UNIVERSITY OF LEICESTER

Research Governance Office Sponsorship Standard Operating Procedures

External Service Provider Selection and Oversight

SOP Reference	S-1037A
Version and Date	V4.0 April 2026
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Date	28 April 2026
Effective Date*	28 April 2026
Next Review Date	April 2029

1.0 Introduction and Scope

Research may require the involvement of persons or parties beyond the Chief Investigator's (CI) immediate team. These could be external service providers (commercial, academic or other); internal collaborators and/or service providers from departments within the University of Leicester (UoL).

This SOP describes the process for the selection, assessment, approval and oversight of **external service providers** in support of research (referred to as 'trial' hereafter) sponsored by the UoL. It does not apply to participating research locations (SOPs S-1002, S-1006, S-1025 and S-1033 apply), academic co-applicants/collaborators (whose activity is governed by the grant level contract between universities), or to internal UoL service providers, the arrangements for which are described in SOP S-1037B.

Whilst the content of this SOP is applicable to all trials sponsored by the UoL, it is of critical importance to CTIMP and Medical Device Trials because all entities involved in the conduct of these are subject to inspection by the regulatory authorities.

2.0 Responsibilities

UoL as the Sponsor retains ultimate responsibility for a trial; however, it relies upon the CI to identify what activity(ies) require service providers of any sort, and to support the UoL by enabling appropriate structures, agreements and ongoing oversight of the service provider(s) so that all relevant regulations are adhered to throughout the life of the research.

As such, the UoL will collaborate with the CI on the following activities with regard to external service providers:

- Identification;
- Selection; and
- Assessment (of suitability).

And delegates the following activities to the CI with regard to external service providers:

- Onboarding;
- Oversight (of performance of delegated activities); and
- Close down.

The level of CI oversight of the delegated activities should depend on the nature of the delegated activities and be proportionate to the importance of the data being collected and the risks to participant safety and data reliability.

The UoL retains responsibility for the **contracting** of all service providers (investigators and research staff **must not** enter into, or sign, agreements on behalf of the UoL).

Specialist teams within the UoL (i.e., the Research Governance Office (RGO), Procurement, Pre-Award and Contracts, and if relevant, the Research Design Service (RDS) and/or the Leicester Clinical Trials Unit (LCTU)) will support the CI and must be involved in the identification (possibly via competitive process), assessment and negotiation with all external service providers.

3.0 Definition

External Service Provider
A person or organisation (commercial, academic or other), external to the UoL, providing a service, function or products to fulfil research-related tasks, duties or functions (hereafter referred to as 'activities').

4.0 External Service Management

Investigators **must** retain accurate records which document the end to end process of identifying, selecting, assessing, onboarding, overseeing, and closing down of external service providers. These records will serve as the primary source of evidence demonstrating effective provider selection and proportionate oversight throughout the trial lifecycle, supports compliance with applicable regulatory requirements, and UoL Sponsor requirements. Copies must be retained in the Trial Master File (TMF).

5.0 External Service Provider Identification, Selection and Assessment

As part of the development of a trial and at the earliest opportunity (i.e., during the grant costing stage), the CI must identify which activities require a service provider(s), and whether the service provider is internal or external to the UoL.

Where external support is required, the CI must ensure that those helping with the costings/grant application are aware, and that the RGO are consulted prior to approaching a potential service provider. The RGO will advise on the requirements for assessing the suitability of a service provider to ensure that the service provider can perform the services to the applicable standards and regulations. The type of assessment undertaken will be determined on a case-by-case basis and will vary depending on the total estimated value of the activity and the risks associated with the activities.

It is likely formal tendering will be necessary as part of the service provider selection. In tandem with discussions with RGO, the UoL procurement regulations and processes will be followed, where the appropriate Category Manager will be engaged at the earliest opportunity to advise on, and manage delivery of, the procurement strategy. The CI is responsible for ensuring the description of activities to be tendered (Statement of Work; SoW) is complete and accurate in all details. For example:

- Detailed description of activities including deliverables, timelines, financial expectations, and any key performance indicators (KPIs) to support the subsequent management of the contract;
- Roles and responsibilities;
- Communication plans;

- Oversight plans (including that of activities further subcontracted by the external service provider);
- Regulatory and data protection requirements (e.g., GDPR, GCP, Clinical Trials/Medical Device Regulations); and
- Any sustainability mitigations and benefits.

