North Bristol NHS Trust

Standard Operating Procedure

Vendor Management

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AUTHOR:	Clinical Trials Manager, Contracts & Quality Management Officer
REVIEWED BY:	Research & Innovation Group
APPROVED BY:	Deputy Director of Research
CONTROLLER:	Contracts & Quality Management Officer

Document Version History

VERSION NUMBER	EFFECTIVE DATE	REASON FOR CHANGE
1.0	13-06-16	SOP renamed and updated to include a robust system for vendor oversight

Adapted with the kind permission of University Hospitals Bristol NHS Foundation Trust

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

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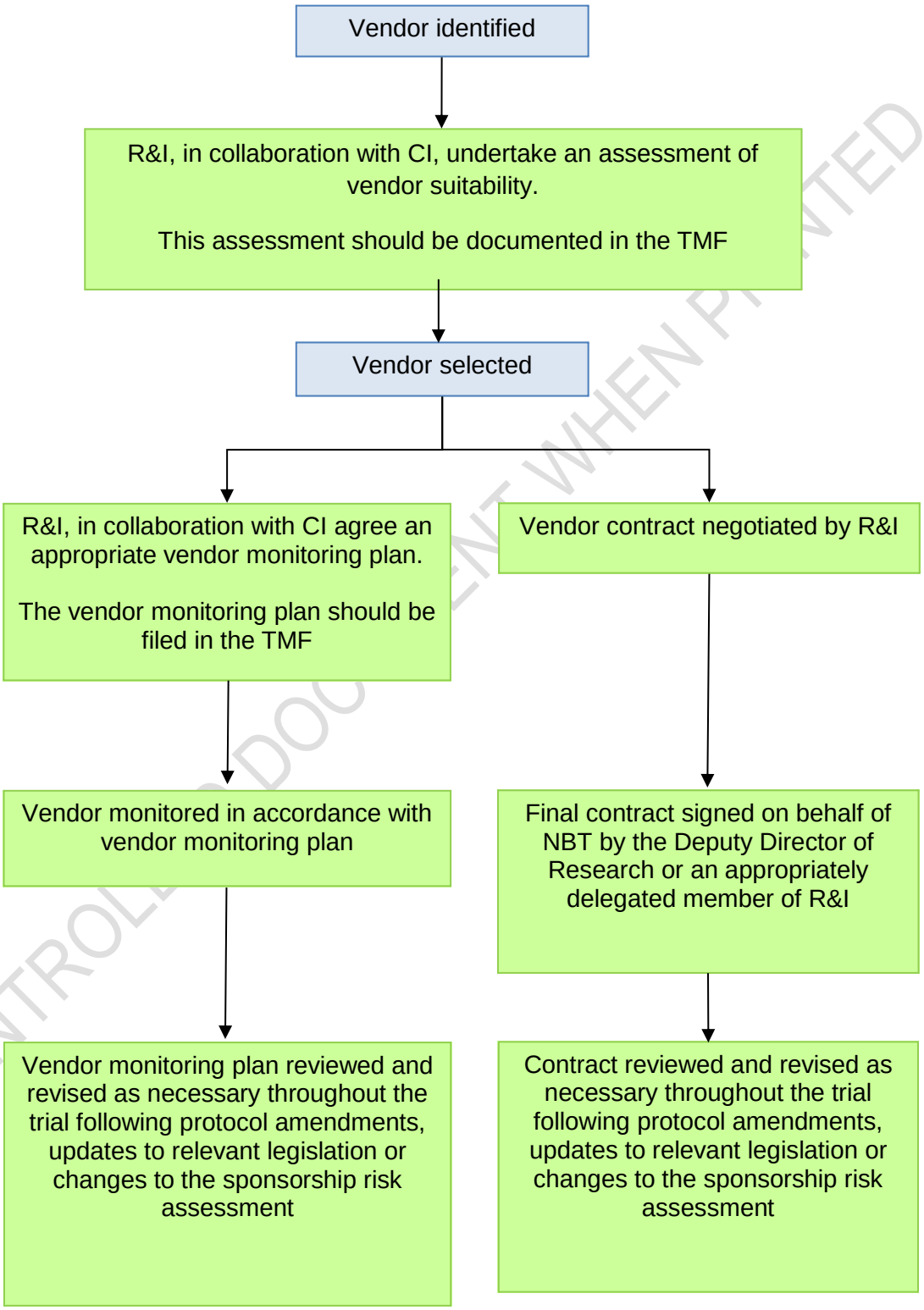
i. SOP Flowchart



