JOINT RESEARCH AND DEVELOPMENT OFFICE

Somers Clinical Research Facility

Vendor Management for GOSH Sponsored Clinical Trials

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Revision History			
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1. Scope /Background

This SOP is applicable to all the clinical trials sponsored, co-sponsored by Great Ormond Street Hospital. The SOP is applicable to Chief Investigators (CI), delegated trial team members involved in Trust-sponsored CTIMPs and the Joint R&D Office Clinical Trials, contracts and Grants Team with responsibility for performing sponsor activities on behalf of the Trust.

2. Legal basis

The legal basis for this OP is Council Directive 2001/20/EC[1] (Article 15). This Directive (published in 2001) is also known as the Clinical Trials Directive (CTD) and relates to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use. In the UK the CTD was transposed into law by the 'The Medicines for Human use (Clinical Trials) Regulations 2004: SI 2004 No 1031[2]. The UK Regulations took effect on 1 May 2004 and then further amendments.

3. Purpose

The purpose of this SOP is to describe the process for the selection, approval and oversight of external vendors to provide a service to support research sponsored by GOSH.

4. Definitions

A vendor is a person, organisation or agency external to GOSH that provides functions, services or products related to the conduct of studies that are sponsored by the Trust. It does not include research collaborators or other trial sites.

5. Personnel responsible

Sponsor has the overall responsibility to facilitate the appropriate oversight of contracted vendors, but for CTIMPs management of vendors may be delegated to the Chief Investigator via sponsor-CI agreement.

The Head of Governance, Clinical Trials and Contracts and Clinical Trials Manager will be involved in the selection, audit, and approval (and disqualification) of vendors. Joint R&D office Contracts Manager will provide contract/legal advice, review, negotiate and draft non-standard agreements and maintain the final signed contracts in ReDA and R&D shared drive folder.

The Deputy Director of R&I will provide final approval or disqualification of all vendors by signing the agreement.

6. Procedure

6.1 Identification of a Suitable Vendor

During the protocol development stage, areas that need external support will be identified. Chief Investigator (CI) must inform the Joint R&D Office Clinical Trials team where the external support is required for the delivery of the protocol. The joint R&D Office will decide upon the services or professional expertise required for the evaluation of the performance of the specific task requested by the vendor.

6.2 Initial Vendor Evaluation

For GOSH sponsored CTIMP, the evaluation of vendors must be assessed during the feasibility stage of the sponsorship review process according to the SOP for Non-commercial clinical trials of IMP (CTIMPs) sponsorship (single/multicentre trials) GOSH/ICH/05/CT01

A variety of assessment methods can be considered when assessing the suitability of a vendor. The evaluation of the vendor can be performed by one or more of the following methods:

- Completing a R&I Vendor Assessment Questionnaire (Appendix 1)
- Ability to meet needs of the study or department on time
- assessment of previous experience via CVs
- referring to prior knowledge of the vendor from use in other trials
- Assessing quality system/written procedures/SOPs
- Company history and stability
- Costs
- conducting audits

If a vendor questionnaire is required, the Clinical Trials Manager will request the vendor to complete the vendor assessment questionnaire. Based on the content of the completed questionnaire, a further audit of the vendor quality system may be required according to the R&D office operating procedure -Audit GOSH/ICH/13/RG30). This audit can be subcontracted to an external party. CI should make sure the costs for the vendor audit is included in the grant application.

Based on a successful vendor evaluation, a contract may then be placed with the vendor.

6.3 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. 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. There must be clear instructions within the contract detailing the processes to be followed in the event of problems or issues identified.

6.4 Maintaining oversight of Vendors

CI is responsible for on-going oversight of vendors. CI should ensure that s/he 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. If the vendor proposes to make changes to their written procedures or SOPs which affect the trial, then the sponsor should be notified. This should be detailed in the contract. The communication plan between the CI/sponsor and the vendor will be reviewed at Sponsorship Risk Assessment stage.

Effective oversight can be achieved through regular teleconferences, face to face meetings or review of specific milestone activities. It must be clearly documented (including the outcome of any discussions) and retained in the TMF.

During the study monitoring conducted by the sponsor, vendor performance will also be monitored.

R&D Clinical Trials Team and Contracts Team will keep a log of approved vendors under I:\R and D\Shared Folders\Clinical_Trials_B_Patel\CTIMPs\31 Approved Vendors . This will enable the identification of suitable vendors for future studies. If vendors are selected from this list and there was no issues identified in the past then further evaluation of the vendor may not be necessary.

6.5 Escalation of Issues

If the vendor represents an unacceptable risk to the conduct of the study then the CI should discuss the status of the vendor with the Joint R&D Office Clinical Trials Team.

The Head of Governance, Clinical Trials and Contracts and/or the Deputy Director of R&I and the CI will make the final decision on vendor disqualification. The R&I Contracts team must be informed of potential vendor disqualification in order for the contract agreements to be terminated.

The Vendor Disqualification Correspondence should be documented in the Trial Master File.

7 Associated documents and SOPs*

Document Name	File Path	Author
Appendix 1 R&I Vendor Questionnaire	Available Upon Request from Joint R&D Office	Praseeda Thaikalloor

8 Recommendations

NA

9 References

DIRECTIVE 2001/20/EC of the European Parliament and of The Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. *Official Journal of the European Communities*, 1 May 2001; L121/34-44.

MHRA Good Clinical Practice Guide, 2012

Statutory Instrument 2004 No. 1031. The Medicines for Human Use (Clinical Trials) Regulations 2004. The Stationary Office Limited. ISBN 0110490487.

10 Appendices

*all these documents are available electronically