

Applying for North Bristol NHS Trust Sponsorship

Specific staff groups to whom this policy <u>directly</u> applies	Likely frequency of use	Other staff who may need to be familiar with policy
Staff at North Bristol Trust involved in clinical research, either directly or indirectly, who are requesting the Trust's sponsorship for a research study	Role dependent	Staff not employed by North Bristol NHS Trust who are requesting the Trust's sponsorship for a research study

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Version:	RD/QMS/SOP/007 - Version 3.1
KEYWORDS:	Sponsor, Sponsorship Application, Risk Assessment, Terms & Conditions of Sponsorship, CI Declaration Form, Regulatory Green Light
Summary of changes since the previous version	SOP naming convention updated R&I reference updated to R&D. New trust wide SOP template used

	<p>Update to differentiate between sponsorship ‘agreement in principle’ and ‘confirmation of Sponsorship’.</p> <p>Sponsorship criteria updated to include removal of prohibition of phase I studies.</p> <p>References updated in relation to updated Medicine for Human Use (Clinical Trial) (Amendment) Regulations 2025 and ICH GCP E6 (R3) 2025.</p>
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1. Purpose	<p>The purpose of this SOP is to describe the process for applying, agreeing and maintaining NBT Sponsorship, and to outline the roles and responsibilities that will be delegated where NBT agrees to act as Sponsor.</p>
2. Key Messages	<p>The Sponsor is the organisation that takes on responsibility for confirming there are appropriate arrangements to initiate, manage, monitor, and finance a study. For any research that takes place in the context of the NHS or Social Care services, it is a requirement that a Sponsor is identified.</p> <p>The Sponsor has the responsibility for ensuring that all the necessary arrangements are in place before a study can proceed, including:</p> <ul style="list-style-type: none"> • ensuring that the research study has obtained scientific quality approval from the necessary bodies. • ensuring that the study has obtained ethical approval, where required. • ensuring arrangements are in place for the monitoring and reporting of research. • ensuring the research team has access to resources and support to deliver the research as proposed. <p>When an organisation agrees to sponsor a research study, it assumes significant responsibility.</p> <p>Identifying a sponsor as early as possible is crucial; many funding bodies require a sponsor to be confirmed in principle before they accept a funding application.</p> <p>ABBREVIATIONS</p> <p>CI Chief Investigator</p> <p>CTIMP Clinical Trial of an Investigational Medicinal Product</p>

