University of Leicester Research Governance Office

Standard Operating Procedures

SOP S-1010 UoL

Delegation of Responsibilities for Research Sponsored by University of Leicester

Version 7.0 January 2024

Office Base
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Effective date: January 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

This Standard Operating Procedure (SOP) describes the process for the formal delegation of sponsorship functions to the Chief Investigator (CI), Principal Investigator (PI) and members of a research team for research sponsored by the University of Leicester (UoL).

The outcome is that (1) the CI is aware of, and has agreed to undertake the roles and responsibilities relating to the conduct and management of a study or trial delegated to them by the Sponsor, (2) the PI and research team are aware of, and has agreed to undertake the roles and responsibilities relating to the conduct and management of a study or trial delegated to them by the CI and PI, respectively, (3) the UoL is assured that all relevant legislation is complied with and that their legal responsibilities are being met, and (4) the safety and well-being of study/trial participants, and the integrity of the data and results generated is ensured.

2.0 Definitions

The UK Policy Framework for Health and Social Care Research definitions of a CI, PI and Research Team will apply to all research sponsored by the UoL.

The CI is the overall lead researcher for a research project and is responsible for the overall conduct of that project. Outside the UK the term Coordinating Investigator or Investigator may be used in place of CI.

The management and conduct of a research project at an individual research site is the responsibility of the PI. If the research project is conducted by a team of investigators and/or staff at a research site, the PI is the leader responsible for that research team.

Additionally, for the purpose of Clinical Trials of Investigational Medicinal Products (CTIMPs) and/or Medical Device trials, the definition of 'investigator' as laid out in Regulation 2 of SI 2004/1031 (and any such amendments) and in accordance with the MHRA and HRA joint statement on who can act as the CI and/or PI, will apply. Specifically, the CI and PI(s) must be **authorised** health professionals, defined as a doctor, dentist, nurse or pharmacist.

In the case of a single site study/trial, the CI may also be the PI. Where this is the case, the roles and responsibilities of the CI will be in addition to those of the PI. Where a study/trial is conducted at multiple research sites, the CI is responsible for the coordination of all the PIs at the different sites and for coordinating the conduct of the study/trial at all sites.

A CI must have the appropriate expertise, experience and training to undertake the design, conduct and analysis of a study/trial to the standards set out in relevant legislation and as relevant to the nature of the study/trial design and its risks.

3.0 Procedure

In accordance with the legislation, whilst the Sponsor retains all responsibility for proportionate, effective arrangements being in place to set up, run and report a research project including the initiation, management and financing (or arranging the financing) of a project, the Sponsor can formally delegate one or more of its functions to another organisation(s) or individual(s).

The UoL formally delegates some of its sponsorship functions to the CI via the 'CI Roles and Responsibilities Agreement' document (Appendix 1) in accordance with the following process:

1. The Research Governance Office will issue the CI Roles and Responsibilities Agreement to the CI during the Sponsor review process (Refer to SOP S-1002)

2. The CI must read the CI Roles and Responsibilities Agreement and must agree to assume responsibility for those functions by way of signing and dating the document
3. A copy of the signed document must be held in the TMF and a copy retained by Sponsor
4. The CI Roles and Responsibilities Agreement must be in place prior to Sponsor Green Light being issued to enable the commencement of the study/trial.

To ensure effective conduct and management of a study/trial at a research site, site-level responsibilities are delegated to the PI via the contractual process between the Sponsor and the participating site. The PI is responsible for ensuring a study is conducted in accordance with the approved Protocol, GCP and all relevant regulations at their site. The PI may further delegate responsibilities to members of the research team at their research site via the Delegation of Authority and Signature Log (DoA Log) (Appendix 2).

The delegation of responsibilities at research sites is dealt with in this SOP, whereas the delegation of Sponsorship functions to vendors and/or third parties is described in SOP S-1037.

In all cases, the formal delegation of responsibilities must be documented, and the delegating individual must be assured that all persons discharged with responsibilities are qualified by training and experience to undertake those tasks (refer to SOP S-1020).

All staff must have Research and Design/Innovation (R&D/I) approval to work within the Trust (e.g., letter of access/honorary contract as required) before they sign the DoA. Copies of CVs, GCPs and evidence of study training spanning the duration of study involvement must be available for each person listed on the DoA Log and must be filed in the ISF/TMF as appropriate. The DoA Log is evidence that the PI has confirmed that the individuals performing study-related tasks/procedures are appropriately trained, experienced and authorised to do so, including any new staff who become involved after the study has begun. Furthermore, the delegating individual must implement sufficient processes to maintain oversight of the study/trial so that they can ensure that the legislation is complied with and that the Sponsor's legal responsibilities are met.

The Sponsor will maintain oversight of delegated functions through several different processes, including but not limited to: the review of CVs and training records, Site Initiation Visits, Audit and Monitoring, Risk Assessment, general correspondence and/or meetings with the CI, progress reports (i.e., annual progress reports) and compliance with Sponsor SOPs.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Research Governance Office	Ensure that the CI Roles and Responsibilities Agreement is completed as part of the Sponsor review process and prior to the commencement of the research and that functions are delegated appropriately and carried out appropriately
Sponsor	Research Governance Office	Ensure that the CI/PI documents any delegated duties appropriately using the Delegation of Authority and Signature log (Appendix 2)
Chief Investigator	Chief Investigator	Ensure that all individuals are appropriately trained and qualified to undertake delegated duties, undertakes the coordination of investigators at a research site(s) and coordinating the conduct of the study/trial at all sites

Responsibility	Undertaken by	Activity
Principal Investigator	Principal Investigator/their delegate	Ensure that all individuals are appropriately trained and qualified to undertake delegated duties and maintains oversight of these duties at their research site

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	19/01/2023

6.0 Review record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
Oct 2013	2	Wendy Gamble	Version 1 amended following review of Sponsor processes
April 2015	3		SOP reviewed and revised to incorporate minor administrative changes to section 3 adding the 2nd 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.
Sept 2021	6.1	Cat Taylor	Administrative changes
January 2024	7.0	Cat Taylor	Change to SOP title from 'Chief Investigator Responsibilities for Research Sponsored by University of Leicester' to 'Delegation of Responsibilities for Research Sponsored by University of Leicester' Administrative and formatting changes to improve accessibility of SOP and appendices Major updates to wording to provide clarity List of CI roles and responsibilities removed and individuals referred out to Appendix 1 Removal of monitoring and audit criteria section. Review period changed from 2 to 3 years Appendix 1 – major changes to roles and responsibilities document. Addition of the Delegation of Authority and Signature Log as Appendix 2 (starting at v5.0). This has been removed as an appendix for SOP S-1021 Informed Consent.