Research Governance Office Sponsorship Standard Operating Procedures

Internal Service Provider Selection and Oversight

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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 internal 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 external UoL service providers, the arrangements for which are described in SOP S-1037A.

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 internal service providers:

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

And delegates the following activities to the CI with regard to internal 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 internal service providers.

3.0 Definition

Internal Service Provider

A person or group, within and employed by UoL (including those under the remit of the CI), providing a service, function or products to fulfil trial-related tasks, duties or functions (hereafter referred to as 'activities').

4.0 Internal Service Provider Management Plan

Investigators **must** retain accurate records which document the end to end process of identifying, selecting, assessing, onboarding, overseeing, and closing down of internal 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 Internal Service Provider Selection

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 functions or services require a service provider(s), and whether the service provider is internal or external to the UoL. Where internal support is required, the CI must ensure that those helping with the costings/grant application are aware and are in contact with the relevant internal service provider teams.

6.0 Contracts

Whilst no formal contract is required for the provision of services from internal providers within UoL, the CI should ensure that there is documentation that supports transparency and allows the reconstruction of the trial. There should also be evidence of agreement by the internal service provider and all documentation must be kept as part of the TMF. Where the activity is to be performed by those under the remit of the CI (i.e., academic laboratory) declaration and records of 'selection' must still be made.

The CI is responsible for ensuring the description of services to be provided (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 work;
- Roles and responsibilities;
- Communication plans (including that of activities further subcontracted by the internal service provider);
- Oversight plans; and

- Regulatory and data protection requirements (e.g., GDPR, GCP, Clinical Trials/Medical Device Regulations).

7.0 Onboarding Internal Service Providers

CIs should plan for an onboarding process for all internal service providers to be scheduled once the grant has been awarded. 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 Internal Service Providers

Records of oversight activities should be proportionate to the importance of the data being collected and the risks to participant safety and data reliability, and must be retained in the TMF and/or Sponsor files.

Effective oversight can be achieved through:

- Regular meetings to review progress (including against any KPIs), discuss issues and confirm compliance with the 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 documentation required for the (TMF);
- Confirm any deviations or breaches that have occurred, and that these have been rectified, documented and reported appropriately;
- Ensuring that the service provider is informed of and complies with any amendments 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);
- Including the service provider in trial closeout and archiving activities.

9.0 Closedown of Internal Service Providers

The CI is responsible for ensuring orderly closedown and preparation of the TMF and other trial materials for archiving. In relation to internal service providers, 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 provides (or maintains) essential records required for the Trial Master File (TMF);

- Confirm the service provider's responsibilities regarding essential records required for the Trial Master File (TMF);
- Confirm that all deviations or breaches were rectified, reported and documented appropriately;
- Ensure that the service provider provides all final reports, data exports, or certificates of analysis (as applicable);
- Reconcile finances/fees owed;
- Remove access to systems or platforms; and
- Include 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.

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