Standard Operating Procedure

S09 – SPONSORSHIP Version 3	
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Date of original policy / strategy/ standard operating procedure/ guideline	August 2011
Approving body and date approved	13/10/2023 R&D Governance Oversight Group (GOG)
Effective date and version number	13/10/2023 v3
Review date (and frequency of further reviews)	13/07/2026
Expiry date	13/10/2026

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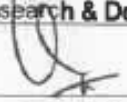
Signature	
Date	02 Nov 2023

Controlled document

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DISCLAIMER

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

Once printed this is an uncontrolled document

Full History			
Version	Date	Reviewed By	Reason
1.0 Final	August 2011	Research Management & Governance Manager	New version
1.1 Final	March 2014	Research Management & Governance Manager	Revised process
1.2 Final	June 2016	Research Management & Governance Manager	Updated terminology
2.0 Final	March 2017	Research Governance & Quality Manager	Revised process; update into Trust template
3 Final	October 2023	Research & Development Manager	Revised process; amalgamation of S48 Application for non-CTIMP sponsorship; updated template

Associated Trust Policies/ Procedural documents:	Research & Development Policy
Key Words:	R&D Research CTIMP Sponsorship Clinical Trial SOP
In consultation with: • Quality Assurance Group • R&D Governance & Oversight Group	

Contents

KEY POINTS OF THIS PROCEDURAL DOCUMENT:

- A research Sponsor is a company, institution or organisation which takes on responsibility for the research project.
- The Research & Development Division delivers the Sponsorship function on behalf of the Trust.
- Clarification of staff responsibilities in the sponsorship process.
- Conditions to be met and maintained in order for Trust sponsorship to be agreed.

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 organisation which takes on responsibility for the research project. The Research & Development Division (R&D) delivers this specific function for the Royal Devon University Healthcare 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 research studies managed by the R&D Division on behalf of the Trust.

3. SCOPE

This SOP is applicable to all research studies sponsored by the Trust.

The SOP is applicable to Chief Investigators (CI), delegated trial team members involved in Trust-sponsored studies 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 & ABBREVIATIONS

CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
R&D	Research & Development

REC	Research Ethics Committee
Regulatory Green Light	Process whereby a trial Sponsor ensures all approvals, contracts and necessary documentation are in place and that records are available to verify all required documentation has been received and checked prior to trial commencement
SOP	Standard Operating Procedure
RSS	Research Support Service
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
Sponsor Representative	An individual with delegated authority to act on behalf of the Sponsor
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** (CI) 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 **Sponsor Representative** provides the authorised signatory on Integrated Research Application System (IRAS) paperwork.

The **NHS Research Advisor** is responsible for providing scientific advice to researchers requiring R&D Sponsorship.

The **R&D Governance and Oversight Group** (GOG) is responsible for ratifying sponsorship of new research projects and providing oversight of all ongoing Trust-sponsored projects.

6. PROCEDURES

6.1 Early engagement

6.1.1 It is strongly recommended that all Investigators who are considering submitting an application for Trust Sponsorship should contact R&D at an early stage of their planning process (i.e. prior to funding application) for specialist advice and guidance. Queries should be submitted via the R&D generic email account: rduh.research-eastern@nhs.net

6.1.2 On receipt of a sponsorship request and/ or query, R&D will contact the Investigator to obtain outline details of the project plan e.g. study design, intended funding stream, planned timelines.

6.1.3 R&D will convene an Early Engagement meeting with the Investigator. Depending on the planned scope of the research project, the meeting will include representation from

Clinical Delivery and Finance, plus as applicable the Research Support Service (RSS), a Clinical Trial Unit (CTU), Pharmacy and/ or CRN Study Support Service. The purpose of this meeting is to discuss the outline of the project, identify project partners, clarify planned timelines for funding application and study delivery and to agree key actions.

6.1.4 Prior to the Early Engagement meeting the Investigator should provide details of the project proposal or draft protocol to R&D and determine CTIMP status of the proposed study if the intervention involves a drug/medicinal product.

6.1.5 In order to determine CTIMP status of the proposed study, the Investigator should refer to the MHRA algorithm and notify R&D of the outcomes of this assessment.

6.2 Sponsorship Review

6.2.1 Upon receipt of the application and an early engagement meeting undertaken, R&D will assess whether the planned research project 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
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
Does not involve co-sponsorship	The Trust is unable to undertake co-sponsorship of CTIMPs or device studies
Trial management	CTIMPs must be supported by an appropriate Clinical Trials Unit

6.2.2 Confirmation that the trial is within scope of Trust Sponsorship does not constitute agreement to sponsor. Agreement to sponsor can only be confirmed once a full review and risk assessment have been undertaken.

6.2.3 In order to be considered for Trust Sponsorship a research project must be deemed feasible within setting, appropriately funded and scientifically sound.

