Vendor Management

NJRO-REG-SOP- 014

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1. Background/Introduction

The Sponsor must ensure oversight of all study activities. A research study may require services that the sponsor is unable to perform in-house thus requiring the sponsor to contract the service out. The vendor must be suitable to carry out the delegated tasks and must show due diligence when performing the required service though the sponsor retains responsibility. The sponsor must ensure that conditions and principles of Good Clinical Practice (GCP) are satisfied and adhered to and the trial is conducted in accordance with the protocol and subsequent amendments.

To ensure the study runs efficiently and compliance is maintained with the current protocol and all associated regulatory approvals, appropriate contracting should be in place with all applicable vendors. This ensures each vendor is clear on their responsibilities and commits to achieve the required work, standard and timescales.

2. Purpose

This Standard Operating Procedure (SOP) is to describe the process for the selection, approval and oversight of external vendors to provide a service to support research sponsored by The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH).

3. Scope of Document

The SOP is applicable to Chief Investigators (CI) and delegated trial team members conducting research studies sponsored by NuTH where a vendor will be required. Where duties are delegated to a Clinical Trials Unit (CTU), the SOP is also applicable to members of the CTU responsible for vendor management/oversight.

Members of the Regulatory Compliance Team (RCT) with responsibility for performing sponsor activities on behalf of NuTH must also abide by this SOP.

4. Definitions

A Vendor is a person, organisation or agency external to NuTH that provides functions, services or products related to the conduct of studies that are sponsored by NuTH.

5. Roles & Responsibilities

It is the overall responsibility of the sponsor to facilitate appropriate selection, approval and oversight of contracted vendors, although some tasks may be delegated to the CI, CTU or equivalent trial management team.

Where responsibility has been delegated to a CTU, this SOP must be followed. However it is acknowledged that CTUs may have their own SOPs and associated processes for managing their third party vendors, and further information may be requested by the sponsor team regarding these to ensure Sponsor and CTU processes align.

Responsibilities delegated to the CI and/or CTU will be clarified within the sponsor Delegation of Duties Agreement.

6. Procedures

6.1. Identification of a Suitable Vendor

During the development stage of a protocol, functions, services or products that are not accessible from within NuTH will be identified. Where external support is required for the delivery of aspects of the protocol, the CI or delegate must inform the relevant sponsor team (see below) in order to seek advice and agreement regarding the use of potential vendors:

- CI or delegate to inform the Regulatory Compliance Team (RCT) for high risk studies via tnu-tr.sponsormanagement@nhs.net
- CI or delegate to inform the Research Governance Team (RGT) for low risk studies via nuth.nuthsponsorship@nhs.net

This is particularly essential for Clinical Trials of Investigational Medicinal Products (CTIMPs), Advanced Therapy Investigational Medicinal Products (ATIMPs) and clinical investigations of medical devices.

It is acknowledged that initial discussions between the CI (or delegate) and sponsor team regarding potential vendors may have already taken place during the funding application stage if potential vendors had already been identified by the CI at this point. If this is the case, these discussions will continue and any potential vendors will be identified and assessed (where appropriate).

A variety of assessment methods can be considered when assessing the suitability of a vendor – examples are listed below:

- Completing a vendor assessment report
- Assessing vendor quality systems/written procedures/SOPs
- Assessment of CVs and previous experience/training
- Referring to prior knowledge/experience of the vendor from use in other studies
- Conducting audits of the external vendor
- Relevant licensing and/or accreditations
- Adequate facility, equipment and staffing to meet the needs of the study.

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 GCP.

It is the responsibility of the sponsor in collaboration with the CI (or delegate) to determine the level of risk associated with the tasks being delegated. Input from the NJRO Quality Assurance (QA) team may also be sought.

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.

6.2 Vendor Assessment Report

6.2.1 Vendor Assessments conducted by the Regulatory Compliance Team (RCT) for NuTH Sponsored, High Risk Trials

Once a potential vendor has been identified and where the sponsor determines the most appropriate vendor assessment method should incorporate the vendor assessment report, this will be sent to the vendor for completion.

