STANDARD OPERATING PROCEDURE

S11 – DELEGATION OF ROLES FOR TRUST SPONSORED STUDIES

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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**	**Author**	**Reason**
V1.1	23 April 2014	Chris Gardner, R&D Directorate Manager	Minor changes to appendix 3.
V2.1	26 September 2014	Chris Gardner, R&D Directorate Manager & Claire Ridler, RM&G Manager	Incorporation of co-sponsorship division of responsibilities with justification of variation from template
V3	01 July 2019	Alison Kerridge, Assistant R&D Manager	New template format and rewritten to incorporate all the divisions of responsibilities used in sponsored trials

Associated Trust Policies/ Procedural documents:	Research & Development Policy S09 – Application for CTIMP sponsorship S22 – Safety Reporting S26 – Providing and Documenting Training for Researchers S48 - Application for non-CTIMP sponsorship
Key Words:	Delegation Sponsorship Chief Investigator
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Contents

1 INTRODUCTION

The UK Clinical Trial Regulations place responsibility for a clinical trial of an investigational medicinal product (CTIMP) firmly on the Sponsor. In relation to delegation, the 2006 Statutory Instrument added the following *"A person who is a sponsor of a clinical trial in accordance with this regulation may delegate any or all of his functions under these Regulations to any person but any such arrangement shall not affect the responsibility of the sponsor"*. Thus the sponsor can delegate but still remains responsible and must therefore ensure that delegated tasks are carried out properly.

ICH-GCP guidelines state that 'prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions.' The need for utmost clarity about roles and responsibilities in research is also fundamental to the UK Policy Framework for Health and Social Care.

It is therefore critical that the sponsor implements procedures to ensure oversight of all delegated roles and responsibilities at the level of organisations and individual.

2. PURPOSE

This SOP establishes a scheme of delegation that allocates Sponsor and trial functions to different members of staff or indeed other organisations. Where there is onward delegation, this must be clearly documented and authorised in writing by the person with primary responsibility under this SOP.

3. SCOPE

This SOP is applicable to all research (both Clinical Trial of an Investigational Medicinal Product (CTIMP) and non-CTIMPs) sponsored by the Royal Devon & Exeter NHS Foundation Trust (here within termed the 'Trust'). This SOP applies to all researchers and Research & Development (R&D) personnel administering delegation on behalf of the Sponsor.

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
ICH	International Conference on Harmonization
IMP	Investigational Medicinal Product
ISF	Investigator Site File
PI	Principal Investigator
R&D	Research and Development
RD&E	Royal Devon & Exeter NHS Foundation Trust
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
TMG	Trial Management Group
TMF	Trial Master File
TSC	Trial Steering Committee
UoE	University of Exeter

5. DUTIES AND RESPONSIBILITIES OF STAFF

The **Chief Investigator** (CI) has responsibility to ensure all delegated Sponsor responsibilities are met as agreed and recorded in the delegation of responsibilities.

The **Principal Investigator** (PI) will ensure and oversight the appropriate delegation of roles within a trial at site level.

Trust R&D Office will, as part of the Sponsorship process for Research, provide a delegation matrix, agreeing onward delegation of sponsor responsibilities in Trust-sponsored studies. The R&D office will agree, and where necessary contract with collaborators and subcontractors their roles and responsibilities in RD&E sponsored studies.

The **Sponsor** retains overall responsibility and should have oversight of all delegated roles and responsibilities within a clinical trial both at the level of organisations and individual.

6. PROCEDURES

The following procedures describe the typical types of delegation that may occur during a study sponsored by the Trust

6.1 *Co-sponsorship delegation*

Co-sponsorship is widely used in England by the NHS where clinical trials are often carried out in partnership with universities.

The RD&E has a partnership with the University of Exeter (UoE) and may decide it is appropriate for a non-CTIMP study to be co-sponsored to enable sponsor duties and indemnity to be shared between each party.

Where the Trust is the co-sponsor, the sponsor duties (including nominating one party as the lead organisation) for each co-sponsor will be defined in a separate signed agreement during study set up.

For co-sponsorship between the Trust and UoE, the R&D Manager at the Trust and the Research Governance and Ethics Manager at the UoE will agree a template document setting out the division of responsibilities between the co-sponsors. This template will be used for all co-sponsored studies and any variation from the template will be clearly identified with justification provided.

A copy of this agreement should be kept in Trial Master File (TMF) and in the R&D file.

6.2 *Sponsorship Delegation via task allocation*

When taking on sponsorship of a trial, the Trust may wish to delegate sponsor function to other parties, eg Clinical Trials Units (CTUs). This delegation of roles and responsibilities should be discussed with R&D early as this forms a vital part of the feasibility, deliverability and costs and should be considered from the beginning. The delegation of sponsor functions should be clearly outlined in a matrix that must be agreed and signed off by all parties prior to trial commencement. Any changes to this delegation must be clearly documented.

A copy of this agreement should be kept both in the TMF and in the R&D file.

