York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S03

Delegation of Tasks for Trust Sponsored Research Studies

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	R&D/S03
Version Number:	8.0
Author:	Deborah Phillips
Implementation date of current version:	5th August 2019

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	8th July 2019
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	8th July 2019

This SOP will normally be reviewed, as a minimum, every 3 years unless changes to the legislation require otherwise

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	Date Implemented	Details of significant changes
1.0	21st June 2007	
2.0	11th January 2010	Significant review. Roles and responsibilities presented in table format. Template version 3.0 used.
3.0	27th February 2012	Slight change to SOP title. Wording altered throughout in order for SOP to be used for studies of all types: clarification of actions required for CTIMPs/Medical Device Studies/Interventional Studies/other research. Some wording changed to clarify that it is tasks not responsibilities that can be delegated. Change of SOP Controller
4.0	19th November 2012	Removal of references to the North and East Yorkshire Alliance R&D Unit. Change of Author.
5.0	6th October 2015	Changes to Pharmacy SOPs cross references. Minor updates throughout.
6.0	14th August 2017	
7.0	20th June 2018	
8.0	5th August 2019	Change of link to R&D website. Minor updates to SOP numbers and addition of Trial Management delegation log.

Contents

		Page No
1	Introduction, Background and Purpose	1
2	Who Should Use This SOP	2
3	When this SOP Should be Used	2
4	Procedure(s)	2
5	Delegation of Trial Management Responsibilities	3
6	Related SOPS and Documents	3
7	Appendix	4

1 Introduction, Background and Purpose

The need for utmost clarity about roles and responsibilities is fundamental to the conduct of research. Specific roles and their accompanying responsibilities are a key aspect of both the Research Governance Framework for Health and Social Care (RGF) and the Medicines for Human Use (Clinical Trials) Regulations and therefore apply to all types of studies.

The Sponsor's role involves a number of tasks or functions (in this SOP these terms are used interchangeably) and these may be delegated by the Sponsor to other organisations, groups or individuals.

In relation to clinical trials of investigational medicinal products (CTIMPs) Statutory Instrument 1928 (2006) stipulates: "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 tasks but still remains responsible and must therefore ensure that delegated tasks are carried out properly.

The need for clear allocation of responsibility arises at organisational as well as individual level. NHS Trusts sponsor studies in circumstances where the Chief Investigator (CI) is an employee of the relevant Trust. However, they may agree to co-sponsor with another organisation, typically a university, where university employees have honorary contracts for clinical work in the Trust.

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 employer.

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.

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 authorised in writing by the person with primary responsibility for the task under this SOP.

2 Who Should Use This SOP

This SOP is aimed at:

- Chief Investigators of studies sponsored or co-sponsored by the Trust;
- Principal Investigators at Participating Sites conducting studies sponsored or co-sponsored by the Trust;
- R&D Unit personnel;
- Pharmacy personnel;
- York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Group;
- Monitors of studies sponsored by the Trust.

3 When this SOP Should be Used

This SOP should be followed when setting up and running a research study that is sponsored or co-sponsored by theTrust.

To avoid complexity, the terminology of 'Trial Master File' / 'Investigator Site File' is used throughout, rather than 'Study Master File' for studies that are not trials.

4 Procedure(s)

4.1 The Delegation Table

The table in the Appendix sets out the expected Delegation Scheme for Trust sponsored or co-sponsored studies. 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/S26). However this should only be done when necessary – the practice is discouraged because it adds complexity and potential for error.

4.2 Onward Delegation

Within the Scheme set out in the Appendix table further delegation of detailed tasks may be made – indeed it is expected. All such delegations must be explicitly made and signed off by the Chief Investigator/PI or other person with responsibility. Form R&D/F16 may be used for this purpose.

Whatever the nature of the study, it is the responsibility of anyone authorising onward delegation of tasks to ensure that the delegate is appropriately qualified for that task. 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". All relevant elements should be considered – not only professional qualifications but also GCP training and familiarity with the Protocol.

In particular it should be noted that in a CTIMP the tasks of:

- 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;

must only be delegated to medically-qualified personnel, whose signatures should confirm this.

