York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
Standard Operating Procedure
R&D/S02

Application to the Trust for Sponsorship of a Research Study

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&I Department's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&I Department SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&I Department website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	R&D/S02
Version Number:	10.0
Author:	Monica Haritakis
Implementation date of current version:	12th May 2026

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	Date:	14th April 2026
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	18th March 2026

As a minimum, this SOP will normally be reviewed 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	Reviewers	Details of significant changes
1.0	13th January 2009		
2.0	21st October 2009		Changes to review dates. Change to SOP number. Inclusion of notification of successful feasibility review to Pharmacy. Put into revised template. Inclusion of green and amber light process.
3.0	1st July 2010		Modified to include registration of trial on eSUSAR database. Template letters added.
4.0	28th March 2012		General update. Change to terminology 'permission to recruit'. Removal of need to submit draft SSI Forms and incorporation of RSS assessment. Change of SOP Controller
5.0	28th October 2013		Removal of references to the North and East Yorkshire Alliance. Shortening of introduction. Removal of requirement to send to Trust R&D lead as now only relevant to York and R&D lead is a member of the R&D Group.
6.0	11th January 2017		Updated to include HRA and confirmation of capacity and capability
7.0	14th August 2017		
8.0	18th July 2019		Withdrawal of F04 and minor updates to incorporate changes to local information pack. Change of link to R&D website.
9.0	13th February 2023	Deborah Phillips	Streamlined documentation required for feasibility review. Removed flowchart appendices. Included the combined review service.
10.0	12th May 2026	Monica Haritakis	Merged S02, S82 and S83 to streamline process. Implementation of new application forms and email templates.

Contents

1 Introduction, Background and Purpose

The Sponsor is the organisation that takes on responsibility for confirming there are appropriate arrangements to initiate, manage and 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.

The Sponsor has the responsibility for ensuring that all the necessary arrangements are in place before the study can proceed, including:

- 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 have access to resources and support to deliver the research as proposed.
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When an organisation agrees to sponsor a research study it takes on a major responsibility. It is important to identify a sponsor as early as possible and, in fact, many funding bodies require a sponsor to be agreed in principle prior to accepting a funding application.

ABBREVIATIONS USED IN THIS DOCUMENT	
CI	Chief Investigator
CRF	Case Record File
CTA	Clinical Trial Authorisation
CTIMP	Clinical trial of an investigational medicinal product
EudraCT	European Clinical Trials Database
GCP	Good Clinical Practice (standards in clinical trials)
GMP	Good Manufacturing Practice (standards for IMPs)
HRA	Health Research Authority
IB	Investigator Brochure
ICH-GCP	International Conference on Harmonisation - Good Clinical Practice (in clinical trials)
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare Products Regulatory Agency

PI	Principal Investigator (at study site)
PIS	Participant Information Sheet
QA	Quality Assurance
R&I Group	York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Group
R&I Department	York and Scarborough Teaching Hospitals Foundation Trust R&I Department
REC	Research Ethics Committee
the Regulations	Regulations under the Medicines for Human Use (Clinical Trials) Regulations 2004 and related Statutory Instruments.
SmPC	Summary of Product Characteristics

2 Who Should Use This SOP

This SOP is relevant to researchers seeking sponsorship by the Trust.

3 When this SOP Should be Used

This procedure applies when an investigator seeks sponsorship of a research study by the Trust. You should refer to the Trusts Sponsorship Policy (R&D/S116) to ensure that your study is eligible for consideration of Sponsorship by the Trust.

4 Procedure(s)

4.1 Determining Sponsorship

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.

The R&I Group will, on behalf of the Trust Board, ensure that the Sponsor responsibilities, as defined in the UK Policy Framework for Health and Social Care Research, are met.

4.2 When to apply for Sponsorship

Where a funding submission is required for a study, a feasibility application for Sponsorship should be submitted prior to a funding submission being made to a funder.

