Standard Operating Procedure (SOP)

Vendor Selection for Studies Sponsored by St George's

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They may print off this document for training and reference purposes.

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	Original Version	Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0050 Site Feasibility and Selection	JRESWPD0023 General Research Definitions	JRESDOC0122 Vendor Assessment Checklist	

Contents

1. Background

St George's (SGUL and SGHFT) sponsors several CTIMP and non-CTIMP research projects. External vendors are sometimes needed to provide support to the set-up, management and conduct of a study, on behalf of the Sponsor.

It is important that a thorough assessment and selection process is in place for external vendors, as the responsibility for their conduct lies with St George's as the Sponsor. A robust selection process and ongoing oversight reduces the risk of any breaches to the protocol, Good Clinical Practice (GCP) and relevant legislation.

External vendors can include laboratories, Contract Research Organisations (CROs), Clinical Trial Units and pharmaceutical companies. Examples of services which may be outsourced by the Sponsor for a specific study include randomisation, IMP management, trial monitoring and the analysis of biological samples.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This SOP describes the process for the assessment, selection and ongoing oversight of external vendors.

This SOP applies to the JRES Governance team and to all Chief Investigators (CIs) working on studies sponsored by St George's.

This SOP is not applicable to the assessment and selection of investigator sites for studies, as this is described in JRESGOVSOP0050 Site Feasibility and Selection.

4. Definitions

For general research-related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023).

'Vendor': a person or organisation external to St George's which provides services or products related to the conduct of a study sponsored by St George's.

5. Responsibilities

It is the responsibility of the CI, in conjunction with the JRES, to identify the need for study-related activities to be outsourced to an external vendor and to identify, assess and select a suitable vendor or vendors.

It is the responsibility of the JRES to manage the contract process for external vendors and to maintain appropriate oversight of external vendors for the duration of the study.

6. Procedure

6.1 Vendor Assessment and Selection

Once a need for a service to be provided by an external vendor has been identified and agreed, a suitable vendor or vendors will be identified. Vendors may be identified via a trusted

recommendation, open tender or because they have worked successfully with St George's on previous studies.

Once identified, the vendor or vendors will be sent the Vendor Assessment Checklist (JRESDOC0122) to complete which will assess their experience and suitability, as well as their compliance with GCP requirements. External vendors must be able to demonstrate GCP compliance, and this is essential for CTIMPs. They must also be able to demonstrate compliance with any other standards/requirements which are compulsory for their particular organisation.

The completed checklist and any related documentation (eg: staff CVs, accreditation certificates) will be returned by the vendor(s) to the JRES.

The completed checklist(s) will be reviewed by the JRES and the CI and a decision made regarding the selection of the vendor. In rare cases, this may require a site visit or an audit to be completed prior to selection, as this will be dependent on the resources available within the JRES.

6.2 Contracts

Once a vendor has been selected, a contract will be put in place between the vendor and St George's, prior to the start of the agreed, delegated tasks/services, by the JRES.

The contract will include the specific tasks and duties to be performed by the vendor and the required standards. It must be clear in the contract that compliance with the study protocol and any relevant legislation supersedes any internal processes and procedures.

The contract must clearly define the roles and responsibilities of the vendor and the Sponsor (eg: any legislative requirements such as the reporting of serious breaches, where applicable).

The final, signed contract must be filed in the Trial Master File (TMF) and in the electronic Sponsor File.

6.3 Sponsor Oversight

The JRES will maintain oversight of the vendor's delegated activities for the duration of the study. This will be agreed with the vendor prior to the contract being finalised and the plan will also be documented on the Vendor Assessment Checklist.

The level and type of oversight will depend on St George's experience with the vendor and the services being provided. The level of risk should be assessed in relation to the tasks being performed and their impact on participant safety and/or data integrity.

Oversight may be maintained by regular teleconferences with the vendor, a review of the study-related work completed to date or auditing their processes.

The CI will provide the vendor with all relevant study documents, including any updated documents as the study progresses, to ensure that the vendor performs their tasks according to the current, approved documentation.

The vendor will inform the CI and JRES if there are any changes to their documents or procedures which may affect the study.

7. References

ICH GCP.

8. Appendices

None associated with this SOP.