STANDARD OPERATING PROCEDURE

S48 – Application for Non-CTIMP sponsorship

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Controlled document

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DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

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Full History			
Version	**Date**	**Author**	**Reason**
V1.0	25 April 2014	R&D Directorate Manager	
V2.0	30 March 2015	R&D Directorate Manager	Introduced deadlines for applications prior to LRM meeting.
V3.0	30 March 2018	Senior Non-Network Facilitator	Changed author. Updated procedure. Formatted into Trusts template.

Associated Trust Policies/ Procedural documents:	Research & Development Policy Application for CTIMP Sponsorship Auditing Processes for R&D
Key Words:	R&D CTIMP Sponsorship Clinical Trial SOP

In consultation with:

- R&D Divisional Manager (February 2018)
- Local Research Meeting (LRM) group members (February 2018)
- Quality Assurance Group (February 2018)

Contents

1 INTRODUCTION

All research which falls within the scope of the UK Policy Framework for Health and Social Care Research requires a research Sponsor. A Sponsor in this context may not be the same as the funding body. Specifically, the research Sponsor is a company, institution or organization which takes on responsibility for the research project. The sponsor 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 Research & Development Division (R&D) delivers the sponsorship role for the Royal Devon & Exeter NHS Foundation Trust (hereafter referred to as the Trust).

2. PURPOSE

This document describes the procedures required to ensure appropriate arrangements for sponsorship are in place for a non-Clinical Trial of an Investigational Medicinal Product (CTIMP) managed by the R&D Division, on behalf of the Trust.

3. SCOPE

This SOP is applicable to all non-CTIMPs sponsored by the Trust.

The SOP is applicable to Chief Investigators (CI), delegated trial team members involved in Trust-sponsored non-CTIMPs and R&D team members undertaking sponsor activities on behalf of the Trust. Where responsibility for performing the regulatory green light procedure (or part of) is delegated to a Clinical Trials Unit (CTU), this SOP is also applicable to the assigned Trial Manager.

4. DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
LRM	Local Research Meeting
MHRA	Medicines and Healthcare products Regulatory Agency
R&D	Research & Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a study. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
TMF	Trial Master File

5. DUTIES AND RESPONSIBILITIES OF STAFF

The **Sponsor** has overall responsibility for proportionate, effective arrangements being in place to set-up, run and report a research project.

The **Chief Investigator** is the Lead Researcher and is responsible for the overall conduct of a research project. It is the responsibility of the CI to actively engage with R&D for Trust sponsorship, Research Ethics Committee (REC) approval, Health Research Authority (HRA) approval and any other applicable regulatory body throughout the sponsorship process.

The **Local Research Meeting (LRM)** is responsible for the assessment and

authorisation of applications for Trust Sponsorship.

The **R&D Divisional Manager** provides the authorised signatory on the Integrated Research Application System (IRAS) paperwork and sponsorship letters.

The **NHS Research Advisor** is responsible for providing scientific advice to researchers requiring RD&E sponsorship. They are the first point of contact for non-CTIMP sponsorship and will advise if a study is potentially in scope for sponsorship consideration by the RD&E.

6. PROCEDURES

It is strongly recommended that all Investigators who are considering submitting an application for Trust Sponsorship should contact the NHS Research Advisor at an early stage (i.e. prior to funding application) for specialist advice and guidance via the R&D generic email account: rde-tr.Research@nhs.net

The NHS Research Advisor will check that the study is suitable for sponsorship and will recommend that a request is made to the LRM. Alternatively, they may suggest that further work/additional information is required.

6.1 Sponsorship review

6.1.1 The Investigator confirms that the study would not be classified as a CTIMP. The MHRA algorithm should be followed to check this. If the Investigator is uncertain whether the study would be classified as a CTIMP, they should email the MHRA Clinical Trial Helpline for an opinion at clintrialhelpline@mhra.gsi.gov.uk, with 'Scope - protocol review' followed by the shortened study title as the subject line. Please see the CTIMP sponsorship standard operating procedure (S09) for more information.

6.1.2 The Investigator requests Sponsorship from the Trust to R&D, supported by the following documentation:

- Study proposal/ draft protocol/ grant application
- MHRA confirmation of non-CTIMP status (if appropriate)
- Outline funding plan

Applications should be sent via the R&D Facilitator at rde-tr.Research@nhs.net marked '*Non-CTIMP Sponsorship review'* in the subject heading.

Applications for sponsorship must be received 7 calendar days before the next LRM.

