Vendor Selection and Management

Division: Trust-Wide

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with policy
Staff employed by North Bristol Trust who directly or indirectly work on Clinical Research within the Trust	Role Dependant	Staff not employed by North Bristol NHS Trust who are working on Research studies sponsored or hosted by NBT

Main Author(s):	Deborah Warbrick, Research Operations Manager Sadia Khurshid, Research Compliance Manager
Consultation:	R&D Sponsorship Team
Approval Authority (Committee/ Group/ Lead Clinician):	R&D Senior Team
Executive Lead (Trust-Wide only):	Tim Whittlestone
Date of Approval:	28th April 2026
Next Review Due:	28th April 2029
Version:	RD/QMS/SOP/016 Version 2.1
KEYWORDS:	Vendor Selection Checklist
Summary of changes since the previous version	Changed format to align with NBT SOP template Changed R&I to R&D Added information in relation to responsibilities when working with Clinical Trials Units. Change the naming convention of R&D SOP's Editorial changes have been made to sentence construction to improve clarity, flow, and consistency across the R&D SOP suite.

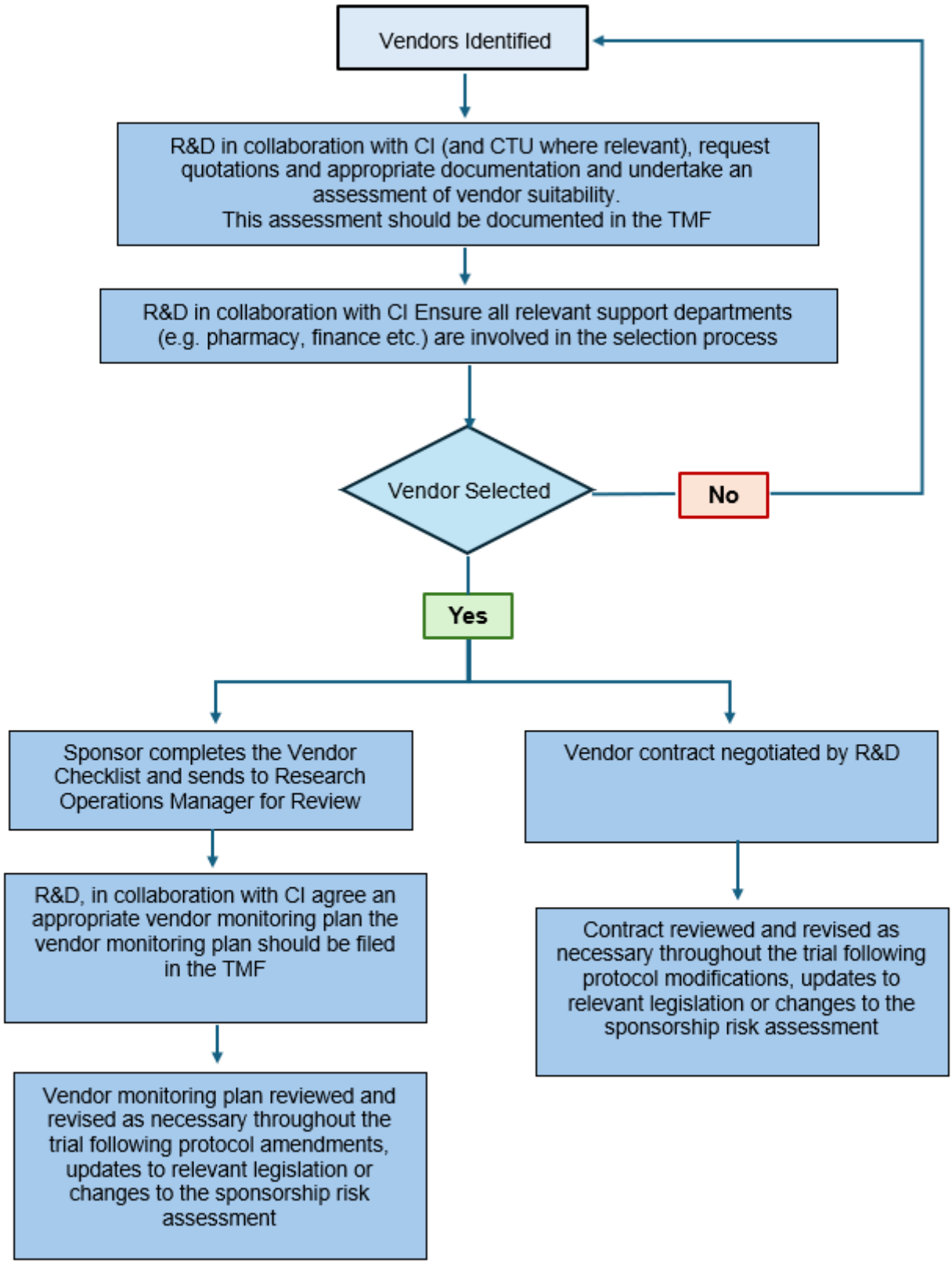
1. Purpose	This SOP describes the processes for the selection, evaluation, and oversight of vendors engaged in CTIMP studies sponsored by NBT, as well as the management of agreements with external parties such as participating sites and service providers.
2. Key Messages	NBT, as Sponsor, retains ultimate responsibility for the conduct of its sponsored studies and for ensuring that any research-related activities delegated to external parties are performed in accordance with applicable legislation, regulatory requirements, and ICH GCP External vendors may be engaged to perform delegated trial-related activities, however delegation of activities does not transfer Sponsor responsibility. NBT must maintain appropriate oversight of all third-party vendors and collaborators throughout the lifecycle of the study. All vendors must be assessed prior to engagement to ensure they are suitably qualified, competent, and resourced to perform the delegated activities to the required standard. The level of assessment must be proportionate to the nature, complexity, and criticality of the service being provided. Vendor selection, qualification, and oversight activities must be documented, including the rationale for vendor selection and the scope of delegated responsibilities, and retained within the Trial Master File (TMF). Formal agreements must be in place to clearly define roles, responsibilities, delegated duties, financial and legal arrangements, and regulatory obligations between NBT and any external organisations involved in the study. Ongoing oversight of vendors is required to ensure continued compliance with contractual obligations, the approved protocol, ICH GCP, and applicable regulatory requirements. Any non-compliance must be identified, escalated, and managed in a timely manner Although this SOP focuses on CTIMP studies sponsored by NBT, the principles of vendor assessment, contractual control, delegation, and oversight apply to all research studies sponsored by NBT, unless otherwise specified. **Abbreviations** **CI** Chief Investigator **CTIMP** Clinical Trial of an Investigational Medicinal Product **CTU** Clinical Trials Unit