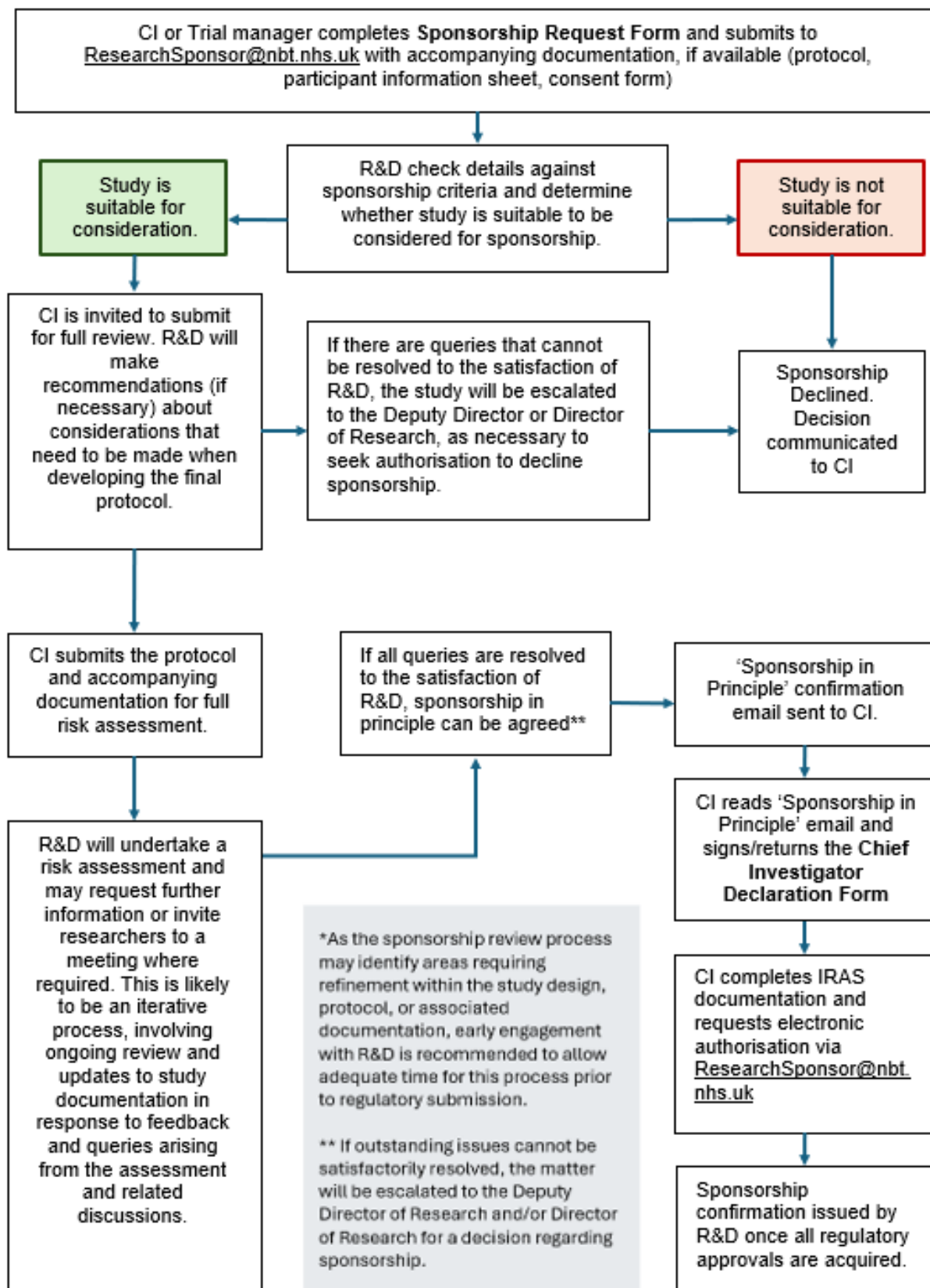
	<p>CIMD Clinical Investigation of a Medical Device</p> <p>GCP Good Clinical Practice</p> <p>HRA Health Research Authority</p> <p>IRAS Integrated Research Application System</p> <p>NBT North Bristol NHS Trust</p> <p>NIHR National Institute of Health Research</p> <p>PI Principal Investigator</p> <p>R&D Research and Development</p> <p>SOP Standard Operating Procedure</p> <p>TMM Trial Management Meeting</p>
<p>3. Relevant Policies & Guidance</p>	<p>Policy and Guidance</p> <ul style="list-style-type: none"> Health Research Authority <i>Roles and Responsibilities</i> www.hra.nhs.uk UK Policy Framework for Health and Social Care Research 2025 The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538) ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (R3) 2025. <p>The following R&D documents are available via LEARN or by contacting the R&D office on Research@nbt.nhs.uk</p> <p>Associated SOPs</p> <p>RD/QMS/TMPL/SOP/007a – Sponsorship request form</p> <p>RD/QMS/SOP/007b – NBT terms and conditions of sponsorship</p> <p>RD/QMS/TMPL/007c – Delegation of responsibilities</p> <p>RD/QMS/TMPL/007d – Delegation of responsibilities log</p> <p>RD/QMS/TMPL/SOP/007e – Chief Investigator Declaration Form</p> <p>RD/QMS/SOP/017- Data management plan</p>
<p>4. Operational Areas Included</p>	<p>This SOP is applicable to all research sponsored by the Trust.</p>

5. Operational Areas Excluded	Research sponsored by other organisations.
6. Who should read this	This SOP should be read by R&D staff, trial managers, and investigators requiring NBT sponsorship of any CTIMP or non-CTIMP study.
7. Roles responsible for carrying out this procedure	<p>NBT Research Sponsor:</p> <p>A sponsor is an organisation which takes responsibility for the quality and conduct of a research study:</p> <p>“The sponsor is ultimately responsible for ensuring that the research is properly designed, ethically approved, and conducted to appropriate standards, with clear documentation of roles, adequate insurance or indemnity, and all regulatory and practical arrangements in place before the study begins” [UK Policy Framework for Health and Social Care Research, 2025]</p> <p>Sponsor responsibilities under the clinical trials regulations encompass the full range of legal obligations required to ensure the initiation, management or financing (or arranging the financing), oversight, and conduct of a clinical trial are carried out in compliance with applicable law (Medicines for Human Trials) (Amendment) Regulations 2025, effective 28 April 2026)</p> <p>These responsibilities include, but are not limited to, the following areas of legal accountability:</p> <ul style="list-style-type: none"> • Oversight of Authorisation for clinical trials and research ethics committee opinion • GCP Compliance and the conduct of clinical trials • Pharmacovigilance • Manufacture and labelling of investigational medicinal products <p>The responsibilities of a sponsor may be delegated. Any delegated responsibilities must be documented. Ultimately the sponsor remains accountable for all functions of sponsorship regardless of whether they have been delegated.</p> <p>The NBT R&D Sponsorship Team are responsible for acting as nominated sponsor representatives, liaising with the CI and managing risk.</p>

