STANDARD OPERATING PROCEDURE

DELEGATION OF ROLES FOR TRUST SPONSORED CTIMPS S11

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Date:	05.02.2015
Signature:	C Ridler
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Date:	06.02.2015
Signature:	C M Gardner

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless;

- A study specific SOP exists
- A departmental SOP dictates a different working practice

Once printed this is an uncontrolled document.

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	Reviewer	Date Implemented	Details of significant changes
V1.1	Chris Gardner, R&D Directorate Manager	23 April 2014	Minor changes to appendix 3.
V2.1	Chris Gardner, R&D Directorate Manager & Claire Ridler, RM&G Manager	26 September 2014	Incorporation of co-sponsorship division of responsibilities with justification of variation from template
V2.2	Chris Gardner, R&D Directorate Manager	13 February 2015	Appendix 4 "Co-sponsorship Agreement" updated.

CONTENTS

1. BACKGROUND

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 provide 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 Research Governance Framework for Health and Social Care.

The need for clear allocation of responsibility arises at organisational as well as individual level. The RD&E Foundation Trust sponsors CTIMPs in circumstances where the Chief Investigator (CI) is a substantive employee. The Trust may agree to co-sponsor with another organisation, typically a university, where university employees have honorary contracts for clinical work in the Trust. See R&D/CTIMP Sponsorship/S09.

An employer is able to direct the actions of its employees. A sponsoring Trust may therefore delegate to its employee Chief Investigator some tasks that are sponsor functions and the CI will carry these out because he is the Sponsor's employee, not because s/he wrote the protocol. Similarly, where there is co-sponsorship the co-sponsorship agreement will set out the division of responsibilities between the co-sponsors. If the co-sponsor that is the substantive employer of the CI delegates some of its responsibilities to the CI, it does so as the employer.

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

2. PURPOSE

This SOP is aimed at:

- Chief Investigators of CTIMPs sponsored or co-sponsored by the Trust
- Principal Investigators (PI) at participating sites conducting CTIMPs sponsored or co-sponsored by the Trust;
- R&D personnel who manage sponsorship functions for CTIMPs on behalf of the Trust;
- Pharmacy personnel with responsibility for providing pharmacy support to CTIMPs sponsored or co-sponsored by the Trust;
- Clinical Trials Group
- Monitors of CTIMPs sponsored by the Trust

3. SCOPE

This SOP should be followed when setting up and running a CTIMP that is sponsored or co-sponsored by the Trust.

4. RESPONSIBILITIES

It is the responsibilities of the Sponsor to ensure that all tasks relating to a CTIMP are carried out properly. Where the tasks are delegated, it will be clearly documented and the responsibility for conducting those tasks lies with the delegated party.

Some Sponsor functions should not be delegated to the CI or other members of the Investigator Team and should be reserved to other members of staff in the sponsoring organisation, typically R&D or Pharmacy staff.

5. PROCEDURES

5.1 The Delegation Table

Where the Trust is the co-sponsor, the sponsor duties for each co-sponsor will be defined in a separate signed agreement. The R&D Manager at the Trust and the Research Governance and Ethics Manager at the University of Exeter will agree a template document (Appendix 4) 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.

The table in Appendix 3 sets out the Delegation Scheme for Trust sponsored or co-sponsored CTIMP. Departures from this may be made if the arrangement is clearly documented in the Protocol, any co-sponsorship contract or a Study-Specific Standard Operating Procedure (see R&D/Preparation, Review & Approval of Study Specific SOPs/S24). However this should only be done when necessary – the practice is discouraged because it adds complexity and potential for error.

5.2 Onward Delegation

Within the Scheme set out in Appendix 3 table further delegation of detailed tasks may be made – indeed it is expected. The CI may, for example, delegate the task of setting up the Trial Master File (TMF) and Investigator Site Files (ISF) for participating sites to another member of the Investigator Team. Similarly, the PI at a participating site may, for example, delegate responsibility for checking equipment used for the trial at the Site to another member of the Site's staff. All such delegations must be explicitly made and signed off by the CI or other person with responsibility under the Appendix 3 table. The Delegation Log should be used for this purpose. The signed and completed Trial Delegation and Signature Logs must be kept in the relevant section of the TMF / ISF.

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. For example, investigational medicinal product should not be prescribed by any doctor in the department – only by doctors identified on the delegation log who have had both GCP training and training on the Protocol. In particular, it should be noted that the following tasks must only be delegated to suitably qualified personnel, whose signatures should confirm their involvement.

