Site Initiation Checklist Guidance

for CE Marked or Proof of Concept Medical Device Studies

This document was designed for use at onsite or remote application for either single site or multisite studies not involving Investigational Medicinal Products as per Sponsor Site Initiation Standard Operating Procedure S-1011 UHL. The form is in the format of a checklist to ensure that all aspects of trial set up and research team requirements have been discussed/completed. Selected aspects, where indicated i.e. randomisation/blinding/labs may not be applicable for all studies and should be marked as not applicable.

Addition of other study specific aspects can be added to the checklist by the investigator if applicable.

The aim is to provide the CI/PI with relevant documentation to ensure that all aspects of site set up have been completed at either single or multiple sites prior to commencement of recruitment as per the relevant Sponsor Standard Operating Procedures.

The report when complete, following resolution of any outstanding issues, should be signed by the person completing the checklist and approved by the CI/PI and where required the Sponsor monitoring lead.

Completion of form

- Complete full study details and document the method of site initiation. Please ensure the Sponsor reference number is that supplied by the Sponsor and not the REC or Protocol number.
- List personnel in attendance at the initiation meeting. This should always include the Principal Investigator/ delegate and relevant members of the research team.
- Provide overview of the study and adherence to the protocol
- Review the CI/PI and Sponsor responsibilities and obligations. Review Sponsor reporting requirements.
- Confirmation that TMF/ISF has been created and is complete prior to study commencement.
- Review all patient facing documents to be utilised within the study and record the version and date of all approved documents that will be in use, at the commencement of the study. This is particularly important with multisite studies, where site commencement may occur at different time points in the study and potentially amendments may have been made to original versions of patient documentation.
- Confirmation that the delegation of authority log has been completed for all members of the research team and that the relevant evidence of experience signed and dated CVs, GCP

certificates, consent certificates(if applicable) and study specific training are on file. All members of the research team must have received training on the protocol.

- Review of the recruitment method and time that participants will have to consider taking part in the study/ completion of screening and enrolment logs. Recording of withdrawal/completion of study.
- Review eligibility criteria and informed consent/reconsent process.
- Ensure all members of staff are aware of the randomisation, and where applicable, blinding processes and requirements. Where appropriate unblinding/code break processes.
- Ensure all members of the team are aware of the requirements for utilisation of Device/softwarespecifically utilised for study purposes and the calibration/maintenance requirements.
- Review of safety reporting and Sponsor notification requirements. Detail any exemptions as recorded on REC application.
- Review data collection process and response requirements to queries and corrections.
- Any deviations from the protocol should be recorded utilising the protocol deviation log.
- Review the process for collection/preparation and analysis of study samples. Samples result verification, signed and dated and marked CS or NCS if out of normal reference ranges.
- Ensure that all study related communication i.e. emails, Investigator/steering committee meeting agendas and minutes are on file.
- Discuss study audit/monitoring requirements. Sponsor response requirements.
- Ensure all members of the study team whether single or multicentre are aware of and adhere to the Sponsor standard operating procedures. Ensure that all team members are aware of where to access the most current versions of standard operating procedures and associated documents.
- Ensure relevant arrangements are in place for the archiving of the study as per Sponsor SOP S-1029 UHL.

Please be aware that Sponsor documentations should be utilised for all centres, unless agreed otherwise with the Sponsor i.e. Delegation of authority log, screening/enrolment logs, protocol deviation log, SAE reporting forms.

If all aspects of study set up have not been completed at initiation visit then an outstanding issues report should be sent to the site for completion and Principal Investigator signature/date. A review and confirmation that all outstanding issues have been resolved should be obtained before site recruitment is commenced.

Sponsor Green light

For individual studies this will be in the format of the R&I approval/authorisation. For multicentre studies, the Sponsor will require confirmation that site initiation has taken place and all outstanding findings addressed prior to Sponsor green light being given for recruitment to start.