Hertfordshire Hospitals R&D Consortium
Incorporating West Herts Hospitals NHS Trust and East & North Herts NHS Trust

VENDOR ASSESSMENT

Research & Development

Standard Operating Procedure for Selection and Oversight of External Vendors for East & North Hertfordshire NHS Trust/ West Hertfordshire Hospitals NHS Trust sponsored Clinical Trials

SOP Number : gSOP-32-02	**Effective Date:** 1-Oct-2014
Version Number: v02	**Review Date:** + 2 - 3 years

1. BACKGROUND

This Standard Operating Procedure (SOPs) describes the process for selection and oversight of external vendors for East & North Hertfordshire NHS Trust (ENHT)/ West Hertfordshire Hospitals NHS Trust (WHHT) sponsored Clinical Trials. SOPs are required to assist Researchers for conducting research in accordance with the principles of ICH Guidelines for Good Clinical Practice (ICH GCP, 1996 version), the UK Medicines for Human Use (Clinical Trials) Regulations 2004 and Amended Regulations (2006), the European Clinical Trials Directives and the Research Governance Framework for Health and Social Care in England Version 2.

The Sponsor may delegate a significant proportion of the functions (e.g. project management and monitoring) or may only delegate discrete activities (e.g. laboratory analysis, data management and statistics). Regardless of the duties delegated to external vendors/ third parties, the Sponsor retains ultimate responsibility for the clinical trial and must maintain sufficient oversight of all external vendors to ensure compliance with the legislation and GCP.

Although the Sponsor retains ultimate responsibility for all functions, all vendors must show due diligence when performing any functions that have been delegated. All persons involved in the conduct of a clinical trial have a legal responsibility to comply with GCP, the protocol and the terms of the MHRA authorisation and favorable REC opinion.

2. PURPOSE

To define the process for ENHT/ WHHT:

- To select, approve and maintain oversight of external vendors and contractors of functions related to the trial conduct, trial management, trial coordination (i.e. project management, monitoring, laboratory analysis, statistics, data management); of trial related services (i.e. data storage, data archiving; archiving; sample shipments); and of trial related products (i.e hard and soft ware; consumables; printing; medical photography; medical devices; temperature monitors)

- To ensure consistency and quality of functions, services or products
- To ensure the best value for money

3. APPLICABLE TO

Any Trust employee involved with Clinical Trials sponsored by ENHT/ WHHT including, Unit Heads, Chief Investigators (CI), Principal Investigators (PI), Consultants, Co-investigators, Research Fellows, Clinical Trial Pharmacists, Research Managers, Statisticians, research nurses, allied health professionals, Trial Coordinators, the Research & Development Steering Group (RDSG) & Data Managers.

4. RESPONSIBILITIES

The Sponsor/ Research & Development Steering Group (RDSG) shall provide oversight of the selection of external vendors used for ENHT/ WHHT sponsored clinical trials. It is the responsibility of the Sponsor, in collaboration with the Chief Investigator of the study to determine the level of risk associated with the tasks being delegated as well as the method to be used in order to assess the suitability of the vendor. Once a vendor has been selected to perform the delegated function(s) from the Sponsor, the rationale for selection and the final decision should be clearly documented.

1. Where there is co-sponsorship the RDSG shall assess the suitability of the co-sponsor and the division of responsibility (Reference section 5.1 and 5.2).