	ICH GCP International Conference on Harmonisation Guidelines for Good Clinical Practice **mNCA** Model Non-commercial Agreement **IMP** Investigational Medicinal Product **NBT** North Bristol NHS Trust **PI** Principal Investigator **PD** Protocol Deviation **R&D** Research and Development **SOP** Standard Operating Procedure **TMF** Trial Master File
3. Relevant Policies & Guidance	**Policies and Guidance:** Guidance for Good Clinical Practice ICH GCP (E6) R3 https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 MHRA Guidance: Oversight and monitoring of clinical trials involving investigational medicinal products UK Policy Framework for Health and Social Care Research (HRA) The following NBT documents are available on the R&D website: www.nbt.nhs.uk/research **Associated SOP's and Templates:** RD QMS SOP 007 Applying for NBT Sponsorship RD SOP 007c Delegation of Responsibilities RD QMS SOP 014a Preparation of a Monitoring Plan
4. Operational Areas Included	This SOP applies to the assessment, selection, and oversight of third-party vendors and external organisations undertaking any contracted research-related activities for CTIMP and non-CTIMP studies sponsored by NBT.

5. Operational Areas Excluded	This SOP does not apply to: Research studies where NBT is acting solely as a participating site and is not the Sponsor. Trust-wide procurement activities unrelated to research, which are governed by corporate procurement policies and Standing Financial Instructions. Assessment and oversight of NHS organisations collaborating in research where no research-related activities have been formally delegated by the Sponsor.
6. Who should read this	This SOP should be read by all investigators, research staff, monitors, service support teams, and R&D staff involved in the design, conduct, management, or oversight of research studies where external vendors or service providers are engaged.
7. Roles responsible for carrying out this procedure	Chief Investigator: Responsible for providing **scientific and operational oversight** to ensure that vendor selection and the delegation of trial-related activities support the approved protocol, data quality, and participant safety. The CI must liaise with relevant Trust support departments (e.g. Pharmacy, Laboratories, Imaging, Finance) to identify potential vendors and contribute to the assessment of their suitability within their area of expertise. Sponsor: Ultimately accountable for the selection, qualification, contracting, delegation, and ongoing oversight of third-party vendors. The Sponsor is responsible for ensuring that vendors are fit for purpose, that delegated responsibilities are clearly defined and documented, and that proportionate oversight arrangements are implemented, maintained, and reviewed throughout the lifecycle of the study. Trial Manager / Study Management Team: Responsible for day-to-day liaison with vendors, monitoring deliverables against agreed timelines, and escalating any quality, performance, or compliance concerns to the Sponsor and R&D team in accordance with agreed oversight arrangements.