6.1.3 Upon receipt of the application, R&D will assess whether the trial is within scope based on the following criteria:

Criteria	Comment
Suitable study type	The Trust is unable to sponsor Phase I CTIMPs involving healthy individuals. This SOP is applicable to non-CTIMP studies.
UK-based location of sites	The Trust is unable to sponsor research conducted outside of the UK
Non-commercial contract research	The Trust is unable to sponsor commercial contract research
Investigator holds employment contract with The Trust	The CI would usually:- have an employment contract with the Trust **or** be a clinical academic practising in the

	Trust with an honorary Trust contract.
Study is not in support of a qualification	The Trust would usually not sponsor research undertaken as part of a qualification. Sponsorship would usually be provided by the university where the student is registered.

6.2 Risk Assessment

6.2.1 Projects deemed as within scope of Trust Sponsorship will be subjected to a risk assessment and review. This will involve assessing whether the study protocol poses any clinical, legal, financial or reputational risk and whether it is well-designed, peer-reviewed and statistically sound.

Assessment of risk will include review of the following non-exhaustive list:

6.2.2
- Suitability of the Trust as study Sponsor/Co-sponsor. *N.B. It may be appropriate, in some circumstances, for the Trust to co-sponsor the study with the University of Exeter (UoE) or for the UoE to sole sponsor the study.*
- Capacity of R&D to fulfil the sponsorship role
- Appropriate support from an experienced CTU, if applicable
- CI suitability to lead the research (based on prior experience)
- Study research costs, evidence of funding and appropriate resources
- Arrangements for meeting excess treatment costs (if required)
- NIHR portfolio eligibility
- Peer review including suitability of study design
- Capacity and capability to undertake the study within the Trust and/ or other trial sites
- Compliance with regulatory standards (advice will be given from R&D re which regulatory approvals are required)
- Standard of the proposal/protocol
- Contractual requirements
- Arrangements for managing study data and documentation

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

6.2.3 The assessment will be carried out by the LRM. Supporting information and/or clarification may be requested by R&D as part of the review, and the Investigator may be invited to attend a meeting with R&D to discuss details of the study and issues raised during the risk assessment process.

6.3 Sponsorship decision

6.3.1 Following review by the LRM, confirmation of 'Sponsorship in Principle' will be communicated to the Investigator within 5 working days via email. If further information is required, or the Trust is unable to sponsor the study, this will also be communicated within 5 working days. Sponsorship in principle will be communicated to the researcher, but this will be subject to a successful funding application and a positive scientific review.

A formal sponsorship letter will be issued to the Investigator once R&D has completed their governance checks. This includes, but is not limited to:

- A successful funding application
- A positive scientific review
- Review of the IRAS application and study documents

- Confirmation of NHS staff and service department involvement/support
- A feasible recruitment strategy/plan
- Appropriateness of those consenting in the study
- Agreements and contracts being in place, if required
- Registration of the study on clinicaltrials.gov, if appropriate

6.4 Sponsorship authorisation

6.4.1 The R&D Divisional Manager (or nominated deputy) will act as authorised signatory and sign all IRAS paperwork prior to submission to the relevant regulatory bodies. IRAS paperwork will only be signed once Sponsorship has been agreed.

6.5 Regulatory Green Light

6.5.1 For Trust sponsored non-CTIMPs, the Sponsor (or delegated agent) will issue Regulatory Green Light for each participating site prior to that site opening to recruitment, if applicable, and subject to receipt of the relevant documentation from each site.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the Trust intranet and external website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

8. MONITORING COMPLIANCE AND EFFECTIVESS OF THIS SOP

8.1 This SOP will be audited in line with S04 Auditing processes in R&D.

8.2 Outcomes from audit will be presented to the R&D Quality Assurance Group which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to the R&D Divisional Governance Group.

