



**University of Leicester Research Governance Office
Standard Operating Procedures**

SOP S-1011 UoL

Site Initiation for Research Sponsored by University of Leicester

Version 7.0, March 2024

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Effective Date: April 2024

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used. For active studies there is no requirement to update appendices to the latest version.

1.0 Introduction and Scope

A site initiation visit (SIV) must be performed where the Sponsor deems it necessary (as determined by the Sponsor Risk Assessment Process SOP S-1003), and prior to site Sponsor Green Light being issued. A proportionate approach to the requirement of an SIV will be applied. For CTIMP, Medical Device and high-risk studies (whether interventional or non-interventional), the SIV will be conducted by, or in collaboration with, the Sponsor (or their delegate as per the relevant contract/agreement). For lower risk non-CTIMP studies only, the Sponsor formally delegates the responsibility of conducting SIVs to the study team and it is recommended that the lead researcher(s)/site conduct the SIV.

This SOP provides information relating to the planning, undertaking of, and the events following the SIV.

2.0 Purpose of an SIV

The purpose of an SIV is to ensure that;

- All required approvals/authorisations and regulatory documentation are in place
- The protocol and relevant SOPs have been discussed with the Principal Investigator (PI) and research staff to ensure compliance with all statutory and applicable regulatory legislation
- Sites have the capacity to run the study
- Each site has the essential records required to conduct the study
- Each site is aware of its roles and responsibilities
- Each site is aware of the Sponsor's requirements and the SOPs to be followed
- The PI is aware of the requirement for all delegated duties to be formally recorded and signed off on the Delegation of Authority and Signature Log prior to any research related activities taking place
- Contact details are up-to-date and clear lines of contact are established between the Sponsor, Chief Investigator (CI), PI, the research team and support departments
- If applicable;
 - Site pharmacy arrangements are in place to allow Investigational Medicinal Product (IMP) ordering, receipt, dispensing and accountability
 - Site arrangements are in place with the supplier of medical devices to allow ordering, receipt, dispensing and accountability of the devices
 - Site arrangements are in place with the laboratory to allow for analysis, storage, shipment of samples

3.0 Overview of the SIV Process

SIVs are a type of monitoring activity and, where the need is identified on the risk assessment, are required prior to the commencement of a research study. The nature of the research will influence the complexity of the SIV and the materials used to deliver training and information to attendees.

3.1 Study documentation and supplies

The Sponsor recommends the use of an agenda as well as slides/presentations, these can act as evidence of what was covered as part of the visit and can be a useful training

resource for staff to refer back to. This can be particularly useful when the background and rationale is complex and/or the day-to-day management of the research requires a lot of resource and/or planning.

For CTIMP, Medical Device and complex interventional research, the CI is expected to provide an overview of the research at the SIV. Where a CI cannot attend a meeting, an appropriate delegate must be available to cascade the information. It is the responsibility of the CI to ensure that anyone involved in cascading information has appropriate understanding of the material and is able to deliver it accurately. A pragmatic approach in accordance with the risk and complexity of the research should be taken when determining the most appropriate individual(s) to lead on SIV training and the Sponsor should be consulted before SIVs take place.

Where the Sponsor are not involved in the delivery of the SIV, it is important that an overview of critical Sponsor processes and SOPs are included in any presentations/discussions. This includes, but is not limited to, the process for serious adverse events reporting, essential records maintenance, Sponsor Green Light (for the site and for amendments), and monitoring (where appropriate). This is particularly important if the SIV presentation is being used in lieu of obtaining individual Training and SOP Read Logs as the attendance sheet will be used as evidence of training on Sponsor processes in the event of monitoring, auditing and/or inspection.

The below is a general overview of the SIV process and not all steps will be applicable or necessary (e.g., if you are conducting an SIV for your own study and with your own team). What is important is that there is an audit trail of the SIV and any outstanding actions being resolved prior to Sponsor Green Light being issued. Whoever leads on the SIV is responsible for ensuring that the following steps are completed, where applicable.