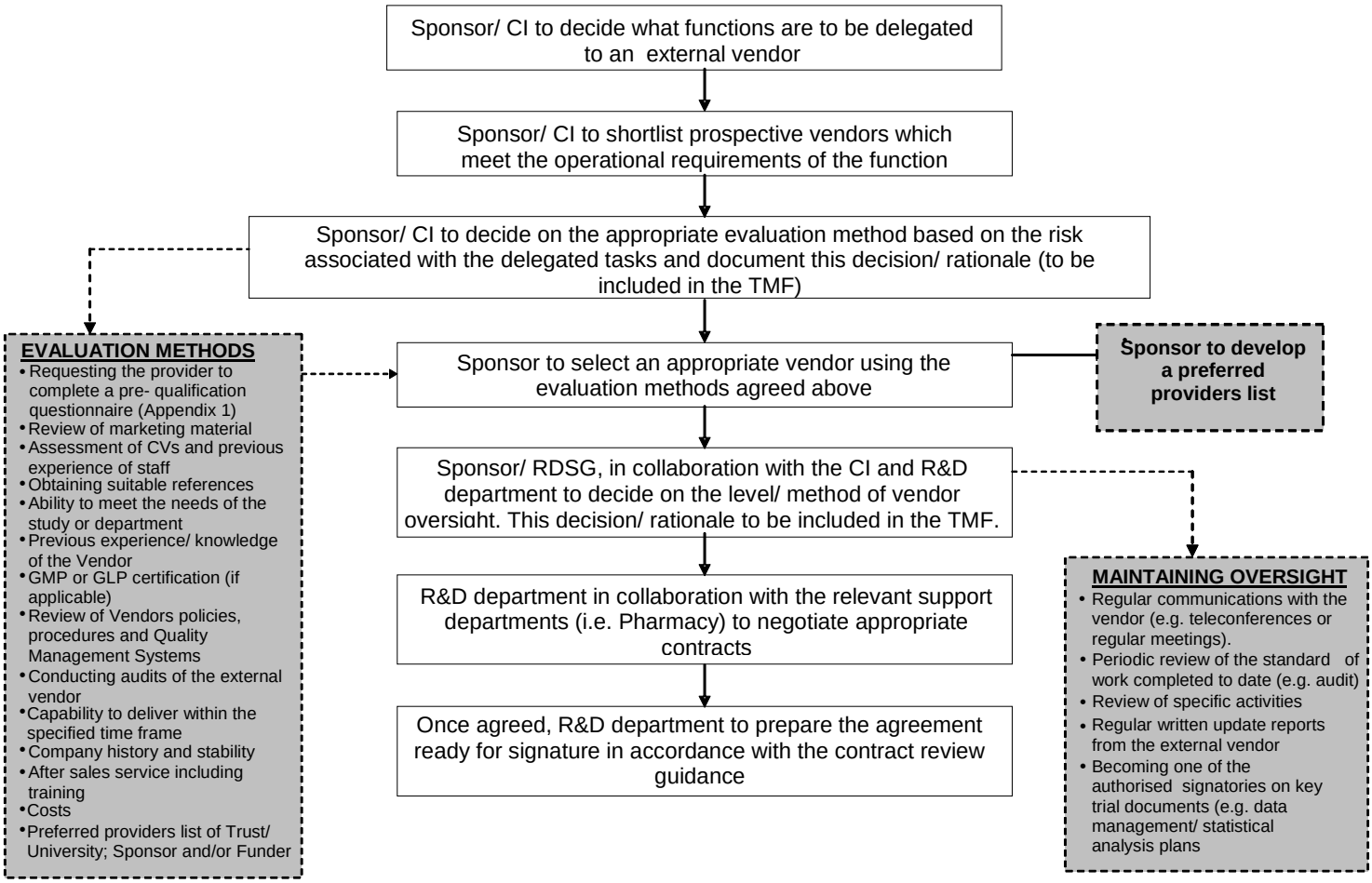
2. Where there are delegated Sponsor responsibilities the R&D Department shall approve the feasibility and funding arrangements for the delegated roles.

The Chief Investigator is responsible for identifying what trial functions may need to be delegated to an external vendor and for determining the level of risk associated with the tasks being delegated.

The R&D Department is responsible for providing advice and support on the selection and oversight of external vendors and ensures appropriate contracts between the Sponsor and the Vendor is in place prior to commencement of the work. In addition it is the responsibility of the R&D department to maintain sufficient oversight of contracts by reviewing any contracts following protocol amendments, updates to relevant legislation or changes to the quality system.

