correct process with regards to the approach, provision of information, timescale for patient review prior to consent is as documented in the clinical investigator plan/protocol and Ethics application and Sponsor SOP requirements.*

*The monitor will check an appropriate proportion of the informed consent form and participant information sheet for subjects to ensure that:*

*1) The current, approved version has been used*

*2) The original signed copy of the informed consent form and participant information sheet is placed in the ISF. These must be correctly completed by both the subject and investigator.*

*The monitor will check that the process of informed consent has been documented in the subject’s medical notes (where appropriate) and that this has been dated and signed by the person authorised and responsible for obtaining the subject’s informed consent.*

*The monitor will check that the person conducting the informed consent procedure is documented as authorised to do so, by review of the Delegation of Authority and Signature log.*

*The monitor will document non-compliance with the correct consent procedure in the Monitoring Visit Report.*

**Source Data Verification**

Source Data is comprised of records where subject information is first recorded. It includes, but is not limited to, hospital case notes, ECG traces, X-rays, etc.

Where there is a Source Data Schedule, any items defined as being entered directly into the CRF cannot be verified. The amount of source data verification will be informed by the risk rating allocated at Sponsor review. The following parameters will be reviewed:

* Subject ID numbers and initials
* Date of written informed consent
* Subject past medical history and demographic data
* Visit dates
* Key efficacy variables
* Adverse events
* Laboratory results
* Other safety and efficacy variables
* Concomitant medications(where applicable)

The monitor will discuss any discrepancies, noted in the source documentation versus study data, with the site staff and request that the data be corrected by an authorised person. If data cannot be altered during the monitoring visit, the monitor must ensure that the changes have been made by the next visit to site.

**Regulatory Compliance**

At each visit the monitor will ensure that any amendments have been correctly notified to the appropriate statutory and regulatory bodies and that all necessary approvals are in place.

The monitor will also ensure that all annual reports have been completed and submitted in a timely manner to the correct regulatory bodies.

**CIinical Investigator Plan (CIP)/Protocol Deviations**

Any deviations from planned assessments or procedures, as defined in the study protocol, should be documented. CIP/Protocol deviations must be documented in the monitoring visits report, in the CRF (if there is a comments field available) and as a file note as appropriate. This documentation must be filed in the Trial Master File/Investigator Site File.

CIP/Protocol breaches/deviations should be logged in a cumulative tracking sheet on an ongoing basis utilising the Protocol/CIP Deviation Log. This will aid decision making at the time of data analysis and interpretation, and can help to spot protocol deviation trends. Protocol deviations that recur across different subjects may highlight a particular section of the protocol/a procedure that is causing the site difficulty.

Protocol deviations should be discussed with the site at the earliest opportunity, to ensure that re-occurrences of the same issue are kept to a minimum, and to discuss whether particular issues highlight a need to revise the study protocol by way of a substantial or non-substantial amendment. Serious breaches of protocol will be reported as per SOP S 1016-UHL.

**Safety Monitoring**

*Processing and reporting of Serious Adverse Events, Serious Device Effects and Unexpected Serious Device Effects and device deficiencies will be undertaken as per SOP S 1010 or S 1041 as appropriate.-UHL.*

As part of Source Data Verification, subject notes and the CRF should be reviewed for evidence of any adverse events/adverse effects and device deficiencies. Any adverse events or deficiencies noted in the CRF must be recorded in the source notes and vice versa.

The research team must notify the CI / PI and the Sponsor within 24 hours of becoming aware of any reported device deficiencies which may have led to a Serious Adverse Event (SAE)/ Serious Adverse Device Effect (SADE) or Unexpected Serious Adverse Effect (USADE).

The monitor must check that the appropriate form has been completed and signed by the CI/PI, submitted, and acknowledgement received and filed in the Trial Master File

**Randomisation/Unblinding Processes (where applicable)**

The monitor will ensure that there is adequate documentation of the randomisation and unblinding processes, are recorded within the site file.

The monitor will ensure that code break envelopes are available at all times. If there has been a need to unblind a particular subject, the monitor should ensure that the reason is document in the subjects’ notes, in the CRF and in the monitoring visit report.

The Sponsor must be informed of any unblinding within 1 day of becoming aware of the unblinding.

Where a blinded evaluator is utilised ensure that processes to ensure that unblinding by either the investigator or subject are in place.

**Out of Range Laboratory Results**

Lab results should be reviewed by the Principal Investigator/or delegate for clinical significance or as otherwise agreed and documented by the Sponsor.

**Investigational Medical Device**

The monitor will review/ perform device/ component accountability as part of routine monitoring, this will encompass:

Labelling of Investigational Medical Device

Storage of Investigational Medical Device (including temperature records where applicable)

Sterilisation processes and records as appropriate

Relevant Training records with regards to user and /or subject

Calibration and maintenance records

Dispensing/return/destruction records are accurate and verifiable.

**Trial Master File/Investigator Site File (TMF/ISF)**

Sections of the TMF/ISF will be reviewed as required at each visit. Any items missing from the file should be documented in the monitoring visit report. The monitor should check that missing items have been filed at the next visit to site.

**Study Personnel**

Details of all new study personnel will be reviewed at each visit. The delegation log and evidence of relevant regulatory, Sponsor and Study/device specific training will be reviewed for new entries at each visit.

**Sample/Specimen Processes and storage (where applicable)**

Laboratory process and storage systems/ temperature monitoring/emergency processes will be reviewed as appropriate.

The monitor will ensure that shipment requirements and processes have been adhered to and documented evidence is available.

**External Vendors**

External vendors will be visited either by the Monitor or external auditor as appropriate.

**Data Management Plan/Data collection /Storage/IT security/Statistical Analysis Plan**

Ensure that an effective data management plan is in place (where appropriate). Ensure secure storage of all data whether electronic/paper. Electronic records must have restricted access and be password protected. Where data is being accessed from an external source, the data sharing agreement will be examined to ensure compliance. Ensure that a Statistical Analysis plan is in place prior to the closure of the study.

**Finance/Contracts**

Ensure that there are processes and evidence in place for all payments for ancillary services and Patient expenses.

**Communication**

Email communication between the site and the monitor should be filed in the Trial Master File/Investigator Site File. Telephone contacts should be documented utilising the contact monitoring Log or by way of an email.

**Monitoring Reports**

Monitoring visit reports will be produced by the monitor, and sent to the CI/PI and where relevant, key study personnel for their review, along with a summary of the findings. This report will be forwarded to the Investigator within 21 calendar days of the monitoring visit.

In line with the Sponsor requirements, the site must respond to the findings raised within 28 calendar days. The response will be in the format of the monitoring visit response document.

A signed copy of the report and responses must be kept in the Sponsor file and also in the Trial Master File/Investigator Site File for reference.

**Escalation of Issues**

Issues should be discussed with the CI/PI and study team during routine monitoring visits, and the resolution followed up at the next visit to site.

Issues of non-compliance should be discussed with the CI/PI and the actions/resolutions documented. Should resolution not be achieved then the non-compliance will be escalated as per SOP S 1016-UHL.

Monitoring Plan Author (Print Name) ………………………………………………..

Role……………………………………………………………………………..

Version…………………………………………………………………………

Authorised by (Print) ……………………………………………………………

Role ……………………………………………………

Date Implemented ……………………………………………………………………..

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| **REVIEW RECORD** |
| **Date** | **Issue Number** | **Reviewed By** | **Description Of Changes (If Any)** |
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