1. Introduction

1.1 This Standard Operating Procedure (SOP) describes the role and responsibilities of the Chief Investigator (CI) for research sponsored by the University Hospitals of Leicester NHS Trust (UHL). 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. An individual designated as the CI for any research undertaken in or through the NHS or social services or using participants' organs, tissue or data must have appropriate experience and qualifications. The CI is the person designated to take overall responsibility within the team of researchers for the design, conduct and reporting of the study.

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

1.3 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 override those of a PI.

2. Scope

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

3. Procedure

3.1 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 role is complex and time consuming. UHL R&I will provide support as required, particularly to individuals undertaking the role for the first time.

3.2 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 CI takes on personal responsibility for the design, management and reporting of the study, and coordinating the personnel at the other sites.

3.3 The CI is responsible for ensuring that:

- The research team gives priority at all times to the dignity, rights, safety and wellbeing 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 CI must ensure that the Sponsor has access to the study record on relevant research databases i.e. EudraCT, Cliniclatrials.gov and ISRCTN database.
- The research is conducted to the standards and follows relevant frameworks as set out 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 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&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&I) authorisation 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, HRA, Trust R&I Office and by the Sponsor.
- Substantive changes to the protocol are submitted for Sponsor approval prior to ethical, regulatory and Trust authorisation 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.
- 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&I, Research Ethics Committee & the competent authority as required
- In accordance with relevant legislation, 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.
- 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 final report to the REC at the end of the study. This includes annual reports, end of study declarations, final study reports and safety reporting.
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- All appropriate databases i.e. EudraCT, ISRCTN, Clinicaltrials.gov must be updated following final report submission within the regulatory time frame.
- There are appropriate arrangements to archive the TMF/ISF and anonymised data when the research has finished, and to ensure it is still accessible when required. Upon receiving Sponsor confirmation that the archiving period has expired, the CI must ensure that appropriate destruction of TMF/ISF is undertaken in accordance with relevant UHL policies and procedures.
- All data and documentation relating to the study are available at the request of the inspection and auditing authorities. The Sponsor must be kept informed of the location of all archived data and the contact details of the person responsible.
- Where the CI delegates responsibilities to members of the research team, this must be clearly documented in a Delegation of Authority Log (template available

through the R&I Webpages on the Public 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.
- Arrangements are in place for the management of any intellectual property arising from the research. Contact the R&I office for further advice.

4. Roles and Responsibilities Document

4.1 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 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	R&I Deputy Chief Operating Officer or their delegate	Confirm roles and responsibilities document signed as part of the Sponsor Green light process
2	Sponsor	R&I Deputy Chief Operating Officer or their delegate	Ensure Chief Investigator documents any delegated duties appropriately using the Delegation of Authority log.
3	Chief Investigator	Chief Investigator	Ensures all roles and responsibilities are undertaken
4	QA & Compliance manager	UHL appointed personnel	Ensure delegated duties are appropriate and carried out as per regulatory requirements and Sponsor SOPs

6. Who Guideline Applies To

6.1 This guideline applies to all staff within UHL and external to UHL who are delivering research atLeicester's Hospitals.

7. Guideline Standards and Procedures

7.1 The SOP is detailed so the process can be clearly followed. No supporting flowchart is required /provided.

8. Education and Training

8.1 None.

9. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UHL has appropriate contracts in place.	Included in the monitoring / audit programme.	Random audits / monitored conducted on a risk-based assessment of research activity.	R&I Deputy Chief Operating Officer

10. Supporting Documents and Key References

10.1 SOP S-1010 Appendix 1

11. Key Words

11.1 Research, Innovation, Volunteers, Participants, CTIMPS, Trials, CI, Chief Investigator, PI,Principal Investigator

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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	**Job Title:** R&I Deputy Chief Operating Officer
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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
March 2015	3	R&I Management Meeting	Updates to Logo and personnel titles.
October 2015	4 & 5	Carolyn Maloney	Version of SOP to correlate with appendix
July 2016	7	CM, LW, JJ	Add in HRA and consistency check.
February 2017	9	Carolyn Maloney	Update to Logo
March, August 2018	10	CM, CCL	Revision to wording in some clauses. Nothing substantial. Updated R&I logo
April 2020	11 & 12	LW, JJ, AM	Updates to CI agreement to reflect UHL transparency responsibilities
Feb 2022	13	LW CS DW	Update

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