5. PROCEDURE

The process of vendor oversight begins with the selection of a suitable vendor. As such, all vendor suitability should be assessed by the R&D Department and reported to the RDSG prior to the signing of contracts. The selection process (including the method used), rationale for the selection and level of oversight must be clearly documented and maintained in the Trial Master File (TMF).



5.1 Identification of a Suitable External Vendor

A shortlist of prospective Vendors, which meet the operational requirements of ENHT / WHHT, can be identified using the following criteria:

- Previous experience with the Vendor
- Approved NHS and/or University suppliers
- Recommendations from other users or UKCRC NIHR registered Clinical Trials Units
- Recommendations by funding body and/or Sponsor

5.2 Evaluation and Selection of External Vendors

Where ENHT/ WHHT are delegating a significant proportion of functions or a discrete activity to an external vendor, the following methods can be used to assess the suitability of shortlisted vendors.

- Requesting the provider to complete a pre-qualification questionnaire (Appendix 1)
- Review of marketing material
- Assessment of CVs and previous experience of staff
- Obtaining suitable references
- Ability to meet the needs of the study or department
- Previous experience/ knowledge of the Vendor
- GMP or GLP certification (if applicable)
- Review of Vendors policies, procedures and Quality Management Systems
- Conducting audits of the external vendor
- Capability to deliver within the specified time frame
- Company history and stability
- After sales service including training
- Costs
- Preferred providers list of Trust/ University; Sponsor and/or Funder

The method used for assessing the suitability of a vendor will vary depending on the risk associated with the tasks being delegated and previous experience/ knowledge of the vendor. Where a vigorous selection process has not been performed, this can result in non compliance with the legislation and GCP (Reference: Appendix 2).

It is the responsibility of the Sponsor/ RDSG, in collaboration with the Chief Investigator of the study to determine the level of risk associated with the tasks being delegated as well as the method to be used in order to assess the suitability of the vendor. The process of Sponsor oversight of Vendor selection/ contracts must be clearly documented in the TMF.

In instances where the Sponsor has previous experience/ knowledge of an external vendor or where an external vendor has already been pre-qualified, a preferred providers list may be developed.

5.3 Oversight of External Vendors

Once the vendor has been selected, the Sponsor/ RDSG, in collaboration with the CI and R&D department will need to consider how oversight of the external vendor's activities are maintained to ensure compliance with the terms of the contract, the study protocol, GCP and the applicable regulations.

This can take the form of:

- 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.

- Periodic review of the standard of work completed to date (e.g. audit) including frequency of review

- Review of specific activities

- Regular written update reports from the external vendor

- Becoming one of the authorised signatories on key trial documents (e.g. data management/ statistical analysis plans)

- Developing an escalation plan for reporting significant non compliance issues. This should also be reflected in the contract between the Sponsor and external vendor.

- Developing a procedure for the flow of information and appropriate key trial documents (e.g. Investigator's Brochure updates, safety updates, copies of the protocol, written procedures). As above, this responsibility should be clearly detailed in the contract between the Sponsor and external vendor.

If the Sponsor decides that the level of oversight will take the form of regular written update reports, it will be the responsibility of the R&D department to obtain and review all reports from external vendors. Should significant concerns be raised, the Research & Development Steering Group (RDSG) are responsible for reviewing and recommending any appropriate corrective and preventative measures.

Regardless of the oversight methods used, a vendor oversight programme should be clearly defined prior to the commencement of clinical trial activities and filed in the TMF.

5.4 Contracts with External Vendors

After the selection of an external Vendor, appropriate contracts between the Sponsor and the vendor must be negotiated by the R&D department in collaboration with the relevant support department (i.e. Pharmacy) prior to commencement of the work.

All contracts should clearly define the following information:

- The delegated tasks

- The duties/ functions agreed between parties

- The required standards of service (i.e. which applicable laws, guidance and procedures to be adhered to)

- Clear instructions that the contract should not take precedence over the protocol

- The process for further sub-contracting by the vendor to ensure that sub-contracting does not occur without the Sponsor's prior knowledge or approval

- The flow of relevant safety information and how this will be provided (e.g. from IMP suppliers to the Sponsor)

- Procedure for informing the Sponsor of any protocol non compliances/ Serious Breaches.

