



**UNIVERSITY OF LEICESTER, UNIVERSITY OF LOUGHBOROUGH
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester (UoL) Research Governance Office
SOP S-1010 UoL**

**Chief Investigator Responsibilities for Research Sponsored by
University of Leicester**

Version 6, March 2018

OFFICE BASE

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1 Introduction

This Standard Operating Procedure (SOP) describes the role and responsibilities of the Chief Investigator for research sponsored by the UoL.

The outcome is that the Chief Investigator (CI) is aware of and has agreed to all roles and responsibilities as delegated to them by the Sponsor prior to the commencement of the research.

A senior individual must be designated as the CI for any research undertaken in or through the NHS or social services or using participants' organs, tissue or data. The CI is the person designated to take overall responsibility within the team of researchers for the design, conduct and reporting of the study.

The CI must ensure that the study is planned, set-up, conducted, documented and reported according to the protocol, relevant Standard Operating Procedures (SOPs), International Conference on Harmonisation Good Clinical Practice (ICH-GCP) and appropriate regulatory requirements.

In the case of a single site study, a CI may also be the Principal Investigator (PI). In these cases, the roles & responsibilities of the CI will over ride those of a PI.

2 Scope

This SOP applies to ALL Chief Investigators of studies sponsored by the UoL.

3 Procedure

The CI must be an individual, with appropriate experience, expertise and training to undertake the design, conduct and analyses of the study to the standards set out in relevant legislation. They must also lead and manage others who have been delegated responsibilities in the research.

The CI has overall responsibility for the conduct of the research and is accountable to their employer, the Sponsor, if different, and the host organisation where the research takes place. If the research is taking place at more than one site, the Chief Investigator takes on personal responsibility for the design, management and reporting of the study, and coordinating the personnel at the other sites.

The CI is responsible for ensuring that:

- The research team gives priority at all times to the dignity, rights, safety and well-being of the participants.
- The research team understand the legal and ethical requirements in research, and are familiar with the appropriate standard operating procedures and policies relating to research.

- The study complies with all legal and ethical requirements.
- The research is conducted to the required standards and follows relevant guidelines and legislation within the UK.
- The Trial Master File is maintained and kept inspection ready at all times.
- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge their role in the study, and their qualifications are documented and retained in the Investigator Site File.
- All researchers involved in a Clinical Trial of Investigational Medicinal Products (CTIMP) are aware of their legal duties.
- Students and new researchers have adequate supervision, support and training.
- A suitable Sponsor is secured and agreements are in place detailing the responsibilities of all parties involved in the research.
- Trust (R&D / R&I) authorisation is obtained from each care organisation and subsequent Sponsor Green Light received prior to commencing the study at each care centre.
- The protocol is submitted for Sponsor review and agreement prior to submitting for ethics/ HRA review.
- The study does not start without a favourable opinion from a Research Ethics Committee, HRA approval, Trust (R&D / R&I) confirmation of capacity and capability and where relevant competent authority (MHRA) approval and Sponsor Green Light approval.
- The research team acts on any conditions attached to the ethics opinion.
- Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, the HRA, the Trust R&D / R&I Office and by the Sponsor.
- Substantive changes to the protocol are submitted for Sponsor approval prior to ethical, regulatory and Trust authorization before implementation, with the exception of urgent safety measures.
- Each member of the research team, who has direct involvement with participants and/or identifiable data, has an appropriate substantive or honorary contract with NHS Trust or an honorary research contract or relevant letter of access via the research passport scheme.
- When a study involves participants under the care of another clinician, the CI must ensure that the clinician responsible for providing care is informed of a subject's participation in research.
- When the research involves a service user, or carer or a child looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information.
- Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate.
- For clinical trials involving medicines, the research follows all conditions imposed by the licensing authority. The list of responsibilities should be documented in the Sponsorship Agreement.
- Report Serious Adverse Events to the Sponsor, R&D / R&I, Research Ethics Committee & the Competent Authority as required
- In accordance with relevant legislations, procedures are in place to ensure collection of high quality, accurate data and to maintain the integrity and confidentiality of data during processing and storage.
- Arrangements are in place for the management of any intellectual property arising from the research.
- The CI should submit annual written summaries of the study status to the Sponsor, Ethics Committee, HRA and the Competent Authority as relevant and provide a summary outcome at the end of the study. This includes annual / end of study reports and safety reporting.

- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- There are appropriate arrangements to archive the data when the research has finished, and to ensure it is still accessible when required.
- All data and documentation relating to the trial are available at the request of the inspection and auditing authorities.
- Where the CI delegates responsibilities to members of the research team, this must be clearly documented in a delegation of authority and signature log (template available through the College website). The CI remains accountable for the actions of their research team.
- Complete and sign Roles and Responsibilities document prior to commencing any part of the research study.

4 Roles and Responsibilities Document

All points listed above are included within the Roles and Responsibilities document. The CI must initial on each page, and sign at the end of the Role & Responsibilities of the CI document during the Sponsor review process. Completion of this document forms part of the Sponsor approval confirmation ([Appendix 1](#)).

5 Responsibilities

	Responsibility Undertaken by	Activity
1	Sponsor Research Governance Office	Confirm roles and responsibilities document signed as part of the Sponsor Green light process
2	Sponsor Research Governance Office	Ensure Chief Investigator documents any delegated duties appropriately using the Delegation of Authority and signature log
3	Chief Investigator Chief Investigator	Ensures all roles and responsibilities are undertaken
4	Clinical Trials Monitor UoL Clinical Trials Monitor / Research Governance Team	Ensure delegated duties are appropriately carried out and delegated appropriately

5 Monitoring and Audit Criteria

Key Performance Indicators	Method of Assessment	Frequency	Lead
All research sponsored by UoL has appropriate Risk Assessment	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Research Governance Manager or their Delegate

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

6 Development and approval Record for this document

Author / Lead Officer:	Wendy Gamble
Job Title:	Research Governance Manager
Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	16/04/2018

7 Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Oct 3013	2	Wendy Gamble	Version 1 amended following review of Sponsor processes
April 2015	3	UoL RSMOG	SOP reviewed and revised to incorporate minor administrative changes to section 3 adding the 2 nd paragraph for clarification, also to the whole of section 3 to incorporate R&D / R&I, logos, dates / footer. Addition of Loughborough University to front page
May 2016	4	Diane Delahooke	Minor amendment to SOP and Appendix 1 to reflect HRA changes.
Nov 2016	5	Diane Delahooke	Minor change to remove Research Governance Framework and replace with relevant legislation. Minor changes to Appendix 1.
Mar 2018	6	Michelle Muessel	Reviewed with minor changes including address.

8 Distribution Record

Date	Name	Department	Received