Nottingham University Hospitals NHS
NHS Trust

STANDARD OPERATING PROCEDURE

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1. Document History

Version Number	Issue Date	Reason for Change
1	30th May 2014	Original SOP.

2. Introduction

Sponsors must ensure oversight of all study activities. A clinical study may require services that the sponsor is unable to perform in-house thus contracting the service from different departments, institutions or commercial entities (known as a 'vendor', or sometimes a supplier or third party service provider). 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 in accordance with Good Clinical Practice (GCP).

To ensure the study runs efficiently and achieves its milestones and deliverables, a contract with Nottingham University Hospitals NHS Trust (NUH) should be agreed with all vendors. This ensures each vendor is clear on their responsibilities and commits to achieve the required work, standard and timescales.

3. Purpose and Scope

This standard operating procedure (SOP) is to define the processes necessary to select and evaluate current and potential vendors to provide services for research studies involving the use of medicinal product, including but not limited to clinical trials of investigational medicinal product (CTIMPs), which require approval by the United Kingdom (UK) competent authority (CA).

The SOP describes the procedures that must be followed by all NUH staff for the selection and evaluation of vendors prior to placing a contract, in order to ensure that the vendor meets NUH business needs and expectations.

Throughout this SOP the term vendor shall be used to cover suppliers and third party service providers.

4. Responsibilities

Sponsor (fulfilled by the Research and Innovation (R&I) department on behalf of NUH as sponsor)
It is the overall responsibility of the Sponsor to facilitate proper oversight of contracted vendors, but some tasks may be delegated to the Chief Investigator (CI).

The R&I Head of Regulatory Compliance (HRC) and Quality Assurance Auditor (QAA) will be involved in the selection, audit, and approval (and disqualification) of vendors, and will maintain the Approved Vendor List.

The R&I Research Contracts Manager (RCM) will provide contract/legal advice, review, negotiate and draft non-standard agreements and maintain the contracts archive.

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

NUH Staff
May identify potential vendors but must ensure that no vendor is used without formal approval from R&I.

5. Definitions

CA	Competent Authority
CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Product
CV	Curriculum Vitae
GCP	Good Clinical Practice
HRC	Head of Regulatory Compliance
NUH	Nottingham University Hospitals NHS Trust
IMP	Investigational Medicinal Product
QAA	Quality Assurance Auditor
RCM	Research Contracts Manager
R&I	Research and Innovation
SOP	Standard Operating Procedure
UK	United Kingdom

6. Procedure

6.1 Vendor Selection

The CI or any NUH staff will identify any potential vendors required to deliver any aspect of the research study, prior to submission of the funding application. The CI will arrange for a provisional quotation in writing for any identified vendor and provide evidence of the quote to the Head of Research Awards, or delegate (refer to SOP-RES-003 Grant Application). The HRC/QAA must be notified by the CI as soon as a vendor is nominated so that checks can be made to verify the vendor status (see 6.3).

The sponsor must ensure any research activities covered by contracts with the vendor are not implemented until the relevant contracts are executed. The RCM must be contacted to ensure final contracts have been approved and signed off (refer to SOP-RES-004 Contracts Management and Insurance/Indemnity) and that any necessary regulatory or ethical approvals are in place.

All vendor evaluations will be assigned a unique reference number by the HRC/QAA and tracked to completion on the Audit Log (TAFQ00401).

6.2 Initial Vendor Evaluation

- R&I will decide upon the services or professional expertise required for the performance of the specific task requested of the vendor.
- If it is a new vendor, or an addition of services or professional expertise required of an approved vendor, then a vendor risk assessment (see Appendix 1) needs to be made to determine the level of evaluation required to establish whether the vendor has the appropriate expertise, experience or qualifications to perform the specific task(s).
- As required, the HRC/QAA will coordinate a pre-contract due diligence on the requested vendor, using either the Vendor Questionnaire (TAFQ00501), a review of the relevant curriculum vitae's (CVs) or an audit (on-site audit, audit of copies of accreditation certificates, audit of the vendor quality system or obtaining references) (refer to SOP-QMS-004 Audit and Inspection).
- The Deputy Director of R&I will approve the vendor in order to proceed with the evaluation process and placing a contract with the vendor.

6.3 Status of Vendors

- The current status of vendors will be assigned within the Approved Vendor List (TAFQ00504); vendors may be designated as 'Approved', 'Pending Approval' or 'Not Approved'.
- The HRC/QAA will update the Approved Vendor List with any changes.

- Any vendor designated as approved may be utilised to provide any specific task without further qualification as long as the service falls under the approval scope. If the vendor is requested to provide services which do not form part of the 'Approved' status, then further evaluation will be required (see 6.2).