- explaining the study to a potential participant so that they understand the risks and objectives; and
- determining that a particular participant meets all eligibility criteria and is suitable for the study.

6. FURTHER READING

R&D/CTIMP Sponsorship/S09
R&D/Preparation, Review & Approval of Study Specific SOPs/S24

TEMPLATE – Delegation Log

APPENDIX 1 – DEFINITIONS
None

APPENDIX 2 – ABBREVIATIONS
None

APPENDIX 3 – DELEGATION SCHEME

Clinical Trials of Investigational Medicinal Products sponsored by Alliance Trusts Delegation Scheme		
Model Agreement Responsibility Table Categorisation	**TASK**	**PERSON/ DEPARTMENT RESPONSIBLE**
Trial Preparation	Establish CTIMP status of trial	Chief Investigator (CI)
	Write Protocol	CI
	Write/compile Patient Information Sheet, data collection instruments etc	CI
	Support preparation of Protocol trial documents	R&D Senior Personnel
	Apply for Trust sponsorship	CI
	Obtain information to Clinical Trial Group in considering sponsorship application – inc. peer, statistical, financial review and quality assurance assessment	R&D
	Complete Clinical Trial Risk Assessment	RM&G Manager
	Write Monitoring Plan	R&D Assistant Manager
	Decide whether Trust can sponsor the trial	LRM
	Approve Monitoring Plan	R&D Directorate Manager
	Ensure appropriate insurance or indemnity arrangements are in place to cover liabilities	R&D Assistant Manager
	Secure funding for the trial	CI
	Administer funding for the trial	R&D Manager and Trust Financial Dept
	Secure and contract for supply of resources	RM&G Manager, CI with support
	Draft, negotiate and manage contracts with other trial sites and sub-contractors as required	RM&G Manager
	Notify R&D of participating sites	CI
	Notify substantive employers of investigators of their participation via a CTA/Trust approval	RM&G Manager
	Identify and check equipment to be used for trial and notify R&D	CI at CI Site PI at Participating Site
Applications and Registration	Register trial – EUDRACT and ISCTRN	CI
	Apply for Clinical Trial Authorisation	CI
	Apply for Ethical Opinion	CI
	Apply for NHS Permission in CT Site	CI
	Apply for NHS Permission in Participating Site	PI at Participating Site
	Grant NHS Permission for trial to begin in any Trust	R&D at Participating Site
Amendments	Write amendments to the Protocol or other essential documents and submit to R&D for review	CI
	Determine whether proposed amendments minor or substantial and whether referral to LRM/CTC necessary	R&D Assistant Manager CRN Caseworker
	Obtain approval or notify amendment as required to MHRA	CI
	Obtain approval / notify amendment as required to Ethics Committee	CI
	Undertake annual update of Investigators' Brochure (IB)	CI

	Undertake annual check on status of Summary of Product Characteristics (SmPC)	CI
	Ensure prompt implementation of any updates of SmPC	CI
	Notify all other involved staff (at CI and Participating Sites) about amendments, including updates of IB and SmPC	CI
Trial Conduct	Overall responsibility for work at Site – ensure it is done in accordance with Protocol, the Clinical Trial Regulations and the terms of Regulatory Approvals	CI at CI Site PI at Participating Sites
	Ensure the rights of individual participants are protected and they receive appropriate medical care whilst participating in the Trial	CI at CI Site PI at Participating Sites
	Prepare Trial Master File	CI
	Prepare Investigator Site Files for other Trial sites	CI
	Arrange Site Initiation Visits at CI and all Participating Sites	CI
	Liaise with all involved support departments (e.g. pharmacy) to ensure readiness at CI site	CI
	Liaise with all involved support departments (e.g. pharmacy) to ensure readiness at Participating Site	PI at Participating Site
	Appoint and ensure GCP training of research staff at CI site and PIs responsible for appointing GCP trained staff at their site and Participating Sites	CI
	Ensure all research staff at CI site and all PIs at Participating Sites are trained on the Protocol	CI
	Participate with Monitor, in Site Initiation training	CI
	Onward delegation of specific tasks; signing of delegation log	CI at CI Site PI at Participating Sites
	Ensure consistent definition of source data across all trial sites	CI
	Manage Royal Devon & Exeter Foundation Trust Standard Operating Procedures	R&D SOP Controller Lead
	Identify any trial-specific SOPs; put list in Trial Master File / Investigator Site Files	CI
	Manage any trial-specific SOPs	CI
	Control arrangements for handling investigational medicinal products including procurement, release, labelling, storage, dispensing, quarantine, recall, reconciliation, return and destruction	Pharmacy at CI Site, Specific elements as delegated to Pharmacies at Participating Sites
	Control use of randomisation procedure, retain code break envelopes	Pharmacy and / or at CI Site
	Arrange Monitoring Contract, oversight of Monitoring and response to Monitoring on behalf of Sponsor	RM&G Manager
	Lead Site Initiation, carry out Interim Monitoring and Trial Close-Out Visits, Report to Sponsor	Appointed contracted Monitor / Trial Co-ordinator as specified in Trial Monitoring Plan
	Notify MHRA of 'Serious Breach'	RM&G Manager unless specified in Protocol
	Maintain Trial Master File	CI
	Report 'Serious breach' to R&D	CI and all research staff

