Extension granted until 02 March 2020 by the Quality Assurance team (R&D) on the 26th July 2019.

STANDARD OPERATING PROCEDURE

S09 - Application for CTIMP Sponsorship

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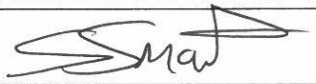
Signature	
Date	21/04/2017
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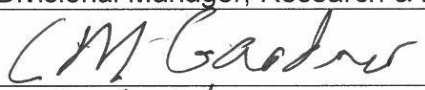
Signature	
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DISCLAIMER

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**
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

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

In consultation with:

- R&D Divisional Manager (January 2017)
- Local Research Meeting (LRM) group members (February 2017)
- Quality Assurance Group (January 2017)

Contents

1 INTRODUCTION

When an organisation agrees to sponsor a clinical trial of an Investigational Medicinal Product (CTIMP) it takes on a major responsibility. The Research & Development Division (R&D) delivers this specific function 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 CTIMPs managed by the R&D Division on behalf of the Trust.

3. SCOPE

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

The SOP is applicable to Chief Investigators (CI), delegated trial team members involved in Trust-sponsored 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
CIMD	Clinical Investigation of a Medical Device
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
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
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
TMF	Trial Master File

5. DUTIES AND RESPONSIBILITIES OF STAFF

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

The **Local Research Meeting (LRM)** is responsible for the assessment and authorisation of applications for Trust Sponsorship.

It is the responsibility of the **Investigator** to actively engage and liaise with R&D prior to submission for Trust sponsorship authorisation to the Research Ethics Committee (REC), the Medicines and Healthcare Products Regulatory Agency (MHRA), Health Research Authority (HRA) and throughout the sponsorship process.

6. PROCEDURES

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

6.1 Sponsorship Review

6.1.1 The Investigator determines CTIMP status of the proposed study, making reference to the MHRA algorithm and notifying R&D of the outcomes of this assessment.

6.1.2 In order to obtain formal confirmation of CTIMP status, the Investigator should email a copy of the study proposal to the MHRA Clinical Trial Helpline at clintrialhelpline@mhra.gsi.gov.uk, with '*Scope - protocol review*' followed by the shortened study title as the subject line.

6.1.3 The Investigator submits an application for Trust Sponsorship to R&D, supported by the following documentation:

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

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

6.1.4 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
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

6.1.5 Confirmation that the trial is within scope of Trust Sponsorship will be provided to the Investigator via email within 7 days.

6.1.6 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 Risk Assessment

6.2.1 Projects deemed as within scope of Trust Sponsorship will be subjected to a comprehensive risk assessment and review which will completed by R&D. 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.

6.2.2 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
- Appropriate support from an experienced CTU
- 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
- Standard of the 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 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.

6.2.4 The Investigator will be invited to attend a meeting with R&D to discuss details of the study and issues raised during the risk assessment process.

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

6.3 Sponsorship Decision

6.3.1 On satisfactory conclusion of the review and risk assessment, the proposal for Sponsorship will be taken to LRM, supported by the following documentation:

- Trial proposal/ draft protocol/ grant application
- Completed risk assessment
- MHRA confirmation of CTIMP status
- Outline funding plan
- Feasibility reviews
- Assessment of proposed Clinical Trials Unit (CTU)

6.3.2 The Investigator may be invited to attend LRM to discuss details of the study.

6.3.3 Following review by LRM, confirmation of ‘Sponsorship in Principle’ will be communicated to the Investigator within 10 working days via email.

6.3.4 The Sponsorship proposal will be re-discussed at LRM following confirmation of a successful grant application in order to determine the final Sponsorship decision. The outcome of this meeting will be communicated to the Investigator within 10 working days via email.

6.4 Terms & Conditions of Sponsorship

6.4.1 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.

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

6.4.2.1 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 1998
- The Trust's Research Policy and SOPs

(Sponsorship may be withdrawn if any of these are breached).

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

6.4.2.3 Where any responsibilities of the CI have been delegated to other members of the research team, these must be recorded in a Delegation of Responsibilities Log and stored in the local site file.

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

- A favourable ethical opinion has been obtained from the relevant NHS Research Ethics Committee (REC) and the Health Research Authority (HRA)
- R&D and the R&D offices of all other NHS organisations participating in the project provide confirmation in writing of their capability and capacity to undertaken the project, and all necessary site agreements are executed
- 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
- Clinical Trial Authorisation has been obtained from the MHRA (or Competent Authorities)
- In the case of a clinical investigation of a Medical Device (ciMD) a Declaration of No Objection has been obtained from the MHRA
- Such other regulatory approval(s) require for the research to proceed have been obtained

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

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

6.5 Sponsorship Authorisation

6.5.1 The R&D Divisional Manager will act as authorised signatory and sign all IRAS paperwork prior to submission to the relevant regulatory bodies.

6.5.2 IRAS paperwork will only be signed once Sponsorship in Principle has been agreed.

6.6 Regulatory Green Light

6.6.1 For Trust sponsored CTIMPs, the Sponsor (or delegated agent) must issue Regulatory Green Light for each participating site prior to that site opening to recruitment.

6.6.2 Sponsorship Regulatory Green Light will only be issued following receipt of a complete set of core 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.

7.3 The 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 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

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)

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