Where time does not allow for a Sponsorship application to be made prior to the submission to the funder, the Head of R&I may give approval for the funding submission being made. The application for Sponsorship should then be submitted at the next available R&I Group meeting.

Where funding is not required an application for Sponsorship should be submitted prior to the submission of regulatory approvals.

4.3 Sponsorship Application

4.3.1 Contacting the R&I Department

It is important to contact the R&I Department at this early stage if you have not already done so. The procedure for applying for Sponsorship will vary depending on the nature of the study and therefore it is essential to seek early advice if in any doubt.

If you are unsure whether your study is a CTIMP or device study please contact the Research Advisor for support in using the MHRA algorithm.

If, after using the algorithm, you are still unsure whether or not the trial is covered by the Regulations send an e-mail to the MHRA Clinical Trial Helpline (clintrialhelpline@mhra.gsi.gov.uk).

4.3.2 Patient and Public Involvement and Engagement

When planning health and social care research in the UK, it is considered best practice to involve patients and the public in the design of the study, and sometimes also in its conduct.

You should consider involving the public as early as possible in the project design process.

REC approval is not required for the involvement of the public in the design of research studies.

For studies where patients, carers or members of the public will be involved in its conduct you will be asked for evidence of how you have involved patients and the public in the design of the project and how it helped in your IRAS application.
You can contact the R&I Department for advice on engaging patients and the public.

4.3.3 Sourcing Funding

As the Sponsor is responsible for determining whether the study is appropriately resourced it is important that the true costs of the research study are assessed at an early stage and appropriate funding secured. A research study sponsored by the

Trust should not have an unacceptable financial cost to the Organisation. If there is no funding to support for the study, then this must be made clear in the sponsorship application.

The R&I Department Grants Team can provide advice and support for any funding application. Costs should be accurate and salary costs must be provided by the R&I Finance Manager.

Funding applications must not be submitted prior to receipt of 'Sponsorship in principle' or permission from the Head of R&I where the deadline for funding submissions is before the Sponsorship review. Please see section 4.4.1 for details on the applying for a feasibility review.

All funding applications must be reviewed and approved by the Head of R&I prior to submission. Applicants should allow sufficient time for this before application deadlines.

4.3.4 Writing the Protocol

Investigators who are still at the "ideas" stage, may contact the R&I Department's Research Advisor for assistance.

Guidance for writing a protocol and a suitable protocol template is available via the R&I Department's website. It should be noted that the protocol template referenced is designed to be applicable to all studies and should be edited to omit those sections that are not relevant to the study being developed.

The R&I Department's Research Advisor can advise you of any additional documents that are required in addition to your protocol at this stage, for example a consent form, patient information sheet or a data collection form. The documents that will be required will vary depending on the nature of your project.

The R&I Department's Research Advisor can offer advice about research questions, the protocol or associated documents. Guidance is also available from the HRA website.

4.4 Sponsorship Review Options

4.4.1 Feasibility review/ Sponsorship in Principle

A feasibility review should be used for CTIMPs and / or where a funding submission is required for a study.

The proposed Chief Investigator (CI) should submit a Research Sponsorship in Principle Application (R&D/T72) which includes a study outline, basic funding plan and details of the investigator team – qualifications, experience, research training, other current research projects, proposed responsibilities in the trial and time available to carry them out.

The purpose is to decide whether the proposal has potential scientific merit, is practicable, is likely to be adequately resourced, and whether the investigator team

has the capacity to carry it out safely and effectively. Where time allows this will be sent to the next R&I Group meeting for review by all members. Where the deadline for submission falls before the next R&I Group meeting this will be sent to the Head of R&I for approval. The application would then be reviewed at the next R&I Group meeting.

Where the Group determines that they wish to support this application they will issue 'Sponsorship in Principle' (R&D/T22).

If funding is confirmed a full Sponsorship Application will be required.

