# Standard Operating Procedure CCTU/SOP045

# Selection and Use of Vendors

## 1. Scope

The SOP applies to non-standard trial-specific arrangements with vendors and contractors used in Cambridge Sponsored CTIMPs and CCTU led trials.

This SOP does not cover:

- Vendors and contractors for the provision of Investigator Medicinal Products and related services; contact the trial pharmacist
- The selection of participating sites, participating Investigators or research/clinical trial collaborators, nor research activities performed as part of a joint sponsorship agreement
- Procurement processes. This must be discussed and agreed with the Trust Procurement or University Finance office
- The setting up of Contracts contact the R&D Legal Team separately
- The assessment of laboratories

## 2. Purpose

The purpose of this SOP is to:

- Ensure consistency and quality of functions or services
- Ensure the best value for money
- Describe the process for the selection, evaluation, approval and oversight of external vendors(Suppliers) and contractors of functions related to:
    - GCP Understanding and compliance
    - Trial conduct
    - Trial management
    - Trial coordination (i.e. project management, monitoring, laboratory analysis, statistics, data management)
    - Non-standard trial related services (i.e. data storage, data archiving; archiving; sample shipments)

## 3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

### 3.1. Definitions

| Term | Definition |
|---|---|
| Cambridge Sponsored | Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC |

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|---|---|
| | OR<br>Sponsored by: Cambridge University Hospitals NHS Foundation Trust (CUH) or CUH jointly with the University of Cambridge<br>or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge |
| Collaborator | A person or organisation that works jointly on the trial and is wholly responsible for their role in the trial. |
| Vendor / contractor | A person, organisation, or agency that provides functions and services related to the conduct of clinical trials but shall exclude research collaborators and clinical trial sites/investigators. |
| Sponsor | An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a clinical research project or trial. |
| Funder | Any organisation providing funding to conduct a specific clinical research project (i.e. charities; industry; research councils; governmental and non-governmental funding bodies) |
| Non-standard | Refers to new services, new vendors providing services, and new activities carried out by existing approved vendors. A new agreement would normally be required for these new services. |

### 3.2. Abbreviations

| Abbreviation | Meaning |
|---|---|
| CCTU | Cambridge Clinical Trials Unit |
| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| CTO | Clinical Trials Officer |
| CUH | Cambridge University Hospitals |
| IMP | Investigational Medicinal Product |
| R&D | Research & Development |

## 4. Undertaken by

The CCTU Operations director, QA manager, Regulatory team, Chief Investigator and delegated trial team members

## 5. Items Required

TPL084 Initial Vendor Assessment Form

TPL085 Follow up Vendor Questionnaire

## 6. Summary of Significant Changes

Significant update to include procedures for evaluation and assessment of Vendors

Addition of new Vendor selection process flow chart (Appendix 1)

## 7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

## 7.1. Responsibilities

- The Sponsor retains ultimate responsibility for all functions
- The Vendor must show due diligence when performing any functions delegated to them
- The Chief Investigator is responsible for identifying the trial functions that may need to be out sourced to an external vendor and for determining the level of risk associated with the tasks being delegated
- The Chief Investigator or delegate is responsible for selection, and assessment of any vendors they wish to use in their trial, including periodic review of existing vendors
- The Trial Team are responsible for sending updated trial documents to Vendor(s) wherever appropriate

## 7.2. Requirements of Vendor

The Sponsor may delegate certain functions to Vendors

Delegation of duties (e.g. how potential Serious Breaches should be reported to the Sponsor) must be clearly documented and unambiguous

Vendors must have sufficient, demonstrable knowledge and experience to perform their contractual obligations

- Vendors that perform trial-specific responsibilities must be able to demonstrate that they are:
    - Trained to applicable sections of the trial protocol
    - Aware of all relevant trial specific documents (including updated versions of documents implemented during the trial)
    - Where appropriate, trained to CCTU procedures, Sponsor requirements and computer systems
    - In possession of applicable employment documentation for provision of services to the NHS

## 7.3. Identification of a Suitable Vendor

Prospective vendors should be identified as early in the trial set up process as possible.

Vendors should meet the operational requirements of the CCTU. The following criteria may be used to identify suitable Vendors:

- Previous experience with the Vendor
- Approved NHS and/or University suppliers (depending on procurement via Trust or University)
- Recommendations from other users or UKCRC NIHR registered CTUs
- Recommendations by funding body and/or Sponsor
- Recommendations from Chief Investigator or other research team member
- To check if a vendor is an existing or past vendor of the CCTU or the Trust, please contact CCTU QA manager and/or Trust procurement

## 7.4. Assessment of Prospective Vendor (Product or Service)

The ability of a Vendor to provide the service according to specification and on time can be evaluated in several ways, including but not limited to:

- Requesting the provider to complete the Vendor Assessment Form or University equivalent (contact the University research office, this is relevant for procurement only)
- Review of marketing material
- Demonstration of product by the Vendor
- Review of Vendor's policies, procedures and Quality Management Systems
- Ability to meet needs of the trial or department
- Experience and qualifications of staff, including GCP training where applicable
- Company history and stability
- GMP or GLP certification (if applicable)
- Regulatory inspection history
- Capability to deliver within specified time frame
- After sales service including training
- Costs
- Preferred providers list of Trust/University; Sponsor and/or Funder

## 7.5. Vendor Register

- During the initial trial set-up and throughout its conduct, trial teams should identify the Vendors they wish to use
- In the first instance check the supplier Module in Q Pulse to determine whether a previous assessment has been carried out by the CCTU and to determine if further assessment is required
- The QA manager/designee will maintain a central register within the Q-Pulse Supplier module of vendors used by the CCTU

### 7.5.1. New Vendors:

When evaluating a new Vendor, the trial team must conduct an assessment of each prospective party before they can be used within a trial.

