UNIVERSITY OF LEICESTER

Site Initiation Checklist Guidance for Non-CTIMP Studies

The Site Initiation Checklist has been designed for use by the Sponsor and/or research teams for either onsite or remote initiation visits for single site or multisite studies not involving Investigational Medicinal Products. The checklist should be used to ensure that all aspects of study and site set-up and research team requirements have been discussed/completed. Some sections, where indicated i.e. randomisation/blinding/labs may not be applicable for all studies and should be marked as such.

Additional study-specific sections can be added to the checklist if required.

When complete, following the resolution of any outstanding issues, the document should be signed by the relevant individuals as per the review and sign-off section.

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 or their delegate and relevant members of the research team.
- Provide an overview of the study and relevant information about 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 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 and re-consent process.
- Ensure all members of staff are aware of the randomisation process, and where applicable, the blinding processes and requirements. Where appropriate unblinding/code break processes.
- 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 requirements for utilisation of equipment specifically utilised for study purposes and the calibration/maintenance requirements.
- 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 the 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 Sponsor Green Light.

Sponsor Green light

For each individual site Sponsor Green Light will be issued once all applicable approvals and contracts are in place, and where all outstanding actions identified at a Site Initiation Visit have been addressed