UNIVERSITY OF LINCOLN

CLINICAL GOVERNANCE - STANDARD OPERATING PROCEDURE

TRIAL INITIATION

CG-QMS SOP CG08

Version Final 1.0 Date 01 May 2021

Effective Date: 01 August 2021

Next review: 2 years

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Approved by: Signature:	UREC See original

Version History	**Reason for change**

NOTE: All SOPs are subject to regular review. Please ensure that the version of this SOP is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

1. PURPOSE

To outline the process for set-up and initiation of clinical trials and studies sponsored by the University of Lincoln or supported by the Lincoln Clinical Trials Unit (LinCTU).

2. SCOPE

This SOP applies to all UoL sponsored clinical research or where LinCTU are providing support in trial initiation.

3. BACKGROUND

This SOP describes procedures that should be undertaken prior to beginning the recruitment of participants into a clinical study/trial. These procedures should be completed prior to, during and following the first study site initiation visit (in a single site study) and for additional new site initiation visits in multi-centre studies and trials.

The Chief Investigator (CI) has overall responsibility for Trial Initiation and for delegating the responsibility of site investigator/principal investigator (PI) to appropriately qualified individuals at trial sites (in the case of multi-centre studies and trials). However, training and initiation may be delegated to a person with the relevant knowledge, skills and experience such as a trial manager/coordinator/monitor or research team member.

Initiation of a trial/study site ensures that all required trial authorisations and documentation are in place, and that the protocol and trial procedures are reviewed with the site Investigator and the Investigator's trial staff in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s).

Trial Initiation is integral to the Quality Assurance of a clinical trial and is designed to guarantee the quality of the trial according to Sponsor / LinCTU requirements and to enhance consistency across sites in terms of the methodology set out in the protocol. It is essential to ensure that all necessary documents and training are in place at each study/trial site to facilitate appropriate conduct and ongoing documentation of the trial.

Proper processed of trial Initiation ensure that the investigators and study staff understand the study protocol, that all the operational steps are in place, and that everyone is clear and well trained in their specific roles and responsibilities. Trial Initiation is conducted prior to the first patient being recruited into a study.

Trial Initiation is usually conducted by the trial coordinator or a monitor on behalf of the sponsor / LinCTU. Essentially their aim will be to work with the sites to ensure that the site's planned operational procedures fit with the requirements of the protocol, will ensure accurate data, and safe and ethical conduct of the trial.

All trials that are in a position to obtain/receive IMP will be initiated. Sites that will not be involved in handling or administering IMP will be assessed on a case-by-case basis as decided by the Chief Investigator or delegated nominee.

Note: Trial initiation is held once sites have had their regulatory and ethics approval in place and after all the essential documents have been retrieved for the site and sponsor files.

4. CROSS REFERENCES

4.1 CG-QMS RF CG01-RF02 Internal / External Training Log

4.2 CG-QMS RF CG08-RF01 Study Delegation Log

4.3 CG-QMS RF CG08-RF02 Site Initiation Checklist

4.4 CG-QMS SOP CG07 Trial Master/Site File(s)

4.5 CG-QMS SOP CG11 Serious Breach

4.6 CG-QMS SOP CG13 Monitoring and Audit

4.7 CG-QMS WI CG08-WI01 Site Initiation

4.8 CG08-RF03 Site Initiation Outstanding Issues Report

5. PROCEDURE

For **Single Site Trials:**

The Chief Investigator or delegated nominee shall:

5.1 Ensure that the Trial Master File (TMF) is set up in accordance with SOP CG07 Trial Master/Site File(s)

5.2 Obtain confirmation of NHS Trust R&D/R&I Capacity and Capability assessment in accordance with the conditions of the HRA approval letter. A copy of this should be retained in the Trial/Site Master File (TMF).

Note: where a participating site is not an NHS organisation, permission must be sought from the host organisation.

5.3 Ensure that trial related duties* are delegated as appropriate to suitably qualified and experienced staff. Delegation is to be authorised by the CI or PI for multi-site studies and documented on CG08-RF01 Study Delegation Log. A copy should be retained in the TMF.

5.4 Ensure that any trial staff conduct the clinical trial in compliance with the final protocol and subsequent protocol amendments if any, as well as Good Clinical Practice (GCP), applicable safety reporting and regulatory requirements and SOPs.

5.5 Ensure that trial/study staff are appropriately qualified/skilled and that staff receive any training required (where this is trial/study specific it should be documented in a training log within the TMF).

