

York and Scarborough Teaching Hospitals NHS Foundation Trust Sponsorship Policy

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Author:	Monica Haritakis
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Approved by:	Name/Position:	Deborah Phillips, Research Advisor
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	Name/Position:	Sarah Sheath, SOP Controller
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This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewer	Details of significant changes
1.0	12 th May 2026		New SOP

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1 Introduction, Background and Purpose

Under the UK Policy Framework for Health and Social Care Research all health and social care research require a sponsor. This includes all research that involve NHS patients, their tissue or information.

The Sponsor of a research study is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. The sponsor has overall responsibility for the research and is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research. The employer or funder is not automatically the sponsor; they must explicitly accept the responsibilities of being the sponsor.

Two or more organisations may agree to act as co-sponsors or joint sponsors. Co-sponsors allocate specific sponsor responsibilities between them whilst joint sponsors each accept liability for all the sponsor's responsibilities.

A sponsor can delegate specific tasks to any other individual or organisation that is willing and able to accept them. Any co-sponsorship, joint sponsorship or delegation of tasks to another party should be formally agreed and documented by the sponsor(s).

The Sponsor's responsibilities are set out in more detail in the UK Policy Framework for Health and Social Care Research.

Deciding to accept sponsorship of a study or trial is an important decision as the organisation accepts responsibility for the study and the risks associated with it.

2 Objective

The objective of this policy is to clarify the principles and conditions under which the Trust will accept sponsorship of a study.

3 Scope

This policy applies to all research studies that Chief Investigators would like to be sponsored by the Trust and lays out the circumstances and conditions under which the Trust will sponsor research studies.

4 Policy

4.1 Principles of York and Scarborough Teaching Hospitals NHS Foundation Trust Sponsorship

The 'Application to the Trust for Sponsorship of a Research Study' SOP (R&D/S02) must be adhered to.

The Trust reserves the right to decline to sponsor any study if the Trust believes the risks are too high and cannot be mitigated and/or the benefits to Trust for acting as sponsor are too low or not well justified.

The Research & Innovation Group (“the R&I Group”) is a Group consisting of the Clinical Director of R&I, Head of R&I, Research Advisor, Research Leads, Independent Members and Academic Members.

The R&I Group has delegated authority from the Trust Board to review and, where appropriate, approve sponsorship applications for research studies. The R&I Group therefore takes overall responsibility for proportionate, effective arrangements being in place to set up, run and report research projects.

4.2 Non-regulated trials and research studies

In principle the Trust will consider applications for Sponsorship when the following conditions are met:

- The applicant holds a substantive employment contract with the Trust, or they have an honorary appointment with the Trust for the duration of the entire study would be required.
- The study is not being undertaken primarily for the purpose of obtaining an educational qualification.
- An application for Sponsorship is made as per R&D/S02.

4.3 Regulated Trials (CTIMP, device trials)

Research studies that fall within the scope of the MHRA’s Clinical Trial or Medical Device Regulations have specific legal requirements that mean Sponsorship from the Trust is not guaranteed (note: not all clinical trials will fall under the Regulations). In principle the Trust will consider applications for Sponsorship when the following conditions are met:

- The Chief Investigator (CI) must be substantively employed at the Trust or hold an honorary contract with the substantive employer being willing and able to co-sponsor.
- The CI is a registered professional within a speciality relevant to the trial and/or participant group in line with The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.
- The CI has previous experience undertaking clinical trials as a PI.
- The CI is currently registered with no restrictions
- The trial has sufficient funding and central resource to ensure its safe and compliant management.
- The grant awarded for the trial is held by the Trust to ensure adequate and continued financial oversight and financial risk control.
- For device studies the device must have been designed by a substantive employee and/or the IP resides with the Trust.
- The study is not being undertaken primarily for the purpose of obtaining an educational qualification.*
- An application for Sponsorship is made as per R&D/S02.

*The Trust does not recommend that projects that fall within the scope of the Regulations are considered as educational projects. Students cannot act as CI or PI for a CTIMP study (a clinical trial that falls under the scope of the MHRA clinical trial regulations). Refer to: Medicines, medical devices and blood regulation and safety: Clinical trials and investigations - detailed information - GOV.UK (www.gov.uk).

