

Standard Operating Procedure

Applying for North Bristol NHS Trust Sponsorship

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Document Version History

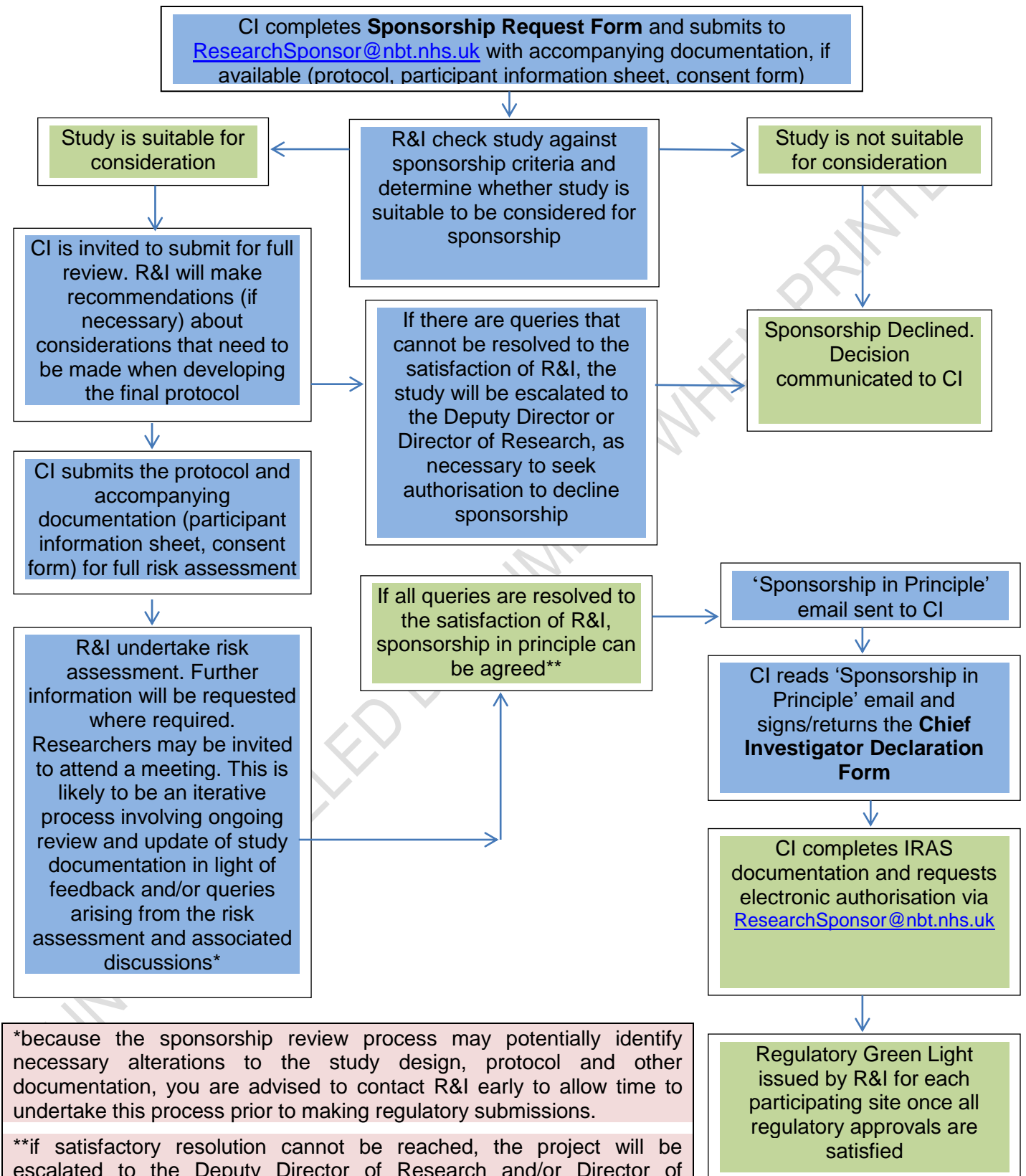
VERSION NUMBER	EFFECTIVE DATE	REASON FOR CHANGE
1.0	27-08-10	SOP renamed, updated in line with new template and recoded from ISOP-E01
2.0	08-02-16	Clarification regarding healthy volunteer studies, and update to delegation of responsibilities to reflect new HRA process
2.1	15-09-16	Clarification of expectations of reporting and monitoring during the study. Requirement for Data Management Plan. Updated references to policy and legislative changes. Appendices removed and uploaded to website separately

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 agreeing NBT Sponsorship, and the delegation of roles and responsibilities that will be assigned where NBT agree to act as Sponsor.

