1. BACKGROUND/INTRODUCTION

Selection of vendors and investigator sites follows a similar process in that they are both required to demonstrate their qualifications and experience prior to being included in a research study. It is essential that a robust appraisal of external vendors and investigator sites is performed as the responsibility for their conduct lies with the research sponsor. A thorough selection process and ongoing oversight minimises the risk of any breaches to the protocol, the favourable ethical opinion, applicable regulations or Good Clinical Practice (GCP).

2. PURPOSE

This Standard Operating Procedure (SOP) describes the processes used for identifying and selecting an external vendor to aid in the conduct or management of a clinical research study and the selection of investigator sites for multicentre studies. It also specifies the procedures to be followed when The Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH FT) is research sponsor.

This SOP does not describe the procurement process for Investigational Medicinal Product (IMP), which is performed by NUTH FT Pharmacy.
3. SCOPE

The SOP is applicable to Chief Investigators (CI) and delegated trial team members conducting research studies sponsored by NUTH FT where an external vendor will be employed or where external investigator sites will be identified. Where this responsibility is delegated to a Clinical Trials Unit (CTU), the SOP is also applicable to the assigned Trial Manager.

Members of the NUTH FT Research & Development (R&D) Team with responsibility for performing sponsor activities on behalf of NUTH FT must also abide by this SOP.

4. PROCEDURE

4.1. Selection and Oversight of Vendors

4.1.1. Vendor Selection

Sponsors can employ a number of methods for identifying and assessing the suitability of a vendor. For those studies where NUTH FT is sponsor, identification and assessment will be by the CI with overview and input from sponsor representatives. Vendors may be identified either by open tender, positive past experience with that vendor or upon recommendation from a trusted source.

Vendors must be evaluated by one of the following methods:

- Completion of a pre-qualification questionnaire
- Review of information supplied by potential vendor
- Review of the vendor’s procedures and quality management systems
- Audit of the vendor’s facilities
- Review of the vendor’s performance in other research studies

Any outstanding queries or audit findings must be resolved prior to confirming vendor selection and the selection process must be documented.

For those studies sponsored and funded by NUTH FT the selection of vendors must comply with NUTH FT’s Standing Financial Instructions Policy.

4.1.2. Contracts

Once a vendor has been selected a contract must be put in place prior to the start of any delegated tasks. This contract should detail the delegated tasks and duties and the required standards for the work.
For studies sponsored by NUTH FT, this contract must be negotiated by the sponsor representative with input from the Newcastle University legal services (when Newcastle University are party to the contract). Contracts must be executed by one of the approved signatories for NUTH FT. Investigators cannot negotiate and sign these contracts on behalf of the Trust.

An original copy of this contract must be filed in the Trial Master File (TMF).

4.1.3. Vendor Oversight

There should be ongoing oversight of the vendor’s activities 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) or periodic review of the standard of work completed to date (e.g. audit).

For studies sponsored by NUTH FT, vendor oversight is delegated to the CI or the applicable Trial Manager. Any concerns regarding a vendor must be escalated to NUTH FT R&D immediately for consideration and to determine if investigation is required.

4.2. Selection and Oversight of Research Sites

Prior to selecting a research site for a multicentre study, an assessment of the suitability of the site must be conducted. This is essential to reduce the risk of the site underperforming and also to reduce the risk of breaches to the protocol or GCP. Research site assessment can be performed by completion of a site feasibility questionnaire and/or a visit to the site itself to assess the facilities along with the experience, qualifications and capacity of the site team.

For those studies sponsored by NUTH FT, all identified potential sites must complete a feasibility questionnaire. The completed questionnaire must be reviewed by the CI (supported by the trial team) prior to the site being officially chosen.

Selected sites must go through the relevant approval process. Before opening to recruitment, each site must be initiated (e.g. through a site initiation visit or initiation teleconference). The initiation process must be documented and filed within the TMF.

Oversight of the research site must be conducted in accordance with the agreed Monitoring Plan and any issues with the site must be escalated to the NUTH FT R&D Team immediately for consideration and possible investigation.
5. REVIEW AND MONITORING OF THIS DOCUMENT

This SOP will be reviewed every 2 years or more frequently in response to changes to the legislation or guidelines. The use of this SOP will be monitored on an ongoing basis and during the annual audit cycle.

6. REFERENCES


7. APPENDICES

N/A