3.2 Before the initiation visit

- The SIV should be scheduled for a date and time which is most appropriate to maximise the number of key individuals needing to attend. SIVs can take place on-site or remotely, and where appropriate, more than one site can attend the same SIV as long as the relevant site-specific information is captured in a site-specific report.
- The Sponsor (or their delegate) must outline the requirements for the SIV in terms of attendance for the PI and research team, time and resources required and any preparatory work.
- The relevant SIV Checklist should be prepared ahead of the SIV
 - CTIMPs/Medical Device Trials = Appendix 1
 - Pharmacy = Appendix 2
 - Non-CTIMPs = Appendix 7

3.2.1 Attendees and Format

All staff who will be involved in the day-to-day operation of the study should be invited to attend the SIV. This may include the;

- CI
- PI
- Trial/Project Management staff

- Research Nurses
- Support staff e.g.
 - administrative staff and those from radiology, pharmacy, pathology etc as appropriate for the study.

A record of attendees should be created and stored in the Trial Master File/Investigator Site File once the meeting is complete. It is recognised that more than one visit may be necessary to include support departments such as pharmacy. Where the CI or PI is not available, an additional meeting to discuss the SIV following that conducted with the research team may be necessary. This should be appropriately documented.

3.3 During the visit

- The relevant SIV Checklist (as detailed above) should be completed in full and outstanding actions report must be created prior to sending the report to the site(s) for action.
- The SIV Attendance Log should be completed to document who was present.
- A review of the TMF/ISF should be undertaken as appropriate to ensure it contains all the relevant essential records.
- Time must be allowed for the research team to raise any queries, if these cannot be resolved during the meeting they must be followed up after the visit and resolved ahead of Sponsor Green Light.
- The Delegation of Authority and Signature Log should be filled in and signed by all staff, and checked for accuracy ahead of Sponsor Green Light being issued. For remote SIVs, a copy should be scanned and provided for checking.

3.4 Following the visit

- The PI (or their delegate) should review and resolve outstanding actions prior to returning the report to the Sponsor (or their delegate) for review and sign off. Requests for clarification and/or further revisions must be made by email.
- Once all outstanding actions have been resolved, the report will be signed off and formally closed by the Sponsor (or their delegate).

NB. For CTIMP, device and high-risk studies, where SIVs are not conducted by the Sponsor, a copy of the report(s) must be provided to the Sponsor for filing.

- Copies of completed SIV reports and relevant correspondence must be retained in the Trial Master File, Investigator Site File(s)/Pharmacy File(s) and by the Sponsor as appropriate.

3.5 Timelines to be observed

All reports must be returned to the Sponsor (or their delegate), and will be reviewed in accordance with stated timelines.

- SIV reports and confirmation of outstanding actions should be provided to sites within 21 calendar days of the SIV taking place
- The PI (or their delegate) should review the report and provide responses to any issues/outstanding actions within 28 calendar days of receiving the SIV report

Requests for additional time must be made and granted by email.

4.0 Guidance on using the SIV Checklist and Supplementary Documents

The SIV Checklists are split into sections that should be followed and used to facilitate discussions with the site research team. It is expected that the items/topics within each section are discussed where these are relevant to the research and/or the site. Where sections/items/topics are not applicable, they should be marked as such rather than being removed/deleted.

The SIV Checklist should also be used to verify that essential records have been checked and that relevant training has been provided on the day-to-day management of the research and its associated documentation. This includes but is not limited to: CVs, GCP and training certificates; approved patient-facing documentation; case report form (CRFs) and data entry; safety documentation (i.e., Investigator Brochure (IB) or Summary of Product Characteristics (SmPC)); pharmacy documentation; laboratory/sample management documentation etc.

It is important that the 'Comments' area documents site-specific information such as how a process may work at a site, who is responsible at the site for a specific task(s) and any other detail that may be referred back to at a later date (i.e., during monitoring, auditing and/or inspection).

Please contact rgosponsor@le.ac.uk ahead of SIVs for additional clarification on a section/item/topic.

The table below provides a guide on how, as the lead of the SIV, to use supplementary documents to train site research staff on the protocol, documents and procedures to be followed.