1. PURPOSE AND SCOPE

The purpose of this SOP is to describe the process for selection, evaluation and oversight of current and potential vendors for NBT-sponsored CTIMPs. This SOP also describes the process for managing agreements with external parties such as participating sites and/or service providers.

NBT-sponsored CTIMPs may require research related-activities to be provided by organisations external to NBT. NBT may delegate activities to these other organisations, however as Sponsor, NBT retains ultimate responsibility for the clinical trial and must maintain sufficient oversight of all external vendors to ensure compliance with the applicable legislation and ICH GCP. All vendors must show due diligence when performing any functions that have been delegated to them.

Although the focus of this SOP is CTIMPs sponsored by NBT, the principles outlined in this SOP apply to all research studies sponsored by NBT.

2. DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
ICH GCP	International Conference on Harmonisation Guidelines for Good Clinical Practice
mNCA	Model Non-commercial Agreement developed by the UK Clinical Research Collaboration
NBT	North Bristol NHS Trust
PI	Principal Investigator
R&I	NBT Research & Innovation Office
SOP	Standard Operating Procedure
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research
TMF	Trial Master File
vendor	Organisation to which research related activities have been contracted, other than other NHS Trusts recruiting patients which should be considered research sites

3. WHO SHOULD USE THIS SOP

This SOP should be used by investigators, research team members, and any other staff involved in CTIMPs sponsored by NBT.

4. WHEN SHOULD THIS SOP BE USED

This SOP should be used to assess, select and maintain oversight of third party vendors undertaking any contracted research-related activities for CTIMPs sponsored by NBT.

This SOP should also be used when putting in place contractual arrangements between NBT and any organisation involved in the management and delivery of a CTIMP.

5. PROCEDURE

5.1. **Vendor assessment and selection**

(a) As Sponsor, NBT may be required to delegate certain research-related activities to other organisations. R&I (in collaboration with the CI, where relevant) will assess the suitability of a vendor, to ensure that the vendor can perform the services to applicable standards and regulations prior to signing a research contract. This does not apply to academic/NHS collaborations, except in circumstances where the vendor service constitutes an essential function for a CTIMP e.g. randomisation.

(b) A variety of assessment methods will be used when assessing the suitability of a vendor, including but not limited to:

- Requesting the vendor to complete a pre-qualification questionnaire.
- Review of marketing material.
- Assessment of CVs and expertise.
- Prior experience of working with the vendor.
- Obtaining appropriate references.
- Confirmation of relevant GCP, GMP or GLP certification (if appropriate).
- Assessment of the vendor's quality system and/or written procedures.
- Summary of recent inspections or audits.
- Ability to meet the needs of the trial.
- Capacity to deliver within required timeframes.
- Cost/budget.

(c) The type of assessment undertaken will be determined on a case by case basis; however the process of assessment and the selection decision should be clearly documented in the TMF.

(d) Some services may already be provided for NBT by external organisations in the clinical setting. Where this is the case, a separate assessment of suitability may not be required for the same organisation to provide the same services for research purposes.

(e) A list of vendors who have previously provided research services will be maintained by the R&I department. This will be used by R&I for future vendor selection. Full re-assessment will not be required if the vendor has previously been assessed as suitable unless the vendor is offering different services, has changed its SOPs, or R&I has concerns over the quality of service previously received. New vendors may also be approached.