		at Participating Site; Trial Monitor
	Co-ordinate Sponsor decision on whether a reportable 'Serious Breach' has occurred, calling on expert advice as required	Directorate Governance Group
	Maintain Investigator Site File	PI at Participating Site
	Notify Temporary Halt in the trial (or at a particular Participating Site)	CI or R&D (Head of R&D)
	Prepare and submit to MHRA and Ethics Annual Safety Reports on the trial	CI
	Prepare and submit Annual Progress Reports to the Ethics Committee	CI
	Notify MHRA and Ethics Committee of the end of the trial	CI
	Prepare quarterly progress reports for the Sponsor	CI
	Receive progress reports and take any necessary consequential action	CTC
Adverse Events	Identify and document all adverse events	CI at CI Site PI at Participating Sites
	Assess all adverse events	CI at CI Site PI at Participating Sites
	Report all adverse incidents occurring in context of the trial in accordance with the relevant NHS Trust's adverse incident reporting policy	CI at CI Site PI at Participating Sites
	Notify R&D of Serious Adverse Events using required notification method and within required timeframe	CI at CI Site PI at Participating Sites
	Follow up Serious Adverse Events	CI at CI Site PI at Participating Sites
	Notify R&D of SUSARS	CI
	Notify MHRA and Ethics Committee of SUSARs within required timeframe	R&D Assistant Manager
	Notify all PIs at Participating Sites of SUSARs	CI
	Follow up pregnancy related adverse events and inform R&D of outcome of pregnancy	CI
	Assess SAEs/SUSARs, unblinding if necessary	R&D Assistant Manager in consultation with Medical Expert
	Expedited reporting of SUSAR in active IMP to holder of manufacturing authorisation	CI
	Consider and discuss other actions on SUSAR with CI	R&D Assistant Manager
	Report SUSARs within required timeframes to MHRA, Ethics Committee and competent authority in any other country where trial conducted	R&D Assistant Manager
	Implement an 'Urgent Safety Measure'	CI at CI Site PI at Participating Sites RM&G Manager
	Report an 'Urgent Safety Measure' to MHRA, the Ethics Committee and the R&D	CI at CI Site PI at Participating Sites
	Inform CI that an 'Urgent Safety Measure' has been taken at a Participating Site	PI at Participating Site
Data Management	Arrange database construction, data entry and ensure appropriate analysis of data	CI
Publication	Prepare abstracts, posters and publications; submit drafts to R&D Committee prior to	CI

	external submission	
	Approve draft publications prior to external submission on behalf of the Sponsor	LRM & CI
Archiving	Ensure trial records are appropriately archived	RM&G Manager

APPENDIX 4 – Co-sponsorship Agreement (TMP43 on Q-Pulse)

UNIVERSITY OF EXETER

NHS

ROYAL DEVON AND EXETER NHS FOUNDATION TRUST

Health or Social Care Research
Sponsor Assignment of Responsibilities

Study title				
R&D Ref		**MREC Ref:**	**CTIMP: N ☐ Y ☐**	
Chief Investigator Name				
Chief Investigator address				
Chief Investigator Employing Organisation		**Lead Sponsor**	RDEFT ☐ UoE ☐	

