Research Governance Office Sponsorship Standard Operating Procedures

Delegation of Activities

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Author	
Name	**Claire Fitzpatrick**
Job Title	**Research Quality Assurance Officer**
Name	**Kyla Harrington**
Job Title	**Clinical Trials Governance Manager**
Reviewer/Approver	
Name	**Dr Cat Taylor**
Job Title	**Head of Research Governance**
Signature	
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1.0 Introduction and Scope

The Sponsor may transfer or the investigator may delegate their tasks, duties or functions (hereafter referred to as 'activities'), but they retain overall responsibility for their respective functions. This Standard Operating Procedure (SOP) describes the process for the formal delegation of activities by the Sponsor and Investigator(s) for research (referred to as 'trial' hereafter) sponsored by the University of Leicester (UoL).

The outcome is that roles, activities and responsibilities for the trial are clearly defined and documented appropriately.

The delegation of activities to the CI and individuals at research locations is dealt with in this SOP, whereas the delegation of Sponsorship functions to service providers (internal or external) is described in SOP S-1037.

2.0 Definitions

The UK Policy Framework for Health and Social Care Research definitions of a Chief Investigator (CI), Principal Investigator (PI) and Research Team apply.

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

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 3B of Medicines for Human Use (Clinical Trials) Regulations (2025; and any such amendments) will apply. Specifically, the investigator, in relation to a clinical trial, shall be a health care professional who is appropriately trained to undertake that role in a clinical trial. Where applicable, investigators will need appropriate support for any medical decisions in regards to the trial.

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

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

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

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 trial including the initiation, management and financing (or arranging the financing) of a trial, the Sponsor can formally delegate one or more of its activities to another organisation(s) or individual(s).

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

1. The RGO 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 undertake the delegated activities 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 for the commencement of the trial being issued.

4.0 Delegation of Activities and Signature Log

4.1 Research Locations

To ensure effective conduct and management of a trial at a research location, site-level roles, activities and responsibilities are delegated to the PI (or Local Collaborator) via the contractual process between the Sponsor and the participating location. The PI is responsible for ensuring a trial is conducted in accordance with the approved Protocol, GCP and all relevant regulations at their location. The PI may further delegate activities to members of the research team at their research location via the 'Research Location Delegation of Activities Log' (DoA Log; Appendix 2).

The DoA Log is evidence that the PI has confirmed that the individuals performing trial-related activities are appropriately trained, experienced and authorised to do so, including any new staff who become involved after the trial has begun (refer to SOP S-1020).

- Copies of CVs, GCPs and evidence of training spanning the duration of involvement must be available for each person listed on the DoA Log,
- Where a regulatory compliant and validated system is being used (i.e., Florence) the UoL will accept a digital DoA. Otherwise, it is expected that the DoA is completed by hand (i.e., wet ink) and follows the guidance provided (page 1 of the templates),
- The original copy of the DoA Log must be filed in the ISF (with a copy retained in the TMF; refer to SOP S-1015 for full guidance).

In addition to being formally delegated activities within a trial, all staff must hold the appropriate approvals and/or contractual agreements required to conduct research at each research location. For example, in NHS settings, non NHS staff must obtain Research and Development/Innovation (R&D/I) approval to work within the Trust (such as a letter of access or an honorary contract, as applicable) and this must be in place before the individual signs the DoA.

The level of approval granted by a Trust, as well as individual Trust policies, may differ and can influence the activities an individual is permitted to undertake, including activities such as participant identification. It is therefore essential that research teams review their local Trust SOPs to ensure that individuals have the appropriate permissions before being formally delegated any activities. Staff are responsible for ensuring that these permissions are in place and that they are only delegated activities for which they are appropriately trained, educated and qualified to undertake.

4.2 CTIMPs and Medical Device Trials

The DoA is an essential record and will be used to facilitate the reconstruction of a trial in the event of audit/monitoring and/or inspection.

Because there is a clear and obvious separation between site-level activity and central/trial management activity, a central/trial management DoA is recommended for all trials, and is **mandatory** for CTIMPs and Medical Device Trials. Appendix 3 is provided (unless a provider has their own template).

5.0 Oversight

The delegating individual must implement sufficient processes to maintain oversight of the 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 activities 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 Investigator, reports (i.e., annual safety reports) and compliance with Sponsor SOPs.

6.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	8.0	• Language updates in accordance with ICH GCP E6(R3) and UK Clinical Trials Regulations. • Title of SOP and appendices updates from 'responsibilities' to 'activities'. • Wording updates throughout SOP and appendices. • Introduction of Appendix 3 (Central/Trial Management DoA for CTIMPs and Medical Device Trials). • Appendix 2 redesigned and simplified for use at research location (removal of central duties). • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive