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JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1037 UoL

Version 3.1, September 2021

Vendor Selection and Oversight for Research Studies Sponsored by the University of Leicester

OFFICE BASE

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Effective Date October 2021

1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the process for the selection, approval and oversight of external vendors to provide a service to support research sponsored by the University of Leicester (UoL). Selection of an external vendor must be done in collaboration with the University of Leicester Purchasing Department and members of the Research Support Services (RSS) team, which is within the Research and Enterprise Division (RED), and the Research Governance Office. Not all research activities are conducted within UoL and a variety of different service models may be required to conduct studies. External vendors may include Contract Research Organisations, Clinical Trials Units, Laboratory services etc. A Chief Investigator must ensure that appropriate processes are adopted when selecting a potential vendor. It is important to remember however, that the Sponsor retains ultimate responsibility and must be involved in the identification and negotiations to contract an appropriate vendor.

2. SCOPE

This SOP applies to all research studies sponsored by the University of Leicester which require the use of external vendors. The only exception to the process is the procurement of Investigational Medicinal Product which must be managed via an appropriate pharmacy department.

3. DEFINITION

A vendor is a person, organisation or agency external to the UoL that provides functions, services or products related to the conduct of studies that are sponsored by the UoL. It does not include research collaborators or other trial sites. It is worth noting and for the purposes of clarity, the Leicester Clinical Trials Unit when not a collaborator must be deemed as an external vendor.

4. IDENTIFICATION OF A SUITABLE VENDOR

It is expected that during the development of a study protocol, functions, services or products that are not accessible from within the UoL will be identified. Where external support is required for the delivery of aspects of a protocol, the Chief Investigator (CI) must make contact with the Research Governance Office to seek advice and to engage with them prior to approaching a potential vendor. Where appropriate the Research Governance Office will involve the UoL Procurement Unit (appropriate Category Manager) and staff in RSS to ensure that the UoL Procurement Regulations are followed.

It is expected that wherever possible, the Leicester CTU is approached in the first instance where the services of a CTU are required. It is not necessary to follow the Procurement Regulations when using the Leicester CTU, however, the Research Governance Office and staff in RSS must be involved at the earliest possible opportunity.

The process adopted for assessing the suitability of any vendors will vary depending on the total estimated value of the contract and the risk associated with the tasks being delegated

The suitability of a vendor is assessed on a value for money basis, considering price and quality, by way of a procurement procedure dependent on the total estimated value of the contract and the nature of the requirement and market. Contracts with a total contract value above the EU Thresholds (£164,176 for goods and services) must be tendered in compliance with the Public Contracts Regulations 2015.

Any vendor involvement which is going to cost over £50,000 must go through the UoL Procurement Unit, for the appropriate Category Manager to manage the tendering process. The threshold is over £25,000 for research equipment intended to be procured using research grant funding. All waivers to the Procurement Regulations over £10,000 must be approved by the Procurement Unit, with waivers over £50,000 needing approval from the Registrar as well as the Head of Procurement. The business justification for the waiver will be reviewed by the Research Governance Office, staff in RSS, and, where appropriate, the CI, ahead of passing to the Procurement Unit for approval. No contract must be entered into with any vendor before this approval has been given. Documentary evidence of the justification and approvals must be retained in the Trial Master File (TMF).

5. MAINTAINING OVERSIGHT OF VENDORS

Ongoing oversight of vendors will be conducted and will be achieved through a variety of different methods. Effective oversight can be achieved through regular teleconferences, face to face meetings, external audit or review of specific milestone activities. Whatever process is chosen, it must be clearly documented (including the outcome of any discussions) and retained in the TMF and/or Sponsor files. The type of oversight chosen will depend on the service to be provided. This will be reviewed on a case by case basis and the vendors informed that their services will be added to the list of routine audit visits conducted as appropriate for the study. It is likely that the audits will be carried out by a third party contracted to work on behalf of the UoL.

It is important that the CI/Sponsor ensures that it provides vendors with all the appropriate documentation to enable them to perform their delegated functions effectively and that there is a mechanism in place to ensure that the vendor receives any updates to these documents. The communication plan will be reviewed at Sponsor Risk Assessment. Likewise, if the vendor proposes to make changes to their written procedures or SOPs which affect the trial, UoL as Sponsor should review the changes and “approve in principle” any amendments. This will be made clear in any contract.

6. Escalation of Issues

There must be clear instructions within the contract detailing the processes to be followed in the event of problems or issues identified. The process must follow the appropriate Sponsor SOPs for Non-Compliance S-1016 UoL and / or CAPA S-1012 UoL.

7. Contracts

In order to minimise delays, trial set up activities may be undertaken by vendors prior to a fully executed contract being in place, however, if this is the case it is important that a letter of intent exists which as a minimum clearly defines what activities are to be undertaken, the standards to be adhered to and a time limit or expiry of the agreement in accordance with S-1005 UoL Contracts SOP.

For CTiMPS, it should be clearly documented that no IMP should be shipped/released and that no trial specific screening or patient dosing can occur before the fully executed contract is in place.

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 found in the Contracts SOP S-1005 UoL.

8. Responsibilities

	Responsibility	Undertaken by	Activity
1	CI	CI	Provide information regarding the requirement for vendor involvement at Sponsor Risk Assessment.
2	CI	CI or delegate	Provide business justification for use of one particular vendor (if applicable).
3	Sponsor	Research Governance Manager (RGM) or delegate, RSS staff and Purchasing Office (as relevant)	Inform Purchasing Department of vendor involvement and instruct regarding the tendering process or review of the business justification as appropriate.
4	CI/Sponsor/ Purchasing Dept	CI/ RGM or delegate/ Purchasing Dept Manager or delegate	Agree and document the decision regarding choice of vendor and the rationale.
5	Sponsor	RGM or delegate and relevant RSS staff	Ensure letter of intent and/or fully executed contracts are in place throughout the trial.
6	Sponsor	RGM or delegate	Ensure ongoing oversight of vendor suitability.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions:

Development and approval Record for this document

Author/Lead Officer:	Cat Taylor
Job Title:	Head of Research Assurance
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Approved by:	Professor Nigel Brunskill 
Date Approved:	13/10/2021

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
August 2015	2	Wendy Gamble	Reviewed and amended to include University of Loughborough on front page and minor administrative changes to version numbers and dates

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Nov 2016	3	Diane Delahooke/ UoL Procurement office	Change of logo and RGO address. Addition of vendor audit and documenting oversight in Sponsor files. Procurement process updated.
Sept 2021	3.1	Cat Taylor	Administrative changes

Distribution Record

Date	Name	Department	Received