	<p>Chief Investigator: The CI is responsible for applying for NBT sponsorship fulfilling the obligations delegated by sponsor to CI through the research.</p> <p>R&D Senior Team: The R&D Senior Team is accountable for reviewing all applications for sponsorship relating to CTIMP and device studies and for maintaining organisational oversight of NBT sponsorship activities.</p>
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8. Procedure

Flowchart illustrating NBT Sponsorship Process



NBT is registered with the Department of Health and holds the necessary authority to act as a Sponsor under the UK Policy Framework for Health and Social Care Research. This does not imply blanket acceptance of sponsorship for all projects. A formal application must be submitted to the Research & Development (R&D) office (via researchsponsor@nbt.nhs.uk) to request NBT sponsorship.

This SOP describes the two-step process required to request NBT sponsorship:

Step 1: R&D Review and assess the completed Sponsorship Request Form to determine suitability for sponsorship.

Step 2: R&D Conduct a full risk assessment of the study protocol and all associated documents.”

8.1 STEP 1: Suitability to be considered for sponsorship.

(a) Researcher submits a request

To enable R&D to determine whether a project is suitable for NBT to act as Sponsor, the Sponsorship Request Form (RD/TMP/SOP007a) must be completed and submitted. This form provides the information required for an initial assessment against local policy and other criteria to establish whether the project is likely to be eligible for NBT sponsorship.

It is recommended that you complete and submit the Sponsorship Request Form as early as possible when developing a project.

Sponsorship Request Forms should be submitted via email to ResearchSponsor@nbt.nhs.uk with ‘Sponsorship Request’ in the subject line.

Initial Assessment of Project Suitability for Sponsorship by R&D

Upon receipt of a Sponsorship Request Form, the R&D Sponsorship Review Team will evaluate the project’s suitability for NBT sponsorship.

The initial assessment will be conducted against the criteria outlined in Table 1. Projects must meet all criteria in Table 1 to proceed. If any criterion is not met, applicants are advised to contact R&D to discuss the project prior to submitting a sponsorship request.

Where the project satisfies the criteria in Table 1, a further review will be undertaken, considering the planned intervention, the nature of the investigational medicinal product (IMP), and the scientific integrity of the study

(b) Initial Suitability assessment outcome

There are two possible outcomes of the suitability assessment:

- i. The project is not suitable to be considered for NBT sponsorship. This outcome will be communicated to the CI, together with the reasons.
- ii. The project is suitable to be considered for NBT sponsorship and will be invited to proceed to the full risk assessment stage. This outcome will be communicated to the CI via email. R&D will also highlight to the CI any considerations that must be addressed to mitigate potential risk. It is recommended these considerations are addressed prior to proceeding to the full risk assessment stage.

Sponsorship Criteria:

Criteria	Comment
Suitable study type	NBT are unable to sponsor Phase I CTIMPs involving healthy individuals*
UK based location of sites	NBT are unable to sponsor research conducted outside of the UK.
Chief Investigator holds employment contract with NBT	For NBT to sponsor, NBT would usually be the CI's substantive employer, or the CI would be a clinical academic practising in NBT and holding an honorary contract with the Trust.
Study is not an academic project	NBT would not usually sponsor research undertaken as part of a qualification, for which the university at which the student is registered should act as Sponsor.
Does not involve co-sponsorship	NBT are unable to undertake co-sponsorship of CTIMPs. Co-sponsorship of device studies or observational studies will only be considered in exceptional circumstances where clear delegation of Sponsor responsibilities can be agreed in writing by all parties

**Sponsorship of any other types of studies involving healthy volunteers will be reviewed on a case-by-case basis with no guarantee of sponsorship.*

8.2 STEP 2: Full risk assessment

(a) Researcher submits a request

Projects that have been reviewed and deemed eligible for NBT sponsorship must undergo a full risk assessment, which will be completed by members of the R&D Sponsorship Team. The Sponsorship team have a booking system in place to manage and review risk assessments; please contact the Sponsorship team to book a review as soon as you have the minimum documentation in place.