6.3 Risk Assessment

6.3.1 Projects deemed as within scope of Trust Sponsorship will be subjected to a comprehensive risk assessment and review which will completed by R&D in conjunction with the CI. This will involve assessing whether the study protocol poses significant clinical, legal, financial or reputational risk and whether it is well-designed,

peer-reviewed and statistically sound. The correct assessment template should be used according to study type, namely regulated trials, interventional (non-regulated) and non-interventional

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

- Suitability of the Trust as study Sponsor
- Capacity of R&D to fulfil the sponsorship role
- Trial management requirements including delegation of responsibilities and use of a CTU if appropriate
- Training and experience including CI suitability to lead the research
- Study research costs, evidence of funding and availability of other appropriate resources
- Capacity and capability to undertake the study within the Trust and/ or other trial sites
- Arrangements for managing study data, documentation and reporting requirements

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

6.3.4 The risk assessment will be carried out in collaboration and conversation with the Investigator. Supporting information and/or clarification may be requested by R&D as part of the review.

6.3.5 The risk assessment will be reviewed and updated as new information is made available or as the project progresses, e.g. at grant application and again post award.

6.4 Sponsorship Decision

6.4.1 Ratification of decision to sponsor new research projects will be undertaken by the R&D Governance and Oversight Group and documented within the meeting minutes.

6.4.2 Prior to presentation to GOG, the Sponsorship Manager will confirm completion of all necessary checks and assessments as evidenced by completion of relevant work flows on Edge.

6.5 Terms and Conditions of Sponsorship

Where the Trust agrees to act as Sponsor for any specific project, the following terms and conditions will apply:

6.5.1 By confirming Trust Sponsorship in Principle, the Trust is not giving permission for the study to commence. Sponsorship in Principle is conditional on all relevant approvals being in place and provision of adequate funding.

6.5.2 The Chief Investigator, Principal Investigator(s) and all members of the research team shall comply with all regulations applicable to the research including, but not limited to:

- The Department of Health Research Governance Framework for Health & Social Care (2nd edition. Apr 2005)
- The World Medical Association Declaration of Helsinki (2000)
- Medicines for Human Use (Clinical Trials) Regulations (2004)

- ICH Guidelines for Good Clinical Practice (E6 (R2) Step 5. Dec 2016)
- Human Tissue Act (2004)
- Mental Capacity Act 2005
- Data Protection Act 2018
- The Trust's Research and Development Policy and SOPs.

6.5.3 The Investigator shall provide evidence of up to date GCP and Trial Master File training.

6.5.4 The project must not commence within the Trust or any other research site until:

- Evidence is provided of appropriate scientific review of the protocol and research methods
- Confirmation of comprehensive project costing and provision of adequate funding
- A favourable ethical opinion has been obtained from the relevant NHS Research Ethics Committee (REC) and the Health Research Authority (HRA)
- Non-Trust employees having direct contact with patients and/or having a direct bearing on the quality of their care have honorary contracts in place
- Arrangements are made for the recovery of associated costs or, if externally funded, financial arrangements are covered by a suitable agreement
- When applicable, Clinical Trial Authorisation has been obtained from the MHRA (or Competent Authorities)
- Such other regulatory approval(s) required for the research to proceed have been obtained
- R&D provides confirmation in writing of their capability and capacity to undertaken the project, and all necessary site agreements are executed

6.5.6 The project must not commence within any other research site until the R&D office of that site provides confirmation in writing of their capability and capacity to undertaken the project, and all necessary site agreements are executed.

6.5.5 Ultimately the Sponsor remains accountable for all functions of sponsorship; therefore, the CI is accountable to the Sponsor.

6.5.6 When confirmation of Trust Sponsorship in Principle is issued, the CI will be provided with a link to an electronic library of Trust R&D SOPs which must be adhered to for the duration of the study.

6.5.7 Sponsorship may be withdrawn if any of these terms and conditions are breached.

6.6 Sponsorship Authorisation

6.6.1 The Trust Sponsor Representative will act as authorised signatory on all IRAS application paperwork prior to submission to the relevant regulatory bodies.

6.6.2 The IRAS application will only be signed by the Sponsor Representative once all terms and conditions of Sponsorship have been met.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the Royal Devon 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.

7.3 If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	R&D will assess whether the planned research project is within scope.	Recorded within R&D records
2.	Trust Sponsorship will be subjected to a comprehensive risk assessment and review which will completed by R&D in conjunction with the CI	Correct assessment template filed in the study R&D folder and ISF.
3.	Ratification of decision to sponsor new research projects will be undertaken by the R&D Governance and Oversight Group	Recorded in GOG meeting minutes
4.	The project must not commence until R&D provides confirmation in writing of their capability and capacity to undertaken the project	Recorded in ISF and R&D folder

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) 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 GOG.

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 Royal Devon website.

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

The Department of Health Research Governance Framework for Health & Social Care (2nd edition. Apr 2005)

The World Medical Association Declaration of Helsinki (2000)

Medicines for Human Use (Clinical Trials) Regulations (2004)

ICH Guidelines for Good Clinical Practice (E6 (R2) Step 5. Dec 2016)

Human Tissue Act (2004)

Mental Capacity Act 2005

Data Protection Act