Vendor Selection and Oversight

POLICY DETAILS	
Document Type	Standard Operating Procedure
Document name	KHP-CTO/CT/SOP21.0 Vendor Selection and Oversight
Version	FINAL v1.1 05/Jan/2021
Effective from	07/Jan/2021
Review date	10/Jan/2026
Owner	King's Health Partners Clinical Trials Office
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Superseded documents	v1.0 14/Dec/2018
Relevant regulations/legislation/guidelines	Statutory Instrument 2004 no 1031 Statutory Instrument 2006 no 1928 *(as amended from time to time)* Trust Standing Financial Instructions Department of Health, NHS Guide to Procurement 2015

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
5th January 2021	1.1	Scheduled review, minor updates to section 4.1.1	Jackie Pullen
19th April 2023	1.1	Scheduled review no changes to SOP content.	Jackie Pullen

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1.0 GLOSSARY

Chief Investigator (CI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse/midwife who has overall responsibility for the conduct of the trial.

Clinical Research Associates – (CRAs) – Part of the KHP-CTO Quality Team. Ensure compliance with the Regulations, GCP and SOPs, by monitoring clinical trials.

Clinical Trial - Any investigation in human participants, other than a non-interventional trial intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal product and/or to identify any adverse reactions to one or more such products and/or to study absorption, distribution metabolism and excretion in one of more such products with the object of ascertaining the safety and/or efficacy of those products.

Co-Sponsors – Where two or more organisations take responsibility for the initiation, management and financing (or arranging the financing in relation to) a clinical trial. Co-Sponsors should decide which organisation will assume responsibility for carrying out the Sponsor functions of that trial and document this accordingly.

Curriculum Vitae (CV) - A summary of a person's education, professional history and job qualifications.

Electronic Data Capture (EDC) - a computerised system designed for the collection of clinical data in electronic format for in clinical trials.

Good Clinical Practice (GCP) - as defined in the Regulations.

Investigational Medicinal Products (IMP) - means a pharmaceutical form of an active substance or placebo being tested, or used as a reference in a clinical trial. This includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial -

- **(a)** used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,
- **(b)** used for an indication not included in the summary of product characteristics (or equivalent document) under the authorisation for that product, or
- **(c)** used to gain further information about the form of that product as authorised under the authorisation

King's Health Partners (KHP) - King's Health Partners Academic Health Science Center is a pioneering collaboration between one of the King's College London (University) and three of London's most successful NHS Foundation Trusts – Guy's & St Thomas', King's College Hospital and the South London & Maudsley.

King's Health Partners Clinical Trials Office (KHP-CTO) - Established in 2006 by King's College London, Guy's & St Thomas' NHS Foundation Trust, South London and Maudsley NHS Foundation Trust and King's College Hospital Foundation Trust to provide a streamlined approach for all aspects of trial administration.

KHP-CTO Quality Team – Comprises the Clinical Quality Manager, Clinical Research Associate(s), Clinical Trial Administrator(s), Systems Executive, Training Executive(s) and Training Assistant.

KHP-CTO Standard Operating Procedures (SOPs) - "detailed, written instructions to achieve uniformity of the performance of a specific function," SOPs are the base on which Quality Systems and Processes are conducted and monitored against.

Monitoring Visit Report (MVR) – A report written by the CRA to the Sponsor (or Representative) after each site visit.

Partner Organisations – King's College London, Guy's & St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, South London and Maudsley NHS Foundation Trust and any other Organisations that may join the KHP-CTO Partnership from time to time.

Research & Development Dept (R&D) – NHS department responsible for confirmation of capacity and capability for all clinical research.

Serious Breach of GCP - a "serious breach" of the principles of GCP that is likely to affect to a significant degree, the safety or physical or mental integrity of the participants of the trial; or the scientific value of the trial.

Serious Breach of trial Protocol - a serious breach of trial protocol that is likely to affect to a significant degree, the safety or physical or mental integrity of the participants of the trial; or the scientific value of the trial.

Sponsor - The organisation who takes responsibility for the initiation, management and financing (or arranging the financing) in relation to a clinical trial. The Sponsor organisation has responsibility for carrying out the Sponsor functions of that trial (as defined in the Regulations).

Standard Operating Procedures (SOPs) – "detailed, written instructions to achieve uniformity of the performance of a specific function," SOPs are the base on which Quality Systems and Processes are conducted and monitored against.

The Regulations - The Medicines for Human Use (Clinical Trials) Regulations 2004, transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928. As amended from time to time.

Trial Master File (TMF) - A standard filing system which allows the effective storage and location of essential documents, that is the large volume of regulatory documents and approvals needed for clinical research. The filing system can be in the form of a single project file or a number of files/filing cabinets, depending on what is deemed most appropriate for a particular clinical trial given its size and complexity. The regulatory documents and approvals within the TMF will be maintained alongside case report forms and source documentation.

Vendor/External Vendor – All the various types of providers a Sponsor may delegate their functions to e.g. IMP manufacture and distribution, laboratory sample analysis, consultants, CTUs, statistics, emergency unblinding, database provider, randomisation provider.

2.0 BACKGROUND AND PURPOSE

The sponsor retains ultimate responsibility for the conduct and reporting of clinical trials and must be involved in the identification and negotiations to contract an appropriate vendor. The purpose of this SOP is to describe the procedures for maintaining sponsor oversight of external vendors for trials sponsored by one or more KHP partner Organisations in order to comply with UK Regulations and European Law.

3.0 SCOPE

All clinical trials sponsored by one or more of the King's Health Partner Organisations.