5.6 Ensure that monitoring procedures are in place. Either in accordance with SOP CG13Monitoring and Audit or according to the protocol.

5.7 Ensure that where the trial involves an investigational medicinal product (IMP) or device that storage, distribution and return is managed according to the trial protocol / investigator brochure and that records are kept for the purposes of audit. Where medicines are involved, these will require appropriate management (re dispensing, packaging and labelling) with assistance from a registered pharmacy.

For **Multi-site trials:**

5.8 The Chief Investigator or delegated nominee shall appoint a local Principal Investigator (PI)/site investigator at each participating site.

5.9 The CI will support the PI/site investigator in obtaining local NHS Trust R&D/R&I Capacity and Capability assessment in accordance with the conditions of the HRA approval letter.

The Principal Investigator/site investigator shall:

5.10 Ensure that the Investigator Site File (ISF) is set up in accordance with SOP CG07 Trial Master/Site File(s)

5.11 Obtain local NHS Trust R&D/R&I Capacity and Capability assessment in accordance with the conditions of the HRA approval letter. Retaining a copy in the Investigator Site File (ISF).

5.12 Ensure appropriate staff, premises and facilitators are available to support the delivery of the trial and any trial related activities.

5.13 Ensure that local trial/study staff are appropriately qualified/skilled and attend the site initiation visit and/or any training provided by the CI and trial management/coordinating team (this should be documented in a training log within the TMF).

5.14 Ensure that trial related duties* are delegated as appropriate to suitably qualified and experienced staff and documented on CG08-RF01 Study Delegation Log. A copy should be retained in the ISF.

5.15 Ensure that local monitoring procedures are in place. Either in accordance with CG13 Monitoring and Audit or according to the protocol.

5.16 Ensure that where the trial involves an IMP or device that local storage, distribution and return is managed according to the trial protocol / investigator brochure and that records are kept for the

purposes of audit. Where medicines are involved, these will require appropriate management (dispensing, packaging and labelling) with assistance from a registered pharmacy.

Trial Training & Site Initiation Visits

The Chief Investigator or Principal Investigator (for multi-site trials) or designated nominee shall:

4.9 Where applicable arrange Training / Site Initiation Visit (SIV) in accordance with WI CG08-WI01 Site Initiation and RF CG08-RF02 Site Initiation Checklist. Retaining a copy of the SIV checklist in the Trial Site File.

5.17 Arrange and/or deliver trial specific training for anyone involved with the conduct of the trial.

Note: Training *must* be given for all participating sites / staff involved in the running of the trial.

Records of training should be maintained using CG01-RF02 Internal / External Training Log. A copy should be retained in the TMF/ISF.

5.18 Ensure that all staff involved with the running and delivery of the trial are aware of, read and adhere to SOPs relevant to their role throughout the duration of the trial. All staff to complete and sign CG01-RF01 SOP Compliance Form. A copy should be retained in the TMF/ISF.

5.19 Follow-up issues, where identified, must be completed prior to trial recruitment.

5.20 A copy of the completed RF CG08-RF02 Site Initiation Checklist and RF CG08-RF03 Site Initiation Outstanding Issues Report, should be submitted to the sponsor (where UoL is the sponsor).

Sponsor Green Light

5.21 For CTIMP studies: Trial recruitment may not commence until all permissions, training and SIV visits have been completed. Sponsor Green Light will only be given when the sponsor is satisfied that outstanding issues raised during the SIV have been resolved. If there is evidence of systematic failure to comply with GCP, the Sponsor will be informed, and procedures outlined in SOP CG11 Serious Breach will be followed.

6. FLOW CHART

Not required.

*Trial related duties:

1. Overall responsibility for study at Site
2. Care and supervision of study participants/patients
3. Obtain ethics and R&D approvals inc. amendments
4. Ensuring all staff delegated to work on the study are adequately informed and trained in study procedures
5. Delegation and authorisation of study related duties
6. Act as document controller for study related documents
7. Set up and maintenance of Site File
8. Implementation of subject recruitment strategy and obtaining informed consent
9. Screening of potential participants
10. Obtaining consent and signing of consent forms
11. Randomisation (allocation of study intervention)
12. Completion and return of CRFs, including electronic entries
13. Authorisation of CRFs
14. Respond to data queries
15. Documentation of adverse events and timely SAE reporting
16. Adhere to CI recommendations in response to SAEs
17. Collection of study related biological samples
18. Initiation (training) of new study personnel
19. Prepare and be available for audit and inspections
20. Archiving of study data
21. Responsibility for data monitoring

    Add additional as required