As a minimum, the following documents are needed to commence the risk assessment process:

- i. draft protocol (including a suitable Data Management Plan);
- ii. draft participant information sheet;
- iii. draft consent form.

These can be submitted via email to ResearchSponsor@nbt.nhs.uk

(b) R&D undertakes full risk assessment

A full risk assessment will involve assessing whether the study protocol poses significant clinical, legal, financial or reputational risks, and whether it is well-designed, peer reviewed, and statistically sound. This includes a review of the following non-exhaustive list:

- i. NBT suitability to deliver/sponsor the study
- ii. CI suitability to lead the research- The CI will be expected to provide a copy of their CV and GCP certificate, completed within the last 3 years, alongside any relevant training records.
- iii. Study research costs and evidence of funding- All Research Incurs costs and R&D will need to see evidence of how these costs will be met.
- iv. Arrangements for meeting excess treatment costs
- v. NIHR portfolio eligibility or other arrangements for covering support costs
- vi. Peer review including suitability of study design- Evidence should be provided that a review of scientific quality has been conducted.
- vii. Capacity and capability to undertake the study at NBT and/or other trial sites
- viii. Compliance with required regulatory standards
- ix. Standard of the protocol
- x. Contractual requirements
- xi. Arrangements for managing study data and documentation, including a Data Management Plan.

The review will also consider how to mitigate any risks that are identified.

Where necessary, the risk assessment will be undertaken in conjunction with the CI and research team. R&D may request additional information to support this assessment, and researchers may be invited to attend a meeting with members of the R&D Sponsorship team to discuss the proposed project. For Clinical Trials of Investigational Medicinal Products (CTIMPs) and medical device studies, review at a senior R&D team meeting forms a mandatory part of the sponsorship assessment process. Agreement for sponsorship will be conditional upon the outcome of this review and formal approval by the senior R&D team.

It is likely that this stage of the sponsorship review process will be iterative, with the CI and research team being asked to review and update the study design, protocol and supporting documentation considering feedback and/or queries raised during the risk assessment.

(c) Sponsorship decision

Once a risk assessment is complete and all queries addressed to the satisfaction of R&D, Confirmation of NBT 'Sponsorship in Principle' will be provided. This outcome will be communicated to the CI in writing via email.

- i. By providing confirmation of 'Sponsorship in Principle', NBT is not giving permission for the study to commence. Sponsorship is conditional on all relevant approvals being in place. In addition, sponsorship regulatory green light must also be given prior to the study starting at each participating site (including NBT) as outlined in section 8.6 of this SOP.
- ii. If there are queries that cannot be resolved throughout the risk assessment process to the satisfaction of R&D sponsorship team, the study will be escalated to the Deputy Director and/or Director of Research as necessary to seek authorisation to decline sponsorship. This outcome will be communicated with the CI in writing via email.

The sponsorship risk assessment will be reviewed and updated as necessary, throughout the course of the study.

Agreement to sponsor in principle and an invitation to proceed with IRAS submission does not constitute confirmation of sponsorship; agreement to sponsor can only be confirmed once all Sponsorship conditions have been met and all regulatory approvals are in place.

8.3 NBT Terms & Conditions of Sponsorship

A range of sponsorship terms and conditions are in effect and require agreement by all parties prior to proceeding. [NBT Terms & Conditions of Sponsorship \(RD/QMS/SOP/007b\)](#) are available on the NBT website.

A number of responsibilities are delegated to the CI (and PIs) of trial sites as documented in the *Delegation of Responsibilities between the Sponsor and CI/NBT-PI* (see [Delegation of Responsibilities \(RD/QMS/SOP/007c\)](#) document). If any of these responsibilities are to be delegated by the CI (and/or PIs) to other members of the research team, this must be recorded in a *Delegation of Responsibilities Log* (see template [Delegation of Responsibilities Log \(RD/QMS/SOP/007d\)](#)) and stored in the local site file.

Ultimately the Sponsor remains accountable for all functions of sponsorship regardless of whether they have been delegated. Therefore, the CI and PI are accountable to the Sponsor.