4.0 PROCEDURE

4.1 Vendor Selection

The vendor selection process may begin prior to submission of a grant application. However, it is anticipated that all vendors will be identified and discussed during the trial kick-off meeting if known. The KHP organisations Research Contracts Managers are responsible for ensuring that an appropriate contract is put in place with each vendor. In some cases a Master Service Agreement may already be in place for a vendor.

A risk-based approach will be taken when assessing vendor suitability based on the level of risk associated with the trial and prior experience of the vendor. Documentation to support the vendor selection will be filed in the TMF.

Examples of how to assess the suitability of a vendor include;

- Assessment questionnaires e.g. GCP Compliance Sample Questions document
- Review of vendor SOPs and quality systems
- On-site audit(s) carried out by a suitably qualified person
- Cost
- Level of Insurance cover

Some vendors will be registered with the KHP Organisations and will already have a contract in place via the organisation's Procurement Department. In this case, a new agreement may not be required as long as the existing agreement includes reference to the company providing resources for research activity and this new activity falls within its scope. The KHP-CTO Quality Manager or delegate will contact Procurement to determine whether such a contract can be used.

Within King's Health Partner organisations the vendors are classed as:-

- preferred
- suppliers on existing database/known
- unknown

Suppliers on existing database/known: this vendor has been procured previously and is listed on a database or has previously been known as acceptable to the Sponsor.

Unknown: the Chief Investigator may source a new supplier who has specialist knowledge required for the trial, but is unknown to the sponsor organisation.

Preferred: Supplier under formal agreement e.g. Viapath and ESMS. A new agreement would not be required as long as the existing agreement includes reference to the company providing resources for research activity. However, depending upon the terms of the Master Service Agreement, a trial specific work order or technical agreement may be required.

If the vendor is "unknown" the contracts manager will liaise with the KHP-CTO Quality Manager to assess the suitability of the proposed vendor in question, prior to the contract being executed. For any technical expert advice needed for the assessment, the KHP-CTO Quality Manager and Research Contracts Manager will seek support from associated technical members of the KHP Organisations (e.g. for IMP manufacturing or distribution, the clinical trial pharmacist can be approached).

Depending on the financial value of the contract, a proposed vendor may also need to be assessed through a procurement process as follows:

4.1.1 King's College London Procurement

Please refer to the current purchasing policy and guidance documents for details of purchasing thresholds and procedures:

https://internal.kcl.ac.uk/about/ps/procurement/purchkings/procurement-procedures.aspx.

If purchases over the procurement threshold are being made from a grant then the procurement department must be contacted to check if a quotation or full tender process will be required in order to use a particular vendor.

4.1.2 KHP partner Trust's Procurement

The partner NHS Trusts must adhere to the requirements detailed in the guideline - "Trust Standing Financial Instructions Department of Health, NHS Guide to Procurement 2015". The Research Contracts Manager for the NHS Trust will ensure compliance with the Trust procurement policy. Vendors must be registered on the Trust procurement system.

4.2 Contracts and Agreements

There will be a fully executed contract in place with a vendor prior to any work being undertaken by a vendor.

Contracts will include statements regarding compliance with the protocol (including amendments) and regulations, sub-contracting, delegation of duties between each party, process for the escalation of issues or disputes, and mechanisms for reporting urgent safety measures and serious breaches of GCP to the sponsor. It is also important to consider whether any performance targets should be met and monitored.

4.3 Maintaining Oversight of Vendors

All external providers may be visited to ensure compliance with GCP, the study protocol and applicable regulations.

The KHP-CTO CRA will ensure oversight of academic laboratories and CTUs by conducting an initiation visit and regular monitoring visits to review SOPs and TMF documentation. The number of visits and level of information reviewed during monitoring visits will be assessed using a risk-based approach and this will be documented in the trial specific risk assessment and monitoring plan.

The KHP-CTO CRA will review minutes of Trial Management Group/Trial Steering Committee/Data Monitoring Committee meetings to ensure that any external vendor issues identified have been escalated as per section 4.4.

If trial essential documents are amended during the course of a trial, the impact of the amendment on the contract with the vendor will be assessed by the KHP-CTO Quality Manager (or delegate). If applicable, the Research Contracts Manager will ensure that the contract is amended and fully executed. The KHP-CTO CRA or delegate will ensure that applicable amended documents are provided to the vendor throughout the trial.

If a vendor is unable to produce evidence of compliance with GCP, the study protocol and applicable regulations a suitably trained individual may be requested to conduct a vendor audit on behalf of the sponsor organisation(s).

4.4 Escalation of Issues

There will be clear instructions within the vendor contract detailing the process to be followed in the event of instances of non-compliance or poor performance. Non-compliance issues identified by the KHP-CTO CRA will be reported to the KHP-CTO Quality Manager or Director. Upon receipt of an issue with a vendor the KHP-CTO Quality Manager or Director will discuss the issue with the Sponsor R&D Directors. If the issue is considered a serious breach of GCP, SOP 6.0 "Notification of Serious Breach of GCP or Trial Protocol" will be followed.

5.0 RELATED DOCUMENTS

5.1 GCP Compliance Example Questions

5.2 KCL Procurement Policy

https://internal.kcl.ac.uk/about/ps/procurement/purchkings/index.aspx

5.3 Trust Procurement Policy

5.4 SOP 6.0 Notification of Serious Breach of GCP or Trial Protocol

6.0 APPROVAL and SIGNATURE

19th April 2023

Jackie Pullen
Director
King's Health Partners Clinical Trials Office

Date