All research conducted in the NHS must have a Sponsor. For Clinical Trials of Investigational Medicinal Products (CTIMPs), this is a requirement of the Medicines for Human Use (Clinical Trials) Regulations. A Sponsor is an organisation that takes responsibility for the quality and conduct of a research study.

The responsibilities of a Sponsor are described in the Regulations. They incorporate the following areas of legal responsibility, which can be delegated as appropriate:

- Authorisation for clinical trials and research ethics committee opinion.
- Good Clinical Practice and the conduct of clinical trial.
- Pharmacovigilance.
- Manufacture and labelling of investigational medicinal products.

2. DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical trials of Investigational Medicinal Products
DMP	Data Management Plan
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
NBT	North Bristol NHS Trust
PI	Principal Investigator
R&I	NBT Research & Innovation Office
R&I Sponsorship Review Panel	Group comprising of two or more of the Research Matron, Clinical Trials Manager, Clinical Trials Officer and Research Operations Manager. The group may convene via full meeting or via email.
REC	Research Ethics Committee
MHRA	Medicines and Healthcare Products Regulatory Agency
NBT	North Bristol NHS Trust
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

3. WHO SHOULD USE THIS SOP

This SOP should be used by R&I staff, and investigators requiring NBT sponsorship of any CTIMP or non-CTIMP study.

All non-CTIMP studies requiring NBT sponsorship must also be notified to R&I, and the process outlined in this SOP will largely be followed.

4. WHEN SHOULD THIS SOP BE USED

This SOP should be used when developing a new research project, prior to submitting the research protocol to the relevant regulatory authorities (e.g. HRA and MHRA).

5. PROCEDURE

NBT is registered with the Department of Health as willing and able to act as a Sponsor under the Research Governance Framework for Health and Social Care. This does not constitute blanket acceptance of sponsorship for all projects requiring a Sponsor. A formal application must be submitted to R&I to request NBT sponsorship.

This SOP outlines the two-step application process that must be followed to request NBT sponsorship:

- Step 1: Suitability to be considered for sponsorship is assessed
- Step 2: Full risk assessment of the protocol

5.1 STEP 1: Suitability to be considered for sponsorship

(a) Researcher submits a request

To make a request for R&I to consider whether it is suitable for NBT to act as Sponsor, a [Sponsorship Request Form \(RI/QMS/SOP007a\)](#) should be completed and submitted to R&I. This enables R&I to make an initial assessment of whether the project is likely to be suitable to be considered 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.

(b) R&I assess suitability to be considered for sponsorship

Upon receipt of a Sponsorship Request Form, the R&I Sponsorship Review Panel will assess suitability for the study to be considered for NBT Sponsorship.

Projects will first be assessed against the criteria detailed in Table 1. Projects must meet the criteria in Table 1 to be deemed suitable for consideration. If the study fails to meet any of these criteria, it is recommended that you contact R&I to discuss your project further before submitting a sponsorship request.

Where a project meets the criteria in Table 1, suitability will next be assessed by reviewing information regarding: the planned intervention, the nature of the IMP, and the scientific integrity of the project.

(c) 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. R&I 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.

Invitation to proceed to full risk assessment does not constitute agreement to sponsor; agreement to sponsor can only be confirmed once a full risk assessment has been undertaken as outlined in the next section of this SOP.

Criteria	Comment
Suitable study type	NBT are unable to sponsor Phase I CTIMPs involving healthy individuals or any other randomised trial involving healthy volunteers*
UK based location of sites	NBT are unable to sponsor research conducted outside of the UK
Not commercial contract research	NBT are unable to sponsor commercial contract research
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 or device studies. Co-sponsorship of 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.**

5.2 STEP 2: Full risk assessment

(a) Researcher submits a request

Projects deemed suitable to be considered for NBT sponsorship must undergo a full risk assessment, which will be completed by members of the R&I Sponsorship Review Panel.