6.3 *Delegation to CI*

In addition to the task allocation matrix (section 6.2), it is essential that the CI of a Trust sponsored study is aware of his/her responsibilities. These are outlined during set up of the study and at the R&D approvals stage. Subsequent contact throughout the trial maintains sponsor oversight of this delegation (eg monitoring plan, Trial Management Group (TMG) & Trial Steering Committee (TSC) attendance, Progress Reports). All CI's of RD&E sponsored studies are expected to be educated in their responsibilities **prior** to starting the study. This may be provided by documented training by the R&D department and is also outlined in correspondence between R&D and the CI eg Sponsorship approval letter, R&D approval letter.

Example responsibilities for the CI include
General

1. Adherence to the applicable clinical trials regulations (eg Medicines for Human Use (Clinical Trials) Regulations 2004, The Human Tissue Act 2004 and the EU Tissue and Cells Directive (2006) for research involving human tissue, The Data Protection Act 2018) and guidance as outlined in the UK Policy Framework for Health and Social Care Research.
2. Adherence to Trust policies & procedures R&D Standard Operating Procedures (SOPs) as found on the RDE Research website.

Pre-Study

1. Protocol written to ICH-GCP standards with the appropriate data management systems in place. Where available the relevant protocol templates should be used (R&D can provide these).
2. Relevant approvals are sought eg HRA, Ethics, MHRA, R&D approval.
3. Ensure all staff involved in the research study understand and work in accordance with the agreed protocol and any relevant management, ethical and regulatory approvals.
4. If applicable study is registered on a public database eg www.clinicaltrials.gov
5. Ensure a Trial Master File and Trial Site File is in place.

During Study

1 Document all Adverse Events (AEs) identified in the protocol as being critical to the evaluation of trial safety and report any Serious Adverse Events (SAEs) unless specified in the protocol or investigator brochure as not requiring expedited reporting. Report all Suspected Unexpected Serious Adverse Reactions (SUSARs) that occur during the life of the trial (for more detail on safety reporting see SOP 22 –Safety Reporting).
2 Ensure study specific duties are appropriately delegated and clearly documented on the study Delegation Log (see section 6.4).
3 Give notice of any study amendments to sponsor and the applicable regulatory bodies.
4 Provide annual progress and safety reports to sponsor and the applicable regulatory bodies.
5 Full co-operation with any monitor and audit visits ensuring CAPA plans are implemented as required.

Study End

1 Complete relevant documentation and give notice that research has ended

to sponsor and the applicable regulatory bodies.

2 Upon completion of this Research, all studies must be archived appropriately and in accordance with the applicable Law.

3 Any publications arising from the Research conducted at this site must be sent to the R&D Office.

For further guidance on researcher responsibilities and training please refer to SOP 26 – Providing and Documenting Training for Researchers.

6.4 *Delegation Log (during trial)*

This log should be used when the CI of a Trust sponsored study (and PI of a hosted trial) onward delegates to individuals in the local research team of the study. This delegation does not absolve the CI of responsibility for the study. The documentation of delegated responsibilities will be refreshed and updated during the life time of the study.

The Clinical Trial Regulations require that "Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks". It is the responsibility of anyone authorising onward delegation of tasks to ensure that the delegate is appropriately qualified for that task, where necessary has undertaken Good Clinical Practice (GCP) training and is familiar with the Protocol.

The log must

- List the names and roles of all staff involved and outline which duties have been delegated to them.
- Confirm the start and end dates for each member of staff performing their delegated duties.
- Be signed and dated by the CI/PI – they should sign off each individual member of staff, considering their evidence of training, education and experience prior to the staff member carrying out any duties for the trial. This delegation confirms that the team member is appropriate for their delegated duties.
- Be updated throughout the study. This may include new staff and staff who leave. Superseded versions must not be destroyed in order to allow an audit trail of who was performing which duties at any time point in the conduct of the study for future inspection.
- Be filed appropriately in the Investigator Site File (ISF), enabling monitors, the sponsor and regulatory authorities access as required.

Trust-sponsored studies should use the R&D template unless previously agreed. For further details please refer to S26 – Providing and Documenting Training for Researchers.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the RDE Research 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, 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 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	A copy of all sponsorship or co-sponsorship agreements should be kept in the TMF and R&D file.	Documents stored on the R&D drive and in the TMF.
2.	Delegation of Sponsor functions to other parties, e.g. CTUs should be clearly outlined in a matrix.	Documents retained in TMF to evidence undertaking of delegated duties.
3.	The CI is required to provide annual progress and safety reports (where applicable) to the sponsor.	Evidenced in the R&D files.
4.	The CI/PI ensures that all onward delegation of tasks is to appropriately qualified staff.	View of the delegation of duty log and staff training in the TMF.

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 RDE Research 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

Department of Health's UK Policy Framework for Health and Social Care Research
(https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

The Clinical Trials Directive 2001/20/EC
(http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:EN:PDF)

ICH Harmonised Tripartite Guideline for GCP (E6)
(http://www.ich.org/)

Health Research Authority (HRA)
(http://www.hra.nhs.uk/)