- Procedure for informing the Sponsor of any routine statutory inspections.

Once a contract is executed, processes should ensure that the contracts remain current and that the requirements of the contract are being met by all parties (Reference section 5.3: oversight of external

vendors). It is the responsibility of the R&D department to maintain sufficient oversight of all contracts between external vendors. In addition the R&D department are responsible for reviewing such contracts following protocol amendments, updates to relevant legislation or changes to the quality system to ensure the contract remains current.

The preparation, review and execution of all contracts should follow the R&D contract review guidance.

5.5 Procurement of Product

For Trust Sponsored studies where the Research grant is held by the Trust, procurement of product should follow the Trust procurement procedures.

5.6 Procurement of IMP

For Trust Sponsored CTIMPs the procurement of IMP must be managed in liaison with the Clinical Trials Pharmacist.

IMP is managed only in accordance with the Pharmacy policies and procedures.

6.0 RELATED SOPS & DOCUMENTS

Contract review guidance
RDSG terms of reference and supplementary guidance
gSOP-06 TMF
Trust procurement procedure

7.0 DEFINITIONS

Acronym	Definition
CI	Chief Investigator
R&D	Research & Development
RDSG	Research & Development Steering Group
REC	Research Ethics Committee
Sponsor	An individual company, institution or organisation that takes responsibility for the initiation, management and/or financing of a clinical trial
Vendor/ External Vendor	All the various type of providers a Sponsor may delegate their functions to (e.g. Contract Research Organisation, Laboratory, Consultant, Freelancer/ Contractor) excluding Research Collaborators and Clinical Trial Sites.
Funder	Any organisation providing funding to conduct a specific clinical research project (i.e. charities, industry, research councils, governmental and non governmental funding bodies)

8.0 AUTHORISATION & AGREEMENT

Author

Signature **Date**

R & D Board Approval

Signature **Date**

VERSION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**
gSOP-32-02	**22/05/2014**	Minor amendments following review
gSOP-32-01		SOP written for implementation at ENHT/WHHT.

Please detach and retain in your training files

I have read and understood the contents and requirements of this SOP and accept to follow by Trust policies in implementing it.

Recipient

Signature: ……Date: ……..

Name & Position: ……

Appendix 1: Example pre-qualification questionnaire

Vendor Assessment

The following to be reviewed

Review of marketing material	
Review of Details of product	
Review of vendor policies, procedures and Quality Management Systems	
Ability to meet needs of project or department	
Experience and qualifications of staff	
Company history and stability including financial viability	
CE marking (if applicable)	
Capacity to deliver within the required time frames	
After sales service including training	
Cost	
Is Vendor on Preferred provider list	
Summary of any recent inspectors or auditors	
Awareness of all relevant study specific documents	
Understanding of sponsor requirements regarding computer systems (if applicable)	
CRB cleared if working with patient related data (if applicable)	
Provide CV's if applicable	

Appendix 2: Examples of inadequate assessment of the vendor's suitability by a Sponsor

#	Description
1	The Investigational Medicinal Product is manufactured by an external Contract Manufacturing Organisation (CMO) however neither the CI or R&D office has assessed the Vendor's suitability. The CMO has been selected based on informal recommendation only. As a result, the IMP is not labelled according to the Clinical Trial Authorisation nor is it Annex 13 compliant.
2	The R&D office is unaware that the investigator has organised an external laboratory to analyse samples and neither party assesses whether the laboratory could perform this activity in compliance with GCP. As a result, samples are analysed using a non-validated method and the results are unreliable and cannot be used. This is a primary end-point of the study.
3	A Sponsor conducts an audit of a CMO and identifies that is has a number of issues related to randomisation activities; however the Sponsor fails to follow-up on these issues before contracting the CMO. As a result, the CMO assembles subject kits in such a way that the randomisation allocation of the kits is incorrect.