5.2. **Contractual arrangements (other than funding arrangements)**

(a) For all CTIMPs sponsored by NBT, R&I will assess what type of contracts are required to be put in place with the other organisations involved in the trial, including but not limited to:

- Site Agreements, with other NHS organisations recruiting patients into the trial.
- Collaboration Agreements.
- Service Level Agreements.
- Material Transfer Agreements.
- Data Sharing Agreements.
- Confidentiality Agreements.

(b) Where possible, NBT will utilise national templates and guidance for contractual arrangements for research (www.ukcrc.org/regulation-governance/model-agreements), for example the model non-commercial agreement (mNCA) developed by the UK Clinical Research Collaboration.

(c) Where national templates do not exist, NBT will use locally adapted template agreements, where available.

(d) In instances where a template for a particular agreement does not exist, R&I may review a template provided by another organisation. Any amendments requested by other organisations to national or R&I templates will be reviewed and agreed with R&I, with a further legal review on behalf of NBT if appropriate.

(e) Where existing overarching research agreements exist between NBT and its partner organisations, trial-specific research contracts may not be required. These will be assessed on a case by case basis.

(f) Contracts are used to document and agree the relationship between NBT and the vendor, including but not limited to:

- Delegated tasks, duties, roles and responsibilities.
- Financial and legal considerations, including indemnity.
- Required standards of service and regulatory obligations.
- Intellectual property and publication provisions.
- Confidentiality provisions.
- Termination provisions.
- Subcontracting process by vendor, to ensure that subcontracting does not occur without Sponsor's knowledge or approval.
- Clear instructions that contract should not take precedence over protocol.
- Procedure for informing Sponsor of statutory inspections.
- Procedure for informing Sponsor of protocol non-compliance issues.
- Flow of relevant safety information.

(g) All contracts will be signed on behalf of NBT by the Deputy Director of Research or an appropriately delegated member of R&I. Hard copies, or electronic copies, of the final contract shall be issued to the third party for signature. In general, NBT shall be

the last party to sign the agreement. It is acceptable to sign a PDF copy of a contract, and to make an agreement in counterparts. A fully executed copy of the contract will be circulated to all the parties and also to the CI and/or Trial Manager for inclusion in the TMF.

(h) R&I will review such contracts following protocol amendments, updates to relevant legislation or changes to the sponsorship risk assessment to ensure the contract remains current. For further guidance on protocol amendments, please refer to the SOP on Research Study Amendments (RI/QMS/SOP/003).

5.3. **Oversight of vendors**

(a) Once the vendor has been selected, R&I (in collaboration with the CI, where relevant) will consider how oversight of vendor activities is maintained to ensure compliance with the terms of the research contract, the protocol, ICH GCP and applicable regulations. A variety of assessment methods will be used, including but not limited to:

- Regular communications with the vendor (i.e. regular teleconference/meeting).
- Review of progress reports from the vendor.
- Review of trial management meeting minutes.
- Review of TMF and specific vendor activities.
- Visiting vendor premises/ conducting audit of vendor performance.
- Becoming a signatory on key documentation i.e. process documents (SOPs) or trial documents (data management plans, statistical analysis plans etc.)
- Developing a plan for escalation and resolution of non-compliance issues.
- Defining a process for the flow of relevant safety information.
- Vendor and collaborator engagement will be regularly reviewed at the meetings between Sponsor and Trial Manager, which are held approximately every two months.

(b) A vendor monitoring plan should be defined prior to the commencement of clinical trial activities and filed in the TMF. Please refer to the SOP on Monitoring (RI/QMS/SOP/014).

(c) The vendor monitoring plan should set out the level and frequency of monitoring. Minutes should be taken of all meetings and decisions should be clearly documented. Should any significant concerns be raised, R&I will review and recommend any appropriate corrective and preventative measures.

6. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP.

The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

7. RELATED SOPS AND DOCUMENTS

- UK Clinical Research Collaboration
  Model Agreements
  www.ukcrc.org/regulation-governance/model-agreements

- The following NBT documents are available on the R&I website: www.nbt.nhs.uk/research

RI/QMS/SOP/003	Research Study Amendments
RI/QMS/SOP/014	Monitoring