4.4.2 Proportionate Review

The R&I Department offers a proportionate review process for some Sponsorship applications.

Research studies that there are therefore considered to be 'low risk' and meet the criteria defined below may be eligible for consideration via this process. The final decision on this resides with the Trust's Clinical Director for Research or the Chair of the R&I Group.

The only types of studies that will be managed under the proportionate process will be those that do not require REC review (or occasionally those that may be eligible for proportionate REC review). The applicable studies include:

1. Studies where the research participants are NHS staff e.g. interviews or surveys involving NHS staff
2. Studies involving previously collected, non-identifiable tissue samples consisting of, or including, cells in accordance with the terms of donor consent
3. Research involving human biological material not consisting or, or including, cells e.g. serum or plasma
4. Research solely involving previously collected, non-identifiable information. This includes research undertaken by staff within a care team using information that has been previously collected during the course of clinical care for their patients, providing that the data are anonymised or pseudonymised when conducting the research.

Studies that are eligible for consideration via this route are required to meet the same quality standards as all other studies, however they may be exempt from ethical review as they are deemed to be of less ethical concern (for example, they may involve NHS staff or anonymised, pre-collected data only). However, regardless of the requirement for REC review, ALL research studies must be reviewed by the Health Research Authority (HRA) before they are able to proceed. [Note: it is possible that there may be an exception to this, such as student projects at a single site that are exempt from REC review, however the R&I Department will advise if this is the case]. As such, sponsorship applications are expected to be carefully considered and must be supplied with a full suite of documentation that would be suitable for submission to the HRA. Applications for Sponsorship from the Trust will only be processed for consideration by the R&I Department when complete so applicants are advised to supply the correct documentation to avoid unnecessary delay.

4.4.3 Full Sponsorship Application

A full sponsorship application should be submitted for studies where:

- no funding is required
- not eligible for proportionate review
- Sponsorship in principle has been issued

4.5 Submitting Sponsorship Applications

4.5.1 Feasibility Review/ Sponsorship in Principle Application

Investigators should email the relevant documents to the R&I Department at yhs-tr.research.enquiries@nhs.net with the subject heading 'Sponsorship Application'. This should include:

- Research Sponsorship in Principle Application (R&D/T72)
- CVs for the investigator team

4.5.2 Full Sponsorship and Proportionate Review Application to the R&I Department

Dates for the R&I Group meetings and deadlines for receiving Sponsorship applications are available on Trusts research website.

Investigators should email a complete set of application documents to the R&I Department at yhs-tr.research.enquiries@nhs.net with the subject heading 'Sponsorship Application'. This should include:

- Full Sponsorship Application (R&D/T73)
- Study protocol (dated and version controlled);
- Patient Information Sheet (where applicable) following HRA guidance;
- Consent Form (where applicable) following HRA guidance;
- Case Record Form (where applicable);
- CVs for Chief Investigator (CI) and all other investigators in the team – use HRA guidance for this;
- GCP for Chief Investigator (CI) and all other investigators in the team (CTIMP only)
- Drafts of any other communication with patients, participants, GPs or recruitment advertisements – use HRA guidance;
- Any relevant draft contracts or confidentiality agreements that investigators have received from other parties;
- Any completed declarations of conflict of interest (see R&D/G06);
- Study risk assessment (see R&D/F15);
- CI declaration (see R&D/T61);
- Funding Plan (where applicable)
- Investigators Brochure or SmPC (CTIMP only)
- Completed Sponsorship Application Checklist
- Associate Chief Operating Officer (ACOO) approval
- Finance Manager approval (where applicable)
- Support department approval e.g. pharmacy, radiology, laboratory (where applicable)

All documents should be version controlled and dated on each page (preferably in the header or footer).
The application must be made to the R&I Department by the Chief Investigator (CI) or Co- Investigator.

Upon receipt of the Sponsorship Application, it will be reviewed by a member of the R&I study management team. Where a complete application has been received the applicant will be informed that the application will be sent to the R&I Group for review at the next meeting.

