UNIVERSITY OF LEICESTER

Research Governance Office Sponsorship Standard Operating Procedures

Agreements, Approvals and Contracts for Trials

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1.0 Introduction and Scope

This Standard Operating Procedure (SOP) applies to all research (referred to as 'trial' hereafter) sponsored by the University of Leicester (UoL) and describes the process used by the UoL to ensure that all types of contracts and agreements necessary are in place.

2.0 Procedure

Advice regarding which agreements are required for the delivery of a trial can be sought from the Research Governance Office (RGO) or by reviewing the information provided on the HRA website and IRAS help section. Where relevant, the RGO will provide contact details for other research support departments who need to be included in the provision of agreements and contracts (i.e., Pre-Award and Contracts (PAC), Procurement).

In addition, as part of the Sponsor Review process (SOP S-1002), and where necessary the Sponsor Risk Assessment (SOP S-1003)/ Modification Process (S-1018), the Head of Research Governance (or their delegate) will identify which agreements are required.

The drafting of agreements will be initiated and facilitated during the Sponsor Review process, and draft agreements should be provided as part of the application for Sponsorship (via Infonetica).

The RGO will facilitate the completion of agreements as part of the process for gaining external approvals.

The template agreements provided by the HRA and accessed via the IRAS help section must be used, and be used without modification.

2.1 NHS and non-NHS Site Agreements (i.e., research locations, PIC locations)

The RGO will facilitate, and provide guidance on, the development of the appropriate agreement to be sent to the participating location(s), this will likely occur as part of the Sponsor Review process. Typically, this will be either an Organisational Information Document (OID), a standard model Non-Commercial Agreement (mNCA) (where the trial falls into the top 4 filter questions within IRAS), and/or a model Non-Commercial PIC Agreement (this may sit either between the Sponsor or the lead site and the PIC depending on the nature of the trial). Different sections, and the various appendices within the agreements, may or may not require completing depending on whether funds are or aren't being transferred from the Sponsor to the NHS site, and whether any additional/supporting agreements (e.g. data sharing or material transfer agreement) will also be in place.

The Sponsor and participating location should finalise, sign and date the agreements prior to confirming approval for the research at the location. The Head of Research Governance, or their delegate is authorised to sign these agreements

on behalf of the UoL. When requesting Sponsor Green Light for a site, the fully executed agreement must be uploaded to Infonetica.

Once fully executed, a copy of the signed agreement must be;

- Uploaded to Worktribe (where relevant, this is not mandatory but is advised so that the PAC team have a record of site agreements),
- Retained by the relevant site R&D/I Office,
- Retained in the Investigator Site File (ISF) at the relevant location,
- Retained in the Trial Master File (TMF) at the lead site/coordinating centre, and
- Retained by the RGO.

2.1.1 Amendments to Agreements with Research Locations

Where an amendment to an existing site agreement is required, a new or revised agreement or addendum should be submitted to the RGO for review, prior to being shared for approval by the relevant site R&D/I (or equivalent) office. The RGO will support appropriate amendments/addendums to existing agreements and will manage the process to full execution.

Where applicable, the Pre-Award and Contracts (PAC) team will be notified.

The Head of Research Governance, or their delegate, are authorised to sign these documents on behalf of the UoL.

Once fully executed a copy of the signed agreement must be filled as per the information provided in section 2.1.

2.2 Non-NHS Contracts

As part of the development of a trial and at the earliest opportunity (i.e., during the grant costing stage), the CI must identify third parties and/or which activities require a service provider(s). Additionally, the Sponsor Review Process (S-1002) and Risk Assessment process (S-1003), may identify whether any agreements with third parties (e.g. funders, collaborators, laboratories and drug/device suppliers) are required. Details should be shared with the Pre-Award and Contracts (PAC) team via Worktribe. Where formal tendering is necessary as part of the service provider selection, the UoL procurement regulations and processes will be followed, where the appropriate Category Manager is engaged at the earliest opportunity to advise on, and manage delivery of, the procurement strategy, in tandem with discussions with RGO.

Agreements are used to document and agree aspects of the relationship between the Sponsor and the third-party organisation(s)/service provider(s), including, but not limited to:

- Roles and Responsibilities.
- Financial and legal considerations including indemnity.
- Termination considerations.
- Standards of service.

- Regulatory obligations including Data Protection and legislation governing clinical research.
- Intellectual property & publication considerations.
- Confidentiality considerations.

The completion of agreements, and any subsequent amendment should be managed in Worktribe or with Procurement (as applicable). It is a requirement that before services commence, a written agreement between the UoL and the third-party/service provider be fully executed. In exceptional circumstances, where it is necessary for a third-party/service provider to commence activity prior to a fully executed (both initial and amended) agreement being in place, this must be agreed by all parties and evidence of said agreements/provisions retained (e.g. emails).

Further guidance on the selection and oversight or service providers can be found in SOP S-1037.

2.3 Site Approvals

2.3.1 Initial site approvals

2.3.1.1 Research Location (i.e., Site) Approval and Sponsor Green Light

Confirmation of approval (i.e., Confirmation of Capacity and Capability*, or equivalent) must be obtained from each research location prior to trial activities commencing at that site. This must be in place before Sponsor Green Light (SGL) will be granted.

Sponsor Green Light must be requested via Infonetica and evidence of approval (where applicable) and a fully executed agreement must be provided (i.e., uploaded to the system) prior to the request being submitted. Sponsor Green Light will be issued via Infonetica. Records of location activation must be retained in the TMF.
*For GP practices, the signing of the relevant agreement acts as Confirmation of Capacity and capability.

2.4 Modification Approval and Sponsor Green Light

Following the introduction of Infonetica and due to the complexity of modification types, the UoL have implemented a pragmatic approach to issuing Sponsor Green Light for modifications.

In brief,

- CTIMP and Medical Device trial modifications are issued Sponsor Green Light for implementation on a per modification and per location basis.
- For all other trial types, the date of Sponsor Green Light is considered to be whichever of the following occurs first:
- The 35th day following notification to a location of the modification (where additional time has not been requested), or

- Upon receipt of approval (or of 'no objection') from a location whether this is within the 35 day notification period or later (where additional time has been requested).

When a modification is reviewed by the RGO, the outcome of the review and the requirement to request Sponsor Green Light (or not) will be communicated via Infonetica.

NB. The addition of a new research site will always require a Site Sponsor Green Light to be requested.

NB. Where a contract/agreement is amended as a consequence, the fully executed agreement must be uploaded as part of the Modification Request and/or Modification Sponsor Green Light request.

For further details on this process, please refer to SOP 1018.

3.0 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	5.1	• Language updates in accordance with ICH GCP E6(R3) and UK Clinical Trials Regulations. • Wording updates throughout the SOP. • Removal of responsibilities table as responsibilities are clearly 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