1. Introduction

This Standard Operating Procedure (SOP) describes the procedures for initiation of:

- All Clinical Trials of Investigational Medicinal Product (CTIMP) /non CE Marked Medical Device research sponsored by the University Hospitals of Leicester NHS Trust (UHL) that are either single or multi-site investigator led studies

- Any other research activity that is considered to be of high risk as determined by the Sponsor Risk Assessment Process as detailed in SOP S-1003 UHL

Where an initiation visit is required, it must be conducted prior to the Sponsor Green Light being confirmed.

The purpose of this SOP is to ensure that initiation confirms the existence of all required study authorisations and documentation (as appropriate to the study), and that the protocol and relevant SOPs have been discussed with the Investigator and study staff to ensure compliance with all statutory and applicable regulatory legislation. Initiation is integral to quality control and is designed to provide assurance of compliance to Sponsor requirements.

2. Scope

This SOP applies to all research using CTIMPs, non-CE Marked Devices & any other research activity that is considered to be of high risk as determined by the Sponsor Risk Assessment Process.

3. Procedure

The Site Initiation Visit (SIV) should be undertaken prior to the Sponsor Green Light being given. Where appropriate in the case of multi-centre studies, it may be necessary / possible to conduct site initiation remotely.

3.1 Preparation for the Initiation Visit

3.1.1 All Studies

The Sponsor must ensure that all approvals and regulatory documentation are in place/are in progress in order to open the study at site. This includes site confirmation of Capacity and Capability, and agreement that staff capacity is available to run the study at site.

Attendance is mandatory for the Chief Investigator at the Host / Lead Site and Principal Investigator(s) at all other Sites. All key research staff working on the study must also be in attendance along with staff from departments that may be involved i.e. Pharmacy. Other team members are actively encouraged to participate in the initiation visit, and make themselves available where appropriate.

It is recognised that more than one visit may be necessary to include staff/departments. Where the CI is not available, a 1-2-1 meeting to discuss the SIV should follow that conducted with the study teams.

The study monitor or designee will outline the requirements for the SIV in terms of attendance for the study team and time / resources. A site initiation Check List will be provided prior to initiation detailing the schedule of the visit and items to be reviewed / discussed (Appendix 1a CTIMP / 1b Non CE Marked Device). This will also include the Pharmacy Check List (Appendix 2) where Pharmacy is involved.

3.1.2 Non CTIMP/ CE Marked/ Proof of Concept (PoC) Medical Device Studies

Where an initiation visit is arranged for a study that is not involving a CTIMP or a CE marked/ PoC Device, the criteria for the visit may change. The study monitor or Sponsor designee will outline the requirements for the SIV in terms of attendance for the study team and time / resources. A Site Initiation Check List (Appendix 6 or 6a) and associated Site Initiation Checklist Guidance (Appendix 7 or 7a) will be provided prior to initiation detailing the schedule of the visit and items to be reviewed/ discussed.

3.1.3 Multi-Centre Studies

For multicentre studies, where indicated by the Sponsor, it may be required that either an onsite or remote initiation visit be undertaken The arrangements for initiation will be discussed as part of the Sponsor review process and communicated as required to the sites.

3.2 During a Site Initiation Visit

The Sponsor / delegate will follow the appropriate Site Initiation Check List, confirming any outstanding actions prior to Sponsor Green Light. For medical device studies this will include the requirement for device accountability (appendix 8)

3.3 Following the Initiation Visit

The Monitor will submit a written report within 10 calendar days of the visit, recording any items outstanding or where clarification is required on the Site Initiation/Pharmacy Outstanding Issues Sign Off Report. (See Appendix 1a/1b/ Appendix 2).

The PI will be asked to review the report and supply responses with regards to any issues that were highlighted. The report will be signed by the Monitor and the Investigator and the original will then be filed in the Trial Master File/ Investigator Site File with a copy retained for the Sponsor file.

The Sponsor green light will not be given until the Sponsor is satisfied that all issues raised at the initiation visit have been resolved.

The Monitor will establish the next monitoring visit date and requirements with the PI in line with the study specific monitoring plan. Monitoring is undertaken as per SOP S-1007 UHL Site management (Monitoring).

3.4 Multi-Site Initiation Visits

Multi-centre site initiation may be delegated to a Clinical Trials Unit or agent of the Sponsor, the Chief Investigator or an appropriate member of the Research Team. A discussion about the most appropriate initiation of sites i.e. remote or site visit initiation will take place as part of the risk assessment process.

In all cases, the relevant site initiation forms must be used and documented in the Investigator Site file / Trial Master File and Sponsor files.

4. Non-Compliance

Site initiation is an important part of the process to ensure that all aspects of the study are clearly understood and appropriate personnel are fully apprised of their individual roles and responsibilities. Failure to comply with this SOP will result in the Non-Compliance SOP S-1016 UHL being implemented at a critical finding. This may mean that the study is suspended before it's even started.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1.	Sponsor or their delegate	Sponsor or their delegate	To ensure that all approvals and regulatory documents necessary for the study to commence at site are in place /in progress prior to the initiation visit occurring.
2.	Sponsor or their delegate & Chief Investigator	Sponsor or their delegate Chief Investigator	To ensure that the CI/PI and all key research staff involved in the study attend the initiation visit.
3.	Sponsor or their delegate	Sponsor or their delegate	To ensure all areas of the study as detailed in the Study Initiation Visit Check List are discussed with the CI/PI and research team so that everyone is aware of their individual and collective responsibilities within the study.
4.	Sponsor or their delegate	Sponsor or their delegate	To ensure that all staff involved in the study have the necessary training/qualifications.
5.	Sponsor or their delegate	Sponsor or their delegate	Submit a detailed written report within 10 calendar days of the visit recording outstanding items and any clarification required.
6.	Sponsor or their delegate	Sponsor or their delegate	Review the Investigator's responses to the written report and ensure the report is signed by the Monitor and Investigator and that the original is filed in the Study Master File/Investigator Site file with a copy in the Sponsor files
7.	Sponsor or their delegate	Sponsor or their delegate	Ensure all issues raised at the initiation visit have been resolved prior to study commencement at site.

6. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or Procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

7. Supporting Documents and Key References

SOP S-1011 Appendix 1a, 2, 3, 4, 5, 6, 6a, 7, 7a & 8

SOP S-1007

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8. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, ICH GCP, TMF, Site Initiation, Monitoring, TMF

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This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney / Julie James	**Job Title:** Head of Research Operations / Clinical Trials Monitor & Trainer
Reviewed by:	R&I Governance Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved:** 16/2/21

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
April 2014	2	Carolyn Maloney	Revisions to bring into line with UoL SOP
August 2014	3	Anne Moore	To add Screening Logs & Enrolment logs as appendices
April 2015	4	Carolyn Maloney	Update to Logo and corporate identify
Sept 2015	5	Carolyn Maloney	Updated processes & addition of source data schedule
April 2016	6	CM/LW/JJ	Review & update of SOP & appendices
Nov 2016	7	Carolyn Maloney	Insertion of RSI check
Dec 2016	8	Carolyn Maloney	To allow use of team specific record keeping of 'Read SOPs'.
Feb 2017	9	Carolyn Maloney	Update to Logo
January, October 2018	10	CM CCL, JJ, AK, CT (UoL)	General review. Update to all appendices Addition of appendix 1b, 6a, 7a, and 8 to cover medical devices Update to R&I logo throughout General review; updated to incorporate medical devices
February 2021	11	JJ LW AM	General review and update, Reformatting to new template

DISTRIBUTION RECORD:			
Date	**Name**	**Dept.**	**Received**