4.4 The Trust declines to Sponsor

The Trust will not consider applications for Sponsorship where:

The applicant does not hold an employment contract with the Trust, or the duration of the employment contract does not cover the duration of the study.

It is not considered possible to legally uphold the requirements of study sponsorship without an active employment contract. Where the applicant does not have an employment contract with the Trust they should seek Sponsorship from their employer.

The study is being undertaken primarily for the purpose of obtaining an educational qualification.

The UK Policy Framework for Health and Social Care stipulates that universities and colleges are expected to accept the role of sponsor for all educational research conducted by their own students, unless the student is employed by a health or social care provider that prefers to do this. Sponsors of educational research should ensure that their supervisors can and do carry out the activities involved in fulfilling this role. It is expected that the sponsor will provide any advice and support to students using this process.

The Trust does not prefer to take this role and will not agree to act as sole Sponsor on educational research. In exceptional circumstances the Trust may consider co-sponsorship provided the main responsibilities for the study resides with the respective University.

Sponsors of educational research should ensure that supervisors can and do carry out the activities involved in fulfilling this role. Where the academic supervisor cannot adequately satisfy the sponsor's oversight responsibilities due to location or expertise, the sponsor should agree co-supervision arrangements with a local care practitioner. Follow Student research toolkit - Health Research Authority (hra.nhs.uk).

Research where the Chief Investigator has previously been found to be in breach of compliance with the R&I approval process or Trust policies and SOPs.

4.5 Co-Sponsorship and Joint Sponsorship

The R&I Forum states that 'where two or more organisations share a significant interest in a study, for example, one as employer of the chief investigator and another as the principal host institution, they may elect to act as co-sponsors or joint sponsors.'

Co-sponsors agree an allocation of defined sponsor responsibilities. The Clinical Trials Regulations group the sponsor's responsibilities by function (Part 3, 4, 5, 6 and 7). Co-sponsors divide amongst themselves both the responsibilities and the liabilities associated with sponsorship. The clinical trial authorisation (CTA) must clearly define the set of sponsorship responsibilities taken on by each party. The allocation of sponsor responsibilities will be determined by the expertise and capacity of the individual or institution to discharge them in relation to the risk posed by the study.

Joint sponsors are partner organisations who accept joint liability for all the sponsor's responsibilities. They are jointly and severally responsible for all the duties of the sponsor, such that all are responsible in the event of a failure of any one of the partner organisations to discharge their responsibilities. Both organisations would have to have suitably qualified and trained staff to oversee all the sponsor's activities

The Trust will not generally consider applications for joint Sponsorship.

The Trust may consider co-sponsorship applications where:

- The applicant has an honorary contract with the Trust.
- The Trust is the Lead NHS site.
- The Trust has significant interest in the study with funds being administered through the Trust. *

* 'Significant interest' would, for example, involve consenting Trust patients, using Trust data and/or images and/or samples. The expectation would be that

the study would take place on the hospital site and that Trust staff would be involved in the study design, delivery and resulting publications.

4.6 Review and Withdrawal of Sponsorship

Should the Trust agree to sponsor a study, if circumstances or the risks change significantly and those risks cannot be mitigated, or there is persistent non-compliance with all applicable regulations, the Trust may, as a last resort, withdraw sponsorship.

For a study which the Trust has agreed to sponsor, should replacement of the Chief Investigator be necessary (for whatever reason), then the Trust will review and approve all reasonable requests, however, the Trust retains the right to decline replacement of the Chief Investigator and may withdraw sponsorship.

For a study which the Trust has agreed to sponsor, any substantial modifications which impact the design or the funding of the study, then the Trust will review and approve all reasonable requests, however, the Trust retains the right to decline.

In instances when it is necessary for the Trust to withdraw sponsorship to, and no alternative sponsor is found, then the Trust will not be liable for any losses if sponsorship is withdrawn.

5 Related SOPs and Documents

R&D/S02 Application to the Trust for Sponsorship of a Research Study

R&D/T72 Sponsorship Feasibility Review Application

R&D/T73 Full Sponsorship Application

R&D/T74 Confirmation of receipt of Sponsorship Application Email Templates

6 Appendix A