Further information including guidance on when procurement regulations apply where relating to research, and instructions for booking onto, and recordings of, the 30-minute Procurement Training session, can be found in the Procurement SharePoint section.

Service Providers must contractually agree to appropriate audits, which may be carried out by third party providers on behalf of the Sponsor. The cost of the audit must be covered by the research grant.

6.0 Contracts

After selection of an external service provider, and having gained approval to award a contract via the (New Supplier) Contract Award Approval Form (CAAF)/process (UoL log in required), appropriate contracts must be put in place prior to commencement of the work. This contract must include explicit reference to the SoW, payment terms, indemnity limits and insurance levels to be maintained by the provider, termination clauses, deviation reporting, document retention requirements, and an agreement that the service provider will comply with the Sponsor's instructions and applicable regulations.

Where inviting tenders, these will be based on a set of University Standard Terms and Conditions, included with the Invitation to Tender pack.

Once a contract is executed, it is important that it remains current and that the requirements of the contract are being met by all parties. Further information can be obtained from the Procurement and Pre-Award and Contracts team. CIs should maintain financial oversight of the ongoing contract.

7.0 Onboarding External Service Providers

CIs should plan for an onboarding process to be scheduled once the contract is in place. The onboarding process is intended to be reciprocal, to align expectations and should be designed on a case-by-case basis; at a minimum it should include:

- Agreement on timelines;
- Communication plans (channels and frequency) and points of contact;
- The reciprocal provision of documents (and modifications/updates) to support their service(s) (i.e., protocol, SOPs, manuals); and
- Providing access to any systems or platforms that they need.

8.0 Ongoing Oversight of External Service Providers

The contract must clearly outline the requirements, and oversight activities should be proportionate to the importance of the data being collected and the risks to participant safety and data reliability.

Effective oversight can be achieved through:

- Regular meetings to review progress (including against any KPIs), discuss issues and confirm compliance with the contract, timelines, protocol, SOPs and instructions;
- Conducting risk-based monitoring or spot-checks of service provider activities (especially for critical services), especially if concerns arise;
- Requesting and reviewing service reports, certificates, quality and output reports;
- Ensuring the service provider provides (or maintains) essential records required for the TMF;
- Confirm any deviations or breaches that have occurred, and that these have been rectified, documented and reported appropriately (refer to SOP S-1016);
- Ensuring that the service provider is informed of and complies with any modifications to the protocol, instructions or regulatory approvals (especially when they impact the providers services);
- Ensuring that the service provider provides all final reports, data exports, or certificates of analysis (as applicable); and
- Including the service provider in trial closeout and archiving activities.

If the service provider proposes to make changes to their written procedures or SOPs which affect the activities, UoL as Sponsor will require that the changes do not materially impact their ability to perform the activities as previously agreed. This will be made clear in the service provider contract.

9.0 Closedown of External Service Providers

The CI is responsible for ensuring orderly closedown, including preparation of the TMF and essential records for archiving; this activity will likely include the following, as a minimum:

- Confirm completion of deliverables and that these are acceptable;
- Request and review service reports, certificates, quality and output reports (where not previously provided);
- Ensure the service provider has the full and complete essential records required for the Trial Master File (TMF);
- Confirm the service provider's responsibilities regarding retention of essential records required for the Trial Master File (TMF);
- Confirm that all deviations or breaches were rectified, reported and documented appropriately;
- Ensuring that the service provider provides all final reports, data exports, or certificates of analysis (as applicable);
- Issue/approve final invoices and reconciliation of finances/fees;
- Remove access to systems or platforms; and
- Including the service provider in trial closeout and archiving activities.

10.0 Escalation of Issues

There must be clear instructions within the service provider contract detailing the processes to be followed in the event of problems or issues identified. Where

required and appropriate the RGO should be notified of issues, and the process outlined in SOP S-1016 should be followed.

The appropriate Category Manager may also be engaged for an material or persistent service provider performance issues. Instructions for booking onto, and recordings of, the 60-minute Contract Management Training session, can be found in the Procurement SharePoint section.

Accurate records of all issues and how they are managed must be retained in the Trial Master File.

11.0 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	4.0	• Clarification that this SOP relates to external service providers. • Language updates in accordance with ICH GCP E6(R3) and UK Clinical Trials Regulations. • Detailed guidance on selection, oversight and management added. • Detail around UoL procurement processes added. • Addition of S-1037B which relates to internal service providers only. • 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.