Supplementary Documents	How to use at an SIV
Training and SOP Read Log (SOP 1020 - Appendix 2)	Records evidence of training in critical Sponsor SOPs, GCP, the protocol etc.
SIV Attendance Log (Appendix 4)	Records who attended the SIV and evidence of training in critical Sponsor SOPs, the protocol etc.
Screening Log (Appendix 5)	Used to demonstrate to site research staff the ethically approved recruitment process and how to accurately record who is participating in the research
Enrolment Log (Appendix 6)	
Screening and Enrolment Log (Appendix 9)	
Delegation of Authority and Signature Log (S-1010 Appendix 2)	Records who is responsible for tasks at the site, as delegated and approved by the PI
Source Data Agreement (Appendix 4 to SOP S-1007)	Defines what will be considered as source data/documentation and where this is located

Trial Master File (TMF)/Investigator Site File (ISF) indexes (appendices to SOP-S-1015)	Verifies that all essential records are present and site research staff understand their responsibility for maintaining an 'inspection ready' file at all times
Safety Reporting Forms (relevant appendices SOP S-1009)	Verifies that the site have the correct reporting form and that site research staff understand the reporting procedure
Monitoring Plan (relevant appendices to SOP S-1007)	Defines the monitoring schedule and the expectations of monitoring visits


5.0 Non-Compliance

Site initiation is an important part of ensuring that all aspects of the research are clearly understood and appropriate personnel are fully apprised of their individual roles and responsibilities. It is important for the successful management of research that teams are trained and prepared prior to commencing. Failure to comply with this SOP may result in the Non-Compliance SOP-1016 being implemented.

6.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor or their delegate	Sponsor or their delegate	To ensure that the relevant site research staff are invited to attend the SIV and all preparatory work is completed ahead of the SIV.
Sponsor or their delegate	Sponsor or their delegate	Use the relevant SIV Checklist(s) and supplementary documents to: (1) discuss individual and collective responsibilities of site research staff in the delivery of the research, (2) ensure site research staff are appropriately trained and qualified to undertake their delegated duties, (3) verify essential documentation is in place, and (4) document outstanding actions.
Sponsor or their delegate	Sponsor or their delegate	Provide a detailed written report including a list of outstanding actions/issues to the site within 21 calendar days of the SIV.
Principal Investigator	Principal Investigator or their delegate	To review the SIV report and outstanding actions/issues, resolve the actions, and provide a response within 28 calendar days of receipt of the SIV report.
Sponsor or their delegate	Sponsor or their delegate	Review the site's response and ensure outstanding actions/issues are resolved prior to signing off and confirming the SIV report as closed. A copy of the report and related correspondence should be filed in the TMF/ISF/Sponsor files as appropriate.

7.0 Development and approval Record for this document

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Management and Operations Group (RSMOG)	Professor Nigel Brunskill 	25/03/2024

8.0 Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Oct 2013	2	Wendy Gamble	Version 1 amended following review of Sponsor Processes
April 2014	3	Wendy Gamble	Version 2 amended to add in section on non-compliance
June 2015	4	Wendy Gamble	SIV checklist updated and introduction of separate pharmacy SIV checklist.
March 2016	5	Diane Delahooke	Review and update of SOP & appendices. Non CTIMP SIV checklist introduced.
Nov 2016	6	Diane Delahooke	Review for consistency against UHL SOP. RSI added.
Sept 2021	6.1	Cat Taylor	Administrative changes and updates to the formatting and content of Appendices. Addition of Appendix 9.
March 2024	7.0	Cat Taylor	Administrative changes Clarification around when an SIV is required Major streamlining of wording to reduce repetition Major reformatting of the SOP to improve understanding Updates to the responsibilities table Removal of Appendix 3 SOP Read Log from this SOP, added as Appendix 2 to S 1020 Removal of Appendix 8 (which is now included within the checklist itself) Major changes and removal of outstanding actions report from Appendix 1, 2 and 7. Outstanding actions report has been added as a separate document (Appendix 10). Administrative changes to other appendices