- For IMP-related services contact the trial Pharmacist
- All other new vendors must complete a:
  - Vendor Assessment form (TPL/084)
  - This must then be reviewed by the QA manager or Regulatory team
  - For each new Vendor this must include the decision with rationale to award the contract
  - The vendor will be added to Q Pulse
  - The assessment will be signed off electronically in Q Pulse using the note box in properties

### 7.5.2. Existing Vendors:

- If the proposed Vendor has supplied the same service to another trial and the Vendor Assessment Form TPL084 was completed within the past 12 months this may be used to support the current proposal. Confirm with the QA manager
- Where TPL084 has been completed outside of this period, a follow up Questionnaire (TPL085) must be submitted
- Where a proposed Vendor has supplied a different service a new Vendor Assessment Form for the new service must be completed
- The CTC will facilitate the process by sending the appropriate documents to the proposed vendor
- For CTIMPs the completed forms must be sent to the CCTU Regulatory Team for other CCTU led trials they must be sent to the CCTU QA manager
- Assessment forms must be reviewed prior to including the Vendor in any trial. The reviewers will advise if any supporting documentation is required

Once agreed the completed forms must be:

- Filed in the appropriate section(s) of the TMF
- Filed in the Sponsor file
- Added to the supplier module in Q Pulse

## 7.6. Amending an Existing Vendor

- Where an existing Vendor supplies a new service during the course of the trial the Vendor will be asked to complete a new Vendor Assessment Form providing information on the new service only
- The new Vendor Assessment Form must be sent to the CCTU Regulatory Team or QA manager for review and subsequent filing and update in Q Pulse
- The trial risk assessment form should be updated if necessary and reviewed and agreed by the relevant trial team members and Sponsor representative

## 7.7. Contracts

Once a Vendor has been selected to provide a service:

- An appropriate contract between the Sponsor and the Vendor must be negotiated by the appropriate legal team
- Fully executed contracts will be retained by R&D Legal. It is the responsibility of Chief Investigator or delegate to review the contract following protocol amendments, updates to relevant legislation or changes to the quality system to ensure the contract remains current

## 7.8. Procurement of Product/Service

- For trials where the research grant is held at Cambridge University Hospitals NHS Foundation Trust or the trial is Cambridge Sponsored follow the Trust procurement process via the Trust's procurement department (Procurement@addenbrookes.nhs.uk)
- For trials sponsored or jointly sponsored with CPFT, contact the CPFT R&D for further guidance

- For trials where the research grant is held at the University, the University procurement process must be followed
- The relevant Clinical School Departmental administrators will provide assistance with the ordering process. Refer to the University's finance department https://www.finance.admin.cam.ac.uk/policy-and-procedures/financial-regulations/f-purchasing
- The relevant department will:
    - Assist with setting up a Purchase Order (where necessary)
    - Negotiate costs with supplier/Vendor
    - Design service specifications
    - Place the order

## 7.9. Maintaining Oversight and On-going Vendor Assessment

The process of ensuring Vendor oversight and the associated risk rating must be clearly documented in the TMF and Sponsor file.

This can be carried out by methods such as:

- Regular communications with the Vendor (e.g. teleconferences or regular meetings). A formal communication plan can be developed to define the level and frequency of communication between parties
- Review of specific activities
- Regular written update reports from the Vendor
- Periodic review of the standard of work completed to date including frequency of review

- Any correspondence pertinent to the Vendor's involvement within the conduct of the trial must be filed in the TMF and a copy provided to the CCTU regulatory team for filing in the Sponsor file
- The QA manager / designee will ensure that Follow up Vendor Questionnaires (TPL085) are completed and kept in Q-Pulse. This task may be delegated to specific relevant member of a trial team
- The form will be reviewed by the QA manager/designee. If there have been no changes since the previous assessment the form will be filed and the process repeated as required
- If any changes have occurred in the past year then the changes should be evaluated for their impact on the trial(s)

## 7.10. Filing Requirements

- Documents generated by the Vendor relating to their conduct within the trial must be contained within the TMF

# 8. Monitoring Compliance with and the Effectiveness of this Document

### a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

### b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

# 9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.

MHRA, Good Clinical Practice "Grey Guide"

# 10. Associated Documents

R&D/SOP005 Management of Contracts for Research Projects

http://connect/index.cfm?articleid=9719 Procurement website

# 11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

# 12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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# Appendix 1: New Vendor selection process flow chart