5 Delegation of Trial Management Responsibilities

In addition to R&D/F16 a Delegation of Duties and Signature Log must be completed by the immediate Trial Management Team and filed accordingly in the Trial Master File. As discussed in section 4.2 all staff on the log will be delegated appropriately and signed off by the Chief Investigator. Template R&D/T62 should be used for this purpose.

To avoid duplication of signatures, the department lead or designated other for all study support departments (pharmacy, labs, and radiology) will have oversight of their area. They will sign R&D/T62 on behalf of their department and then delegate as necessary to their immediate team on a local basis at the Sponsor site. The Chief Investigator retains primary responsibility for all tasks delegated to team members on the log.

6 Related SOPs and Documents

R&D/F16 Study Delegation and Signature Log

R&D/T62 Delegation of Duties and Signature Log for the Trial Management of Trust Sponsored Studies

7 Appendix

Research Studies sponsored by the Trust - Delegation Scheme

Applicable to all studies except where stated in square brackets

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
Study Preparation	Establish status of study - CTIMP / medical device /interventional	Chief Investigator (CI)	R&D/S02 orR&D/S82 or R&D/S83
	Write Protocol	CI	
	Write / Compile Patient Information Sheet, Data Collection Instruments etc.	CI	
	Write / procure Investigator Brochure or Summary of Product Characteristics [CTIMPs ONLY]	CI	
	Support preparation of Protocol and study documents	R&D Unit (Research Adviser or Trial Manager)	
	Apply for Trust sponsorship	CI	R&D/S02 or R&D/S82 or R&D/S83
	Obtain information to assist York and Scarborough Teaching Hospitals NHS Foundation Trust Research and Development Group (R&D Group) in considering sponsorship application – inc. peer, statistical, financial review and quality assurance assessment	R&D Unit (Research Adviser lead)	R&D/S02 or R&D/S82 or R&D/S83
	Complete Risk Assessment [INTERVENTIONAL STUDIES ONLY]	CI with R&D Unit input	R&D/S18
	Write Monitoring Plan	R&D Unit (Research QA Manager lead)	R&D/S08
	Decide whether the Trust can sponsor the study unless study is eligible for consideration under the proportionate review process	R&D Group (or R&D Unit with Clinical Lead for Research for low risk studies)	R&D/S02 or R&D/S82 or R&D/S83

Research Studies sponsored by the Trust - Delegation Scheme

Applicable to all studies except where stated in square brackets

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
	Approve Monitoring Plan	R&D Group (CTIMPS) or Research Adviser/Head of R&D	R&D/S08
	Ensure appropriate insurance or indemnity arrangements are in place to cover liabilities	R&D Unit (Head of R&D lead)	R&D/G01
	Secure funding for the study	CI	
	Administer funding for the study	R&D Unit (Head of R&D lead) and Trust Finance Dept.	
	Secure and contract for supply of resources	R&D Unit (Head of R&D lead) and Trust Legal Department	R&D/S23
	Draft, negotiate and manage contracts with other study sites and sub-contractors as required.	R&D Unit (Head of R&D lead) and Trust Legal Department	R&D/S23
	Notify substantive employers of investigators of their participation	CI	
	Identify and check equipment to be used for study	CI at CI Site PI at Participating Site	R&D/S09
Applications and Registration	Apply for Clinical Trial Authorisation [CTIMPs ONLY]	CI	R&D/S02
	Apply for MHRA letter of no objection [MEDICAL DEVICE TRIALS or TYPE A IMP TRIALS ONLY]	CI	R&D/S02 or R&D/S83
	Apply for REC & HRA approval	CI	R&D/S02 orR&D/S82 or R&D/S83
	Provide Local Information Packs to Sites	CI	R&D/S02 orR&D/S82 or R&D/S83
	Obtain confirmation of Capacity and Capability at Sites	Principal Investigator (PI) at Participating Site	R&D/S02 orR&D/S82 or R&D/S83
	Confirm Capacity and Capability	R&D Unit	R&D/S14