8. Procedure:

SOP Flowchart



8.1 Vendor Assessment and selection

a. As Sponsor, NBT may be required to delegate certain research-related activities to other organisations or service providers. The R&D in collaboration with the Chief Investigator (CI) and Clinical Trials Unit (CTU), where relevant, will assess the suitability of proposed vendors to ensure they are competent, qualified, and able to perform delegated activities in compliance with applicable legislation, regulatory requirements, and ICH GCP prior to contract execution.

   This process does not apply to routine academic or NHS collaborations, except where an external organisation is performing an essential trial function for a CTIMP (e.g. randomisation, data management, central laboratory services), in which case vendor assessment and oversight requirements apply.

b. For CTIMPs there may be circumstances where no licensed medicines meet the clinical needs of a patient or cohort of patients. In this situation the off-label use of a licensed medicine is preferable. If this is not possible and the decision is to seek a new unlicensed medicine, it should be assumed the medicine is unavailable until it has been assessed by the Pharmacy Quality Assurance (QA) Team. Any product that does not pass the QA Risk Assessment will not be procured within the Trust

c. A variety of assessment methods will be used when assessing the suitability of a vendor. NBT as sponsor must complete the Vendor Checklist (R&D/QMS/TMPL/016a). This includes assessment of suitability, 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.

The level and extent of vendor assessment undertaken will be proportionate to the nature, complexity, criticality, and risk of the delegated activity, with enhanced assessment applied to vendors undertaking essential trial functions.

d. 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.

e. 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.

f. When procuring a new service, if the cost is more than £25k excl. VAT, the NBT central procurement will need to be involved. This can be done in two ways:

1. **Central procurement** - Send a request via email to the procurement team to run the tender process. This will be a centralised process where R&D will not receive any quotes and will not be able to state their preferences.
2. **Single Tender Action** – This allows R&D to retain some control over the process. What would need to happen in this case is:

i. R&D will need to obtain 3 quotes from the market

ii. If R&D have a preferred service (either due to prior experience in working with them in other trials or prior existing relationships), the Sponsor team would need to complete their vendor selection process as explained in 8.1 (c) for that preferred supplier to check the appropriate quality systems, and SOPs are in place.

iii. R&D will then contact the central NBT procurement team and inform them regarding the single tender action providing the justification for a preferred supplier. For new suppliers above the Trust Standing Financial Instruction (SFI) threshold please complete an RFx form, available here: http://nww.bwpc.nhs.uk/Pages/RFx.html. Once received this request will be allocated and a member of the team will be in touch to advise regarding applicable procurement process.

g. A list of vendors who have previously provided research services will be maintained by the R&D department. This will be used by R&D 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&D has concerns over the quality of service previously received. New vendors may also be approached.

a. For the purpose of invoicing, suppliers may need to set up an account on SAP Ariba. Suppliers should aim to complete a 'New supplier form' on their company letterhead provided by emailing IQMQueries@nbt.nhs.uk. Once IQM receive the competed form, they will contact the supplier directly.

8.2 Contractual Arrangements

a. For all CTIMPs studies sponsored by NBT, R&D as sponsor is responsible for determining, establishing and maintaining appropriate contractual arrangements with all external organisations involved in the conduct of the trial.

Contracts may include, but are 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.

Contracts must not take precedence over the approved protocol or applicable regulatory Requirements.

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&D may review a template provided by another organisation. Any amendments requested by other organisations to national or R&DI templates will be reviewed and agreed with R&DI, 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&D. 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 with 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&Dwill review such contracts following protocol modifications, updates to relevant legislation or guidance, or changes to the sponsorship risk assessment to ensure the contract remains current valid a. For further guidance on protocol modifications, please refer to the SOP on Research Study Modification (RD/QMS/SOP/003).

8.3 Oversight of Vendors

a. Once the vendor has been selected, R&D, 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 throughout the lifecycle of the study

The level and frequency of vendor oversight will be proportionate to the nature, complexity, criticality, and risk of the delegated activities and their potential impact on participant safety and data integrity.

A variety of assessment methods will be used, including but not limited to:

- Regular communications with the vendor (i.e. regular teleconference/meetings).
- 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 (RD/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&D will review and recommend any appropriate corrective and preventative measures.

9. Dissemination and Training

SOPS will be distributed in accordance with the SOP on Preparation of R&D Research SOPs (RD/QMS/SOP/001). This SOP and any associated templates and forms will be uploaded to the NBT website (www.nbt.nhs.uk/research) 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.