6.4 Review of Vendors

- All vendors must undergo a routine re-evaluation as per the risk assessment in Appendix 1 or when necessary, and documented using the Vendor Review Form (TAFR00503).
- The HRC and Deputy Director of R&I will perform an ongoing assessment of performance if a vendor is an individual providing a specific service, for example Monitoring. Areas of re-evaluation may include:
    i. Quality performance;
    ii. Recent audit observations;
    iii. NUH feedback;
    iv. Other – any additional information that may be relevant to the risk.
- Following review vendor status may be maintained or amended at the discretion of the HRC/QAA/Deputy Director of R&I.

6.5 Disqualification of Vendor

- HRC/QAA/Deputy Director of R&I may determine that continued use of an approved vendor represents an unacceptable risk to NUH. In such cases, a vendor may be disqualified.
- The CI or NUH staff will notify R&I if a disqualification is necessary.
- The HRC/QAA will discuss the status of the vendor with the Deputy Director of R&I.
- The Deputy Director of R&I will make the final decision on vendor disqualification status and the need to approve an alternate vendor, the decision will be recorded on the Vendor Disqualification Form (TAFQ00502).
- The HRC/QAA will change the status of the vendor on the Approved Vendor List (TAFQ00502) and review the status of active contracts for the vendor and liaise with CIs accordingly if study amendments are required.
- In order for a disqualified vendor to be re-approved, an on-site audit may be conducted and/or evidence of satisfactory close out of previous issues must be evident. The Deputy Director of R&I will make the final determination on vendor re-approval status.

7. References and Associated Documents

The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
International Conference on Harmonisation Guidelines for Good Clinical Practice E6 (R1)

TAFQ00401	Audit Log
TAFQ00501	Vendor Questionnaire
TAFQ00502	Vendor Disqualification Form
TAFQ00503	Vendor Review Form
TAFQ00504	Approved Vendor List
SOP-QMS-004	Audit and Inspection
SOP-RES-003	Grant Application
SOP-RES-004	Contracts Management and Insurance/Indemnity

8. Appendices

Appendix 1. Risk Assessment for Determining the Evaluation Type and Frequency of Vendors

This appendix describes the process for performing a risk assessment of vendors to determine the type and frequency of evaluation. Where the vendor is providing multiple types of services the type and frequency of evaluation will be as per the service which presents the highest risk.

i. Define each supplier by type, for example:
    a. Investigational Medicinal Product (IMP) Manufacturer
    b. Study Management
    c. Sample Analysis
ii. Perform a risk assessment which should include a risk scenario and risk scenario impact on regulatory compliance and participant safety.
iii. Assigning severity levels (High, Medium or Low) to vendor activities relating to regulatory compliance and participant safety will allow the Risk Class to be determined. The security levels are as follows:

Severity Level	Regulatory Compliance	Participant Safety
High	Major deviation from regulatory guidelines and potential critical observations, possibly resulting in termination of activities.	Patient safety compromised.
Medium	Deviation from regulatory guidelines and potential major observations.	Potential impact on patient safety.
Low	Minor observations or comments.	Minimal or no effect on patient safety.

iv. The Risk Class can then be determined according to the combination of severity levels, as follows:

Regulatory Compliance	Participant Safety	Risk Class
High	High	High
High	Medium	High
High	Low	Medium
Medium	High	High
Medium	Medium	Medium
Medium	Low	Low
Low	High	Medium
Low	Medium	Low
Low	Low	Low

v. A severity level should also be assigned according to the probability of detecting the risk, before harm to participant safety occurs.

Severity Level	Probability of Detection
High	The detection probability is high therefore the exposure risk is low.
Medium	The detection probability is medium therefore the exposure risk is medium.
Low	The detection probability is low therefore the exposure risk is high.

vi. By applying scores to the Risk Class and Probability of Detection the overall risk score can be determined by adding the two scores, as shown in the example below:

Regulatory Compliance	Patient Safety	Risk Class	Probability of Detection	Risk Class Score High = 9 Medium = 6 Low = 3	Probability of Detection Score High = 3 Medium = 6 Low = 9	Risk Score
High	High	High	Low	9	9	18

vii. The overall Risk Score will determine the audit type and frequency, as follows, although at the discretion of the HRC/QAA the audit type/frequency may be increased or decreased (the decision will be fully documented):

Risk Score	Audit Type	Frequency
18	Audit	1 year
15	Audit	2 years *with a questionnaire annually between audits*
12	Audit	4 years *with a questionnaire every 2 years between audits*
9	Questionnaire	2 years
6	Questionnaire	3 years