If an incomplete application is received the applicant will be advised of the missing information and advised of the next steps. If a complete application is not received by the deadline for submission, it will be deferred to the next meeting without exception.

4.6 How a Sponsorship application is reviewed

4.6.1 Proportionate Sponsorship Review

The R&I Department Research Advisor will review the application and liaise with the Clinical Director for Research or alternatively the Chair of the R&I Group. A decision will be reached as to whether the application can be considered under the proportionate review process. This decision is final.

Where an application is eligible for consideration via the Trust's proportionate review process, this will be communicated to the applicant. The R&I Department will organise a review of the application that is appropriate for the study being proposed. This may include external reviews where necessary.

The Research Advisor will communicate with the applicant within 15 working days from receipt of a complete application (R&D/T22).

Once confirmation of Sponsorship has been received, the applicant should proceed with making a submission to the Health Research Authority (see section 4.9).

4.6.2 Full review

Where a study is not eligible for consideration via the proportionate process then the Research Advisor will organise the external and internal reviews required before the application is submitted to the Trust's R&I Group for a Sponsorship decision. Reviews may include (where applicable), but are not limited to:

- Peer review
- Statistical review
- Pharmacy review
- Laboratory review
- Financial review by the R&I Department
- Any other support department review
- Research QA Manager review and a monitoring plan developed

Once received, copies of the reviews will be sent to the CI/PI as soon as possible. The aim is to do this within 4 weeks, but investigators will appreciate that we can only request external reviewers to meet our deadlines, and they may be unable to do so.

The CI/PI will have the opportunity to respond to the reviewers' comments. Once a response from the CI/PI has been received or confirmation of no response is given, the complete application will be booked into the next available slot at an R&I Group meeting.

The R&I Group will consider the complete application and make a decision as to whether the Trust is able to act as sponsor for the trial. The CI/PI will be invited to attend the relevant part of the meeting. The Group's decision will be communicated to the CI/PI in writing usually within 7 working days (R&D/T23).

The agreement of the Trust to act as sponsor for a research study will allow the applicant to proceed with identifying other Sites (where applicable), putting in place other practical arrangements, and proceeding with applications for an ethical opinion (where required), any other regulatory bodies and HRA approval.

4.7 Radiology assurance

All studies taking place in the NHS involving ionising radiation require review by a Medical Physics Expert (MPE) and Clinical Radiation Expert (CRE). You can contact the R&I Department to arrange this or alternatively the study may be submitted through Radiation Assurance.

Radiation Assurance is a UK-wide process managed by the HRA for studies which are taking place in NHS secondary care settings. The process ensures that the information regarding radiation exposures in study documents are clearly set out at an early stage in the research regulatory approvals pathway. It also coordinates the lead Clinical Radiation Expert (CRE) and lead Medical Physics Expert (MPE) reviews in Part B section 3 of the Integrated Research Application System (IRAS) application form.

Radiation Assurance is a pre-submission process and must take place before the IRAS application is submitted or an application is made to the Administration of Radioactive Substances Advisory Committee (ARSAC) where applicable.

Further details can be found though the IRAS help pages IRAS Help - Preparing & submitting applications - Radiation Assurance.

4.8 Pharmacy Assurance

All multicentre clinical trials of investigational medicinal products (CTIMPs) where the lead NHS R&I office is in England or Wales should be submitted through Pharmacy Assurance.

Pharmacy Assurance simplifies the pharmacy capacity and capability assessments carried out by participating sites by providing a single technical pharmacy review, which is accepted by all participating sites. This replaces the need to complete separate technical reviews at each participating organisation. The single review therefore speeds up the site set-up process, meaning research activities can start much quicker.

Pharmacy Assurance is a pre-submission process and must take place before the IRAS application is submitted.

Further details can be found though the IRAS help pages IRAS Help - Preparing & submitting applications - Pharmacy Assurance.

