**York Foundation Trust R&D Unit**
**Standard Operating Procedure**
**R&D/S82**

# 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&D Unit'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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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&D Unit 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&D Unit website: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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| Author: | Deborah Phillips |
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| Approved by: | Name/Position: | Lydia Harris, Head of R&D |
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| | Date: | 17th June 2019 |
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| | Signature: | Signed copy held by R&D Unit |
| | Date: | 17th June 2019 |

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 | Details of significant changes |
|---|---|---|
| 1.0 | 24th August 2017 | |
| 2.0 | 15th July 2019 | Change to website address. Incorporation of new HRA processes (SoA changes). Clarification as to which studies can be considered by proportionate review. |
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## 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.

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.

# 2 Who Should Use This SOP

This SOP is relevant to researchers seeking sponsorship by the Trust of a research study that is not a Clinical Trial of an Investigational Medicinal Product (CTIMP) or Medical Device study. Processes for applying for Sponsorship for these studies is covered in other SOPs referenced in Section 5.

# 3 When this SOP Should be Used

This procedure applies when an investigator seeks sponsorship of a research study by the Trust. This SOP should not be used when applying for sponsorship of a CTIMP study or a medical device study. The procedures are covered on other SOPS (refer to Section 5). If you are unsure as to which SOPs apply to your application for sponsorship, seek early advice from the R&D Unit.

# 4 Procedure(s)

If your study is not a CTIMP and does not involve a non-CE marked medical device, the following process should be followed in order to apply for sponsorship from the Trust.

This SOP makes reference to information contained on the Health Research Authority (HRA) web pages. This information is not reproduced here but readers are advised to refer directly to the HRA website for the most up to date information and advice. http://www.hra.nhs.uk/

## 4.1 Contacting the R&D Unit

It is important to contact the R&D Unit 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. Regardless of the process, a written protocol is always required (see section 4.2).

## 4.2 Writing the Protocol

Investigators who are still at the "ideas" stage, may contact the R&D Unit's Research Adviser for assistance. Guidance for writing a protocol and a suitable protocol template are available via the R&D Unit's website. It should be noted that the protocol template 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.

One of the R&D Unit's Research Advisors will 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 sheet. The documents that will be required will vary depending on the nature of your project.

The Unit's Research Adviser can offer advice about research questions, the protocol or associated documents. Refer to R&D/G05 for further guidance.

## 4.3 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 external competitively awarded funding for the study has already been sourced then submit the protocol and supporting documents (including funding award letter and copies of peer reviews) to the R&D Unit as described in section 4.5.

If there is no funding to support the study then this must be made clear in the sponsorship application.

## 4.4 The Sponsorship Review Process

The R&D Unit 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 Lead for Research.

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&D Unit 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&D Unit when complete so applicants are advised to supply the correct documentation to avoid unnecessary delay (see Section 4.5).



## 4.5 Submitting the Application to the R&D Unit – all studies

Investigators should email a complete set of application documents to the R&D Unit at research.governance@york.nhs.uk. This should include:

- Study protocol (dated and version controlled);
- Patient Information Sheet (where applicable) following HRA guidance;
- Consent Form (where applicable) following HRA guidance;
- Case Record File (where applicable);
- CVs for Chief Investigator (CI) or Principal Investigator (PI) and all other investigators in the team – use HRA guidance for this;
- 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);

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&D Unit by the Chief Investigator (CI) or Principal Investigator (PI).

## 4.6 How a Sponsorship application is reviewed

### 4.6.1 Proportionate Sponsorship Review

The R&D Unit Research Adviser will review the application and liaise with the Clinical Lead for Research. 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&D Unit will organise a review of the application that is appropriate for the study being proposed. This may include external reviews where necessary.

The Research Adviser will communicate with the applicant within 15 working days from receipt of a complete application.

Once confirmation of Sponsorship has been received, the applicant should proceed with making a submission to the Health Research Authority (see section 4.7)

### 4.6.2 Full review

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

- Peer review
- Statistical review
- Pharmacy review (where applicable)
- Laboratory review (where applicable)
- Financial review by the R&D Unit
- Any other support department review (where applicable)
- 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&D Group meeting.

The R&D 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.

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 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.

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).

Advice on setting up an IRAS account or completing the form can be obtained from the R&D Unit's Research Adviser. 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 Adviser 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 Adviser 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 a Organisation Information Document (OID) and Schedule of Events (SoE) or SoECAT as the OIDwill form the site agreement between sponsor and participating organisations. The completed documents must be reviewed and approved by the R&D Unit 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. It is essential to consider any changes made to the study documentation during this process and to consider whether this would require an amendment to be submitted to any other bodies.

## 4.8 Application to commence at Sites (capacity and capability)

Once approval has been received in writing (email) from the REC (where necessary) and HRA (all studies) then the final approved set of documents must be submitted to any NHS Organisation that is to be a study site (including York Teaching Hospital NHS Foundation Trust (refer to 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 Teaching Hospital before being sent to other Sites.

Following receipt of the application documents, the R&D Unit 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&D Unit 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&D 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&D Unit's SOPs (refer to Section 5).

# 5 Related SOPs and Documents

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| R&D/S02 | Application to the Trust for Sponsorship of a CTIMP |
| R&D/S14 | Confirming Capacity and Capability |
| R&D/S74 | Making Amendments to Trust Sponsored Research Studies |
| R&D/S83 | Application for Sponsorship of a Medical Device Study |
| R&D/G05 | R&D Unit Research Adviser Services |
| R&D/G06 | Conflicts of Interest in Research |
| R&D/F15 | Risk Assessment Form |

http://www.hra.nhs.uk/