8.3.1 Chief Investigator acceptance of NBT Terms & Conditions of Sponsorship

When sponsorship in principle confirmation is provided, the CI will be asked to review NBT's suite of SOPs, these must be adhered to throughout study delivery.

The CI will also be sent a [Chief Investigator Declaration Form \(RD/QMS/TMPL/SOP/007e\)](#), which they must sign to confirm that they agree to the NBT Terms & Conditions of Sponsorship and that they accept the *Delegation of Responsibilities*. The Chief Investigator Declaration Form must be signed and returned to R&D before sponsorship authorisation can be granted in IRAS. A hard signed copy must be provided, or confirmation can be accepted via email if received from the CI's NBT or NHS.net (or, where relevant, University of Bristol) email account.

The CI holds overall responsibility for ensuring that the study is conducted in accordance with the expectations of the National Institute for Health and Care Research (NIHR), including compliance with applicable national performance metrics. These metrics require that studies recruit participants in line with the agreed recruitment trajectory and within the planned study timelines. The CI is responsible for overseeing the timely submission of regulatory applications via Integrated Research Application System (IRAS), responding promptly to requests for further information from regulatory authorities, and proactively monitoring study recruitment. The CI must also identify potential risks to study delivery at an early stage and implement appropriate mitigation strategies where required.

8.4 Sponsorship Authorisation

An authorised signatory from R&D must approve all IRAS documentation prior to submission to the relevant regulatory bodies. IRAS documentation will only be signed once confirmation of sponsorship in principle has been provided and the CI has returned the signed *Chief Investigator Declaration Form*. Other items that must also be agreed between the CI and R&D prior to IRAS sign-off are outlined in the *NBT Application Checklist*.

All requests for electronic authorisations via IRAS should be sent to: researchSponsor@nbt.nhs.uk. A letter confirming NBT sponsorship will be provided to the CI upon request.

8.5 Formal Sponsorship Confirmation

Sponsorship confirmation is issued once all regulatory approvals are in place. R&D will Issue a full sponsorship letter to the CI and trial team. This must be filed in the TMF and local R&D records.

8.6 Regulatory Green Light

For all NBT sponsored studies, R&D or authorised delegate must issue regulatory green light for each participating site (including NBT) prior to that site opening to recruitment. R&D will require evidence that a set of core documentation from each site has been received to be able to issue sponsorship regulatory green light.

8.7 Duration of the study

Once the required approvals are in place the research team are expected to show full engagement with the sponsorship team, including attendance at trial management meetings. Trial management meetings between the Sponsor and Trial Manager will be held approximately every 6 weeks for CTIMPs, Device studies and other complex non-CTIMPS. The requirement for trial management meetings for other types of studies will be based on risk.

A trial management report will be drafted by the sponsor representative prior to the meeting. The CI should attend the trial management meeting, but if this is not possible then the trial manager must attend on their behalf. The report will be reviewed at the TMM, to ensure all aspects of the study have been discussed. The sponsor will distribute the report to all attendees at the end of the meeting. All action items outlined in the report should be assigned to the appropriate individuals and completed within the specified timeframe.

Any amendments to the study, after regulatory approvals are in place should be reviewed by the R&D Sponsorship Team, in line with the SOP RD/QMS/SOP/003 Research Study Amendments.

8.8 Publications

All publications (including poster presentations and annual reports) must be submitted to the Sponsor for review and approval (CTIMPs/device studies) or acknowledgement (non-CTIMPs/device studies) before submitting for publication.

8.9 DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on [Preparation of Research SOPs \(RD/QMS/SOP/001\)](#).

This SOP and any associated templates and forms will be uploaded to the Managed Learning Environment “LEARN” system on the Trust intranet shortly after having been released, The trust website (www.nbt.nhs.uk/research) will be updated to capture the list of current SOP’s in place

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP, this is monitored and audited via LEARN.

9. References (if applicable):

- ...
- Health Research Authority (2025)
UK Policy Framework for Health and Social Care Research. Version 4.0
www.hra.nhs.uk
 - ICH Secretariat
Guidelines for Good Clinical Practice (E6 R3, Step 4, adopted 6th January 2025)
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

UK Government

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, SI 2025 No. 538. Laid before Parliament 10 April 2025; into force 28 April 2026.

<https://www.legislation.gov.uk/ukxi/2025/538/contents>