4.9 Completing the IRAS application – all studies

Before making regulatory submissions, the investigator must incorporate all protocol and related document amendments, as specified during the sponsor review process and pharmacy and/ or radiology assurance (where applicable).

Once any requested changes have been incorporated the investigator can use the Integrated Research Application System (IRAS) to complete the necessary application forms. The IRAS system can be used to make applications all the approvals required (e.g. REC, MHRA, HRA).

For CTIMP and/or device studies the application will be submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC) by Combined Review.

Advice on setting up an IRAS account or completing the form can be obtained from the R&I Department's Research Advisor. It is ESSENTIAL to consider very carefully the filter questions on the first page of the form as the responses to these will amend the form content so that it is appropriate for the application being submitted. If in any doubt, investigators should contact the Research Advisor for advice to avoid spending time completing sections of the form that are not applicable to their study or to omit sections that would be required and will subsequently invalidate the application.

Once completed, the IRAS form should be transferred to the Research Advisor (or delegated individual) for review and electronic authorisation on behalf of the Sponsor. Submission to the relevant external bodies can then be made following the instructions on the HRA website.

For multisite studies the investigator should complete an Organisation Information Document (OID) and SoECAT as the OID will form the site agreement between sponsor and participating organisations. The completed documents must be reviewed and approved by the R&I Department prior to being submitted to the HRA along with the IRAS application. Templates and further information can be found on the HRA website.

The applicant should liaise with the REC (where appropriate), any other regulatory bodies, and the HRA to respond to any queries and submit further information as required.

The applicant should subsequently receive approval from the regulatory bodies to which an application has been submitted.

4.10 Application to commence at Sites (capacity and capability)

Once approval has been received in writing (email) from the HRA (all studies) and the REC and /or MHRA (where necessary), then the final approved set of documents must be submitted to any NHS Organisation that is to be a study site (including York and Scarborough Teaching Hospitals NHS Foundation Trust (refer to R&D/S14). The documentation that should be included in the local information pack to participating sites is detailed on the HRA website. For multisite studies the application pack must be submitted to and reviewed by York and Scarborough Teaching Hospitals NHS Foundation Trust before being sent to other Sites.

Following receipt of the application documents, the R&I Department will review the documentation and make any insurance, contract or similar arrangements that are required.

Where appropriate a suitably qualified Medical Expert will be appointed for the study and any study oversight committees established and terms of reference agreed.

Site Initiation and appropriate study/SOP training should be undertaken as instructed by the Sponsor and documented.

At the end of the setup process, and once all arrangements are in place, confirmation of capacity and capability will be issued along with permission to begin recruitment.

If, however, the R&I Department considers that significant changes have been made to the study as a result of the regulatory applications, it may be necessary to return the study to the R&I Group for further consideration as to whether the proposed changes affect sponsorship of the study.

Note that any change to the approved study documentation or study management after confirmation of capacity and capability has been issued will constitute an amendment to the study. All amendments must be processed following the R&I Department's SOPs (refer to Section 5).

It is important to remember that FINAL sponsorship approval and confirmation of Capacity and Capability are both required before the trial can commence.

5 Related SOPs and Documents

R&D/T72	Research Sponsorship in Principle Application
R&D/T73	Full Sponsorship Application
R&D/T74	Confirmation of receipt of Sponsorship Application Email Templates
R&D/S03	Delegation of Tasks for Trust sponsored CTIMPs
R&D/S08	Monitoring of Trust Sponsored Research Studies
R&D/S09	Set up and management of Research Studies
R&D/S14	Local New Study Set-Up: Capacity and Capability Assessment
R&D/F11	Trial master File/Investigator Site File contents
R&D/S18	Risk Assessment
R&D/T22	Sponsorship in Principle Decision Letter/Email
R&D/T23	Full Sponsorship Decision Letter/Email

6 Appendix A