As a minimum, the following documents are needed to undertake this risk assessment:

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

If these were not provided when the Sponsorship Request Form was submitted, or they were submitted but R&I recommended any amendments, up-to-date copies must be provided as soon as they are available.

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

(b) R&I undertakes full risk assessment

This 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
- iii. Study research costs and evidence of funding
- 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
- 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 carried out in conjunction with the CI and research team. Where required, R&I may request further information to facilitate this assessment, and researchers may be invited to attend a meeting with members of the R&I Sponsorship Review Panel to discuss the project.

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 in light of feedback and/or queries raised during the risk assessment.

For further details on the Data Management Plan, please refer to the SOP on [Data Management \(RI/QMS/SOP/017\)](#).

(c) **Sponsorship decision**

Once a risk assessment is complete and all queries addressed to the satisfaction of R&I, NBT sponsorship in principle, will be agreed. This outcome will be communicated to the CI in writing via email.

- i. By agreeing to sponsorship in principle, NBT is not giving permission for the study to commence. Sponsorship in principle 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 5.5 of this SOP.
- ii. If there are queries that cannot be resolved to the satisfaction of R&I, 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.

5.3 NBT Terms & Conditions of Sponsorship

[NBT Terms & Conditions of Sponsorship \(RI/QMS/SOP/007b\)](#) 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 \(RI/QMS/SOP/007c\)](#) document on NBT website). 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 \(RI/QMS/SOP/007d\)](#) on NBT website) 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.

(a) Chief Investigator acceptance of NBT Terms & Conditions of Sponsorship

When issued with a sponsorship in principle decision, the CI will be emailed a link to NBT's suite of SOPs which must be followed throughout study delivery.

The CI will also be sent a [Chief Investigator Declaration Form \(RI/QMS/SOP/007e\)](#), available on NBT website, 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&I 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.

5.4 Sponsorship authorisation

An authorised signatory from R&I must sign all IRAS paperwork prior to submission to the relevant regulatory bodies. IRAS paperwork will only be signed once sponsorship in principle has been agreed and the CI has returned the signed *Chief Investigator Declaration Form*. Other items that must also be agreed between the CI and R&I 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 of confirmation will be provided to the CI upon request.

5.5 Regulatory Green Light

For NBT sponsored CTIMPS and complex non-CTIMPS, R&I must issue regulatory green light for each participating site (including NBT) prior to that site opening to recruitment. R&I will require that a set of core documentation be received from each site to be able to issue sponsorship regulatory green light.

5.6 Duration of the study

Once the correct approvals are in place the research team are expected to show full engagement with the sponsorship team, including attendance of trial management meetings. Trial management meetings between the Sponsor and Trial Manager will be held, approximately every two months for CTIMPS and complex non-CTIMPS. Less invasive studies should discuss with the Sponsor the requirements for trial meetings.

A trial management report (in a format agreed with the Sponsor) should be submitted to the Sponsor at least two working days before the meeting. The CI should attend the trial management meeting, but if this is not possible then the CI should submit the report to the Sponsor to confirm that they have ratified the content.

5.7 Publications

All publications relating to the study should be submitted to the Sponsor for review before formal submission. 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.

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

- Health Research Authority
UK Policy Framework for Health and Social Care Research
www.hra.nhs.uk
- ICH Secretariat
Guidelines for Good Clinical Practice (E6 R2, Step 4, 2016)
www.ich.org
- UK Government
Medicines for Human Use (Clinical Trials) Regulations 2004
www.legislation.gov.uk
- The following R&I documents are available on the NBT website: www.nbt.nhs.uk/research

RI/QMS/SOP/007a	Sponsorship Request Form
RI/QMS/SOP/007b	NBT Terms & Conditions of Sponsorship
RI/QMS/SOP/007c	Delegation of Responsibilities
RI/QMS/SOP/007d	Delegation of Responsibilities Log
RI/QMS/SOP/007e	Chief Investigator Declaration Form
RI/QMS/SOP/017	Data Management