Research Studies sponsored by the Trust - Delegation Scheme

Applicable to all studies except where stated in square brackets

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
	Register trial – EUDRACT [CTIMPs ONLY] & ISCTRN [CTIMPs AND OTHER CLINICAL TRIALS ONLY]	CI	
Amendments	Write amendments to the Protocol or other essential documents	CI	R&D/S74
	Apply for Sponsor permission to make amendments	CI	R&D/S74
	Determine whether proposed amendments minor or substantial and whether referral to R&D Group necessary	R&D Unit (Research Adviser Lead)	R&D/S74
	Obtain approval or notify amendment as required to MHRA [CTIMPs / RELEVANT MEDICAL DEVICE TRIALS ONLY]	CI	R&D/S74
	Obtain approval / notify amendment as required to REC and/or HRA	CI	R&D/S74
	Undertake annual review/update of Investigators' Brochure (IB) [CTIMPs ONLY]	CI	R&D/S74
	Undertake annual check on status of Summary of Product Characteristics (SmPC) [CTIMPs ONLY]	CI	R&D/S74
	Assess and consider implementation of any updates of RSI [CTIMPs ONLY]	CI	R&D/S74
	Notify all other involved staff (at CI and Participating Sites) about amendments, including updates of IB or SmPC [CTIMPs ONLY]	CI	R&D/S74

Research Studies sponsored by the Trust - Delegation Scheme

Applicable to all studies except where stated in square brackets

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
Study Conduct	Overall responsibility for work at Site – ensure it is done in accordance with the protocol, the Clinical Trial Regulations and / or Research Governance Framework and the terms of regulatory approvals.	CI at CI Site PI at Participating Site	R&D/S09
	Ensure the rights of individual participants are protected and they receive appropriate medical care whilst participating in the study.	CI at CI Site PI at Participating Site	
	Prepare Trial Master File	CI	R&D/S09
	Prepare Investigator Site Files for other study sites	CI	R&D/S09
	Arrange Site Initiation at CI and all Participating Sites	CI	R&D/S08
	Liaise with all involved support departments (e.g. pharmacy, labs) to ensure readiness at CI site	CI	R&D/S09
	Liaise with all involved support departments (e.g. pharmacy, labs) to ensure readiness at Participating Site	PI at Participating Site	R&D/S09
	Appoint and ensure study-appropriate training of research staff at CI site and PIs at Participating Sites	CI	R&D/S09
	Ensure all research staff at CI site and all PIs at Participating Sites are trained on the Protocol	CI	R&D/S09
	Participate, with Monitor, in Site Initiation training	CI	R&D/S09 or R&D/S08
	Onward delegation of specific tasks; signing of delegation log	CI at CI Site PI at Participating Site	R&D/S03 or R&D/S09

Research Studies sponsored by the Trust - Delegation Scheme

Applicable to all studies except where stated in square brackets

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
	Ensure consistent definition of source data across all study sites	CI	R&D/S09
	Manage York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit Standard Operating Procedures	R&D Unit (SOP Controller lead)	R&D/S01
	Identify Standard Operating Procedures to be used including any study – specific SOPs; put list in Trial Master File / Investigator Site Files	CI	R&D/S09
	Manage any study – specific SOPs	CI	R&D/S26
	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	All Pharmacy Research SOPs
	Control use of randomisation procedure, retain code break envelopes	Pharmacy at CI Site	PHARM/S54
	Control use of randomisation procedure, retain code break envelopes	R&D Unit (Research Adviser Lead)	R&D/S62
	Arrange Monitoring Contract, oversight of Monitoring and response to Monitoring on behalf of the Sponsor	R&D Unit (Head of R&D Lead)	R&D/S08
	Lead Site Initiation, carry out Interim Monitoring and Study Close-Out Visits, Report to Sponsor	Appointed or contracted Monitor / Study Co-ordinator as specified in Study Monitoring Plan	R&D/S08

