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 Hospitals of Leicester NHS Trust (UHL).

Selection of an external vendor must be done in collaboration with the Head of Research Operations and refer to the UHL Standing Orders: Section 9. http://insitetogether.xuhl-tr.nhs.uk/corp/migrated/Documents/Procurement/Procurement%20Web%20Pages/Standing%20Orders.pdf

Not all research activities are conducted within UHL 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, Monitoring 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 UHL 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 UHL that provides functions, services or products related to the conduct of studies that are sponsored by the UHL. It does not include research collaborators or other trial sites. It is worth noting and for the purposes of clarity,that when the Leicester Clinical Trials Unit is not a collaborator the organisation 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 UHL 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 Contracts Team, to seek advice and to engage with them prior to approaching a potential vendor. Where appropriate the Sponsor will involve the UHL Procurement Department to ensure that the UHL procurement processes are followed.

The process adopted for assessing the suitability of any vendors will vary depending on the risk associated with the tasks being delegated and what is previously known about the vendor. i.e. does the UHL have a track record with the vendor from previous studies?

A variety of assessment methods can be considered when assessing the suitability of a vendor some examples of which are:

- Pre-qualification questionnaires
- Assessment of CVs and previous experience
- Obtaining suitable references
- Referring to prior knowledge of the vendor from use in other trials

- Assessing quality system/written procedures/SOPs
- Conducting audits

Any vendor involvement which is going to cost over £25,000 must go through the UHL Procurement Department tendering process, unless a clear business justification is provided by the CI for use of one vendor in particular. No contract must be entered into with any vendor in this circumstance until the necessary approvals have been given. Documentary evidence of the justification and approvals must be retained in the Trial Master File (TMF).

The business justification will be reviewed by the Head of Research Operations, the Research Contracts Manager and Procurement Department as appropriate.

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 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. 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 UHL.

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, UHL 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 UHL and / or CAPA S-1012 UHL.

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 SOP S-1005 UHL 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 UHL Contracts SOP S-1005 UoL.

8. Responsibilities

	Responsibility	Undertaken by	Activity
1	CI	CI	Provide information re 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	UHL Sponsor	Head of Research Operations / Research Contracts Team	Inform Purchasing Department of vendor involvement and instruct re the tendering process or review of the business justification as appropriate.
4	Procurement Department	Procurement Manager	Agree and document the decision re choice of vendor and the rationale.
5	UHL Sponsor	Head of Research Operations / Research Contracts Team	Ensure letter of intent and/or fully executed contracts are in place throughout the trial.
6	UHL Sponsor	Head of Research Operations / Research Contracts Team	Ensure ongoing oversight of vendor suitability.

9. Supporting Documents and Key References

SOP S-1016

SOP S-1012

SOP S-1005

10. Key Words

Research, Innovation, Volunteers, Participants, Trials, Vendor, Finance, Procurement, CTU, CAPA, Contracts

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

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