Responsibility	**Allocation of responsibility**	**Comments; e.g: reasoning behind delegation/ clarification of responsibility**
1. The research proposal respects the dignity, rights, safety and well-being of participants and the relationship with care professionals.	University and NHS Trust	This is the responsibility of the Chief Investigator and also the co-sponsors; specific duties to be identified on a case by case basis.
2. The research proposal is worthwhile, of high scientific quality, is compliant with applicable legislation and represents good value for money.	University and NHS Trust	This is the responsibility of the Chief Investigator and also the co-sponsors; specific duties to be identified on a case by case basis.
3. Intellectual property rights and their management are appropriately addressed in research contracts or terms of grant awards.	University and NHS Trust	This is the responsibility of the employer of the Chief Investigator; specific duties to be identified on a case by case basis.
4. Organisation responsible for reviewing the recruitment strategy of the proposed research to ensure this is achievable and the Chief Investigator is aware of their responsibilities.	University and NHS Trust	This is the responsibility of the Chief Investigator and also the co-sponsors; specific duties to be identified on a case by case basis.

5. The research proposal and supporting documentation has been approved by an appropriate research ethics committee.	NHS Trust	The expertise in dealing with NRES lies with the Trust as well as duty of care to patients.
6. Appropriate arrangements are in place for the registration of trials.	Employing Organisation	This is the responsibility of the Chief Investigator.
7. The Chief Investigator, and other key researchers, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully.	Employing Organisation	This is the responsibility of the Chief Investigator.
8. The arrangements and resources proposed will allow the collection of high quality, accurate data and the systems and resources being proposed are those required to allow appropriate data analysis and data protection.	University and NHS Trust	This is the responsibility of the Chief Investigator and also the co-sponsors; specific duties to be identified on a case by case basis.
9. Arrangements proposed for the work are consistent with the Department of Health Research Governance Framework and (where applicable) the Medicines for Human Use (Clinical Trials) Regulations 2004.	NHS Trust	Expertise and experience lies with the Trust.
10. Organisation responsible for the generation, provision and management of contracts between the Sponsors and participating site(s).	Lead Sponsor	It is normally the lead sponsor who initiates contracts.
11. Organisation responsible for the ongoing management and monitoring of the study, whether this is the organisation employing the researchers, the sponsor, or another organisation.	NHS Trust	Expertise and experience lies with the Trust.
12. Organisation responsible for judging the substantiality of amendments	Lead Sponsor	Expertise lies with the Trust and the Trust is normally the lead sponsor.
13. Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction.	University and NHS Trust	Both are involved because the Trust deals with the safety reports and the University deals with scientific direction, specific duties to be identified on a case by case basis.
14. Assistance is provided to any enquiry, audit or investigation related to the funded work.	University and NHS Trust	Where both institutions are involved both must provide support for investigations, specific duties to be identified on a case by case basis.
15. In the event of a non-negligent harm claim being made, the necessary financial arrangements have been made to offer compensation.	Lead sponsor	This is considered rare and would sit with the lead sponsor.
16. Arrangements are proposed for disseminating the findings.	Employing Organisation	This is the responsibility of the Chief Investigator to disseminate findings in the form of a publication.

17. Organisation responsible for archiving all essential documents in line with applicable legislation/SOPs	Employing Organisation	This is the responsibility of the employer of the Chief Investigator.
18. All scientific judgements made by the sponsors in relation to responsibilities set out here are based on independent and expert advice.	NHS Trust	Expertise lies with the Trust's research advisors and statisticians.
19.Subject to Ethics /Research Tissue Bank (RTB) approval, samples collected within this study may be stored and/or analysed in laboratories owned by the University of Exeter and/or Royal Devon & Exeter NHS Foundation Trust and may be transported between sites as required for the duration of the study. Once the study has been completed a formal application to store samples under the HTA licence of either the University of Exeter or the Royal Devon & Exeter NHS Foundation Trust must be made and any transfer of samples beyond the remit of this study must be accompanied by Material Transfer Agreements.		

Deviation from the default response:

Please complete the table below, and italicise the relevant section above, where there is a deviation from the default response, explaining the rationale behind the deviation.

No.	Responsibility	Allocation of responsibility	Comments; e.g: reasoning behind delegation/ clarification of responsibility

Signed on behalf of the:

University of Exeter

Name: Gail Seymour

Position: Research Ethics and Governance Manager

Signature: ..... Date: .....

Signed on behalf of the:

Royal Devon and Exeter NHS Foundation Trust

Name: Chris Gardner

Position: Directorate Manager – Research & Development

Signature: ..... Date: .....