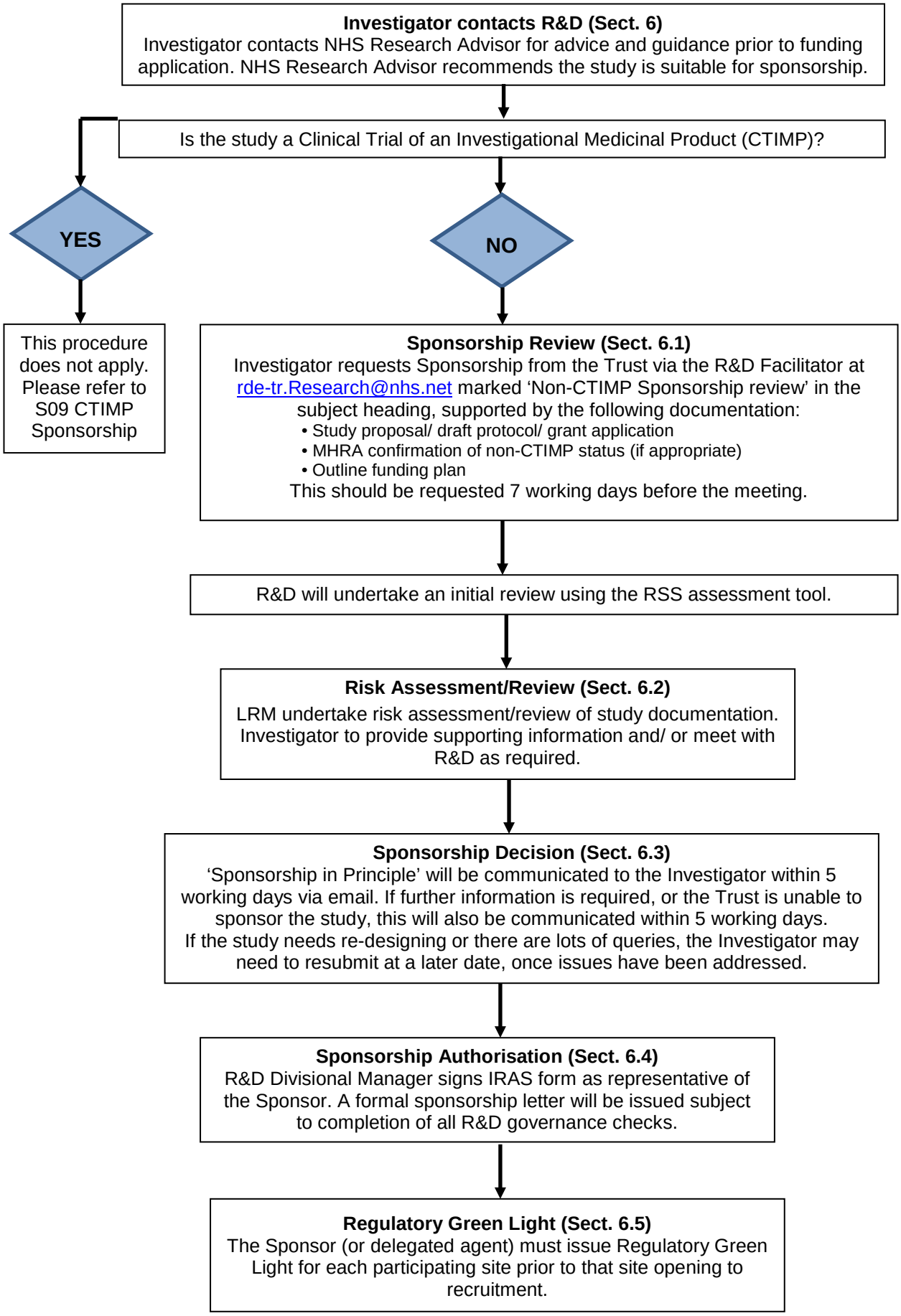
9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Trust Intranet.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

UK Policy Framework for Health and Social Care Research (v3.3 07/11/2017)
Health Research Authority


Investigator contacts R&D (Sect. 6)
Investigator contacts NHS Research Advisor for advice and guidance prior to funding application. NHS Research Advisor recommends the study is suitable for sponsorship.
Is the study a Clinical Trial of an Investigational Medicinal Product (CTIMP)?
YES
NO
This procedure does not apply. Please refer to S09 CTIMP Sponsorship
Sponsorship Review (Sect. 6.1)
Investigator requests Sponsorship from the Trust via the R&D Facilitator at rde-tr.Research@nhs.net marked 'Non-CTIMP Sponsorship review' in the subject heading, supported by the following documentation:
• Study proposal/ draft protocol/ grant application
• MHRA confirmation of non-CTIMP status (if appropriate)
• Outline funding plan
This should be requested 7 working days before the meeting.
R&D will undertake an initial review using the RSS assessment tool.
Risk Assessment/Review (Sect. 6.2)
LRM undertake risk assessment/review of study documentation. Investigator to provide supporting information and/ or meet with R&D as required.
Sponsorship Decision (Sect. 6.3)
'Sponsorship in Principle' will be communicated to the Investigator within 5 working days via email. If further information is required, or the Trust is unable to sponsor the study, this will also be communicated within 5 working days.
If the study needs re-designing or there are lots of queries, the Investigator may need to resubmit at a later date, once issues have been addressed.
Sponsorship Authorisation (Sect. 6.4)
R&D Divisional Manager signs IRAS form as representative of the Sponsor. A formal sponsorship letter will be issued subject to completion of all R&D governance checks.
Regulatory Green Light (Sect. 6.5)
The Sponsor (or delegated agent) must issue Regulatory Green Light for each participating site prior to that site opening to recruitment.