Research Studies sponsored by the Trust - Delegation Scheme

Applicable to all studies except where stated in square brackets

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
	Report 'Serious Breach' to the R&D Unit	All research staff (including pharmacy and laboratory staff) at CI or Participating Site; Trial Monitor	R&D/S04 R&D/S12
	Co-ordinate Sponsor decision on whether a reportable 'Serious Breach' has occurred, calling on expert advice as required	Nominated R&D Unit staff as detailed in SOP	R&D/S04
	Notify REC of 'Serious Breach' (non-CTIMPs ONLY)	CI	R&D/S04
	Notify MHRA and REC of 'Serious Breach' [CTIMPs ONLY]	R&D Unit (Head of R&D or Research Adviser) unless otherwise specified in the Protocol	R&D/S04
	Maintain Trial Master File	CI	R&D/S09
	Maintain Investigator Site File	PI at Participating Site	R&D/S09
	Notify Temporary Halt in the study (or at a particular Participating Site)	CI and R&D Unit (Research Adviser lead)	R&D/S72
	Prepare and submit to MHRA and REC Development Safety Update Reports on the study (copied to R&D Unit) [CTIMPs ONLY]	CI	R&D/S06
	Prepare and submit Annual Progress Reports to the REC (copied to R&D Unit)	CI	R&D/S06
	Notify MHRA [CTIMPs ONLY] and REC of the end of the study – copy to R&D Unit	CI	R&D/S06
	Prepare progress reports for the Sponsor	CI	R&D/S06

Research Studies sponsored by the Trust - Delegation Scheme

Applicable to all studies except where stated in square brackets

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
	Receive progress reports and take any necessary consequential action	R&D Unit or R&D Group where deemed appropriate	R&D/S06
Adverse events	Identify and document all adverse events	CI at CI Site PI at Participating Site	R&D/S05
	Assess all adverse events	CI at CI Site PI at Participating Site	R&D/S05
	Report all adverse incidents occurring in context of the study in accordance with the relevant NHS Trust's adverse incident reporting policy	CI at CI Site PI at Participating Site	R&D/S05
	Notify R&D Unit of Serious Adverse Events using required notification method and within required timeframe	CI at CI Site PI at Participating Site	R&D/S05
	Follow up Serious Adverse Events	CI at CI Site PI at Participating Site	R&D/S05
	Notify MHRA [CTIMPS only] and REC of SUSARs within required timeframe	R&D Unit (Research Adviser lead)	R&D/S05 R&D/S13
	Notify all PIs at Participating Sites of SUSARs	CI	R&D/S05
	Follow-up a pregnancy reported in a trial participant in line with the protocol and keep R&D Unit fully informed	CI	R&D/S05
	Assess SAEs / SUSARs, unblinding if necessary.	CI and/or R&D Unit in consultation with Medical Expert. Maintaining blinding of investigator where possible.	R&D/S05 and R&D/S13
	Expedited reporting of SUSAR in active IMP to manufacturing authorisation holder [CTIMPs ONLY]	R&D Unit	R&D/S05
	Consider and discuss other actions on SUSAR with CI	R&D Unit	R&D/S05

Research Studies sponsored by the Trust - Delegation Scheme

Applicable to all studies except where stated in square brackets

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
	Report SUSARs within required timeframes to MHRA, REC and competent authority in any other country where study conducted [CTIMPs ONLY]	R&D Unit	R&D/S05 R&D/S13
	Implement an 'Urgent Safety Measure'	CI at CI Site PI at Participating Site R&D Unit (Research Adviser or Head of R&D)	R&D/S68
	Report an 'Urgent Safety Measure' to MHRA [CTIMPs ONLY], the REC and the R&D Unit	CI at CI Site PI at Participating Site	R&D/S68 R&D/S13
	Inform CI that an 'Urgent Safety Measure' has been taken at a Participating Site	PI at Participating Site	R&D/S68
Data Management	Arrange database construction, data entry and ensure appropriate analysis of data in line with approved DMP and SAP	CI	R&D/S29 R&D/S85
Publication	Prepare abstracts, posters and publications; submit drafts to R&D Unit prior to external submission	CI	
	Approve draft publications prior to external submission on behalf of the Sponsor	R&D Unit referring to R&D Group where necessary	
Archiving	Ensure study records are appropriately archived.	CI with assistance of R&D Unit	R&D/S11