The vendor assessment report will be completed by the vendor and once finalised must be sent returned to the RCT for sponsor review via the following e-mail address: tnu-tr.sponsormanagement@nhs.net

The RCT will then acknowledge receipt of the report and complete a sponsor review. Follow up will take place with the CI, trial management team (if applicable) and/or vendor if specific concerns or queries are raised. The Quality Assurance (QA) team (where required) will provide feedback/input in to the sponsor review. Appropriate actions will then be taken as required (e.g. approval of the vendor, requests for further information, objection etc.).

The vendor may provide an alternative vendor assessment if this is their standard practice, however the sponsor team may submit requests for additional information where necessary.

Some examples of when the RCT may complete a vendor assessment include (please note that this is not an exhaustive list):

- Vendors involved in primary & secondary outcomes.
- Key trial activities deemed critical to the outcome of the study e.g. IMP, randomisation, database, eCRF, translation services.
- Others, as deemed appropriate.

Where CTUs utilise third parties to complete their delegated duties, the CTU retain responsibility for conducting the relevant vendor assessments and putting in place appropriate agreements. This is documented in the sponsor Delegation of Duties Agreement. Copies of these assessments along with associated contracts may be requested by the sponsor team for oversight purposes.

6.2.2 Vendor Assessments conducted by the Research Governance Team (RGT) for NuTH Sponsored, Low Risk Trials

Where the RGT feel it is appropriate to conduct a vendor assessment, the vendor assessment report (or equivalent documentation) will be sent to the vendor for completion. This may be in the form of sponsor queries via email correspondence.

The report (or sponsor queries) will be completed by the vendor where applicable and returned to the following e-mail address: nuth.nuthsponsorship@nhs.net

The RGT will acknowledge receipt of the report (or responses to queries raised), and these will be reviewed by the sponsor representative and appropriate feedback returned.

Appropriate actions will then be taken as required (e.g. approval of the vendor, requests for further information, objection etc.).

6.3 Contracting

After the review of an external vendor, a Technical Agreement may be used (where deemed necessary) to detail the responsibilities of the vendor and the sponsor in relation to the outsourced work.

Where a Technical Agreement is deemed necessary by the sponsor team, this will be sent to the vendor and completed with input from both the sponsor (and/or delegate) and vendor.

The Technical Agreement will clearly define the following information:

- The delegated tasks
- The duties/functions agreed between parties
- The required standards of service
- 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.
- Procedure for informing the sponsor of any protocol non-compliances/serious breaches.
- Procedure for informing the sponsor of any routine statutory inspections.

Once the Technical Agreement has been agreed and fully executed, appropriate processes will ensure that the agreement remains current and that the requirements of the agreement are being met by all parties. It is the responsibility of the sponsor or delegated CTU to maintain sufficient oversight of all Technical Agreements between external vendors.

In order to minimise delays, activities may be undertaken by vendors prior to a fully executed Technical Agreement being in place, however, if this is the case it is important that this is discussed with the sponsor team and sponsor approval to proceed is obtained.

Where the Technical Agreement duplicates or conflicts with information already contained within other agreements (e.g. sponsor Delegation of Duties Agreement), alternative agreements may be implemented or documentation already in place may be deemed sufficient. In such cases where the sponsor confirms a Technical Agreement is not required (e.g. such as when a NuTH contract is already in place with the vendor that covers the information contained within the Technical Agreement), a file note will be saved in the SOF to document why a Technical Agreement is not required.

It is also important to note that where CTUs utilise third parties to complete their delegated duties, the CTU retain responsibility for conducting the relevant vendor assessments and putting in place appropriate agreements. Copies of these assessments/contracts may be requested by the sponsor team for oversight purposes.

6.4 Maintaining Oversight of Vendors

Ongoing oversight of applicable vendors will be ensured and must be clearly documented and retained in the Sponsor Oversight File (SOF).

It is important that the CI, CTU or delegate ensures that vendors are provided 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.

7. References

The Medicines for Human Use (Clinical Trials) Regulations 2004, Part 4, Regulation 28, Schedule 1

The Medicines for Human Use (Clinical Trials) Regulations 2004, Part 4, Regulation 29

ICH GCP E6 (R2) guidelines and addendum, 2017

8. Appendices

8.1 Appendix 1 – Vendor Assessment Report