South Eastern Health and Social Care Trust

Standard Operating Procedure (SOP)
Research and Development Office

Title of SOP:	Delegated Responsibilities in Research Projects
SOP Number:	11
Version Number:	2.0
Supercedes:	1.0
Effective date:	August 2013
Review date:	August 2015

Author:	Alison Murphy, Research Manager Endorsed by Paul Carlin
Approved by:	Dr David Hill
Signed:	
Date:	01 August 2013

Version No.	Date	Author	Reason for Change
1.0	Sept 2007	Katrina Hughes	N/A
2.0	Aug 2011	Alison Murphy	Update and expand process for SOPs and revise documents in appendices

Table of contents

1. INTRODUCTION

Some sponsorship responsibilities are delegated to other organisations involved in the study, for example where the Chief Investigator or other investigators are based at other sites. The Principal Investigator may also delegate trial-related duties to members of his or her team.

The Associate Medical Director (Research) along with the Research Manager is ultimately responsible for the delegation of responsibilities.

2. PURPOSE

The Standard Operating Procedure (SOP) describes the process for delegating research responsibilities.

3. SCOPE

This SOP applies to all studies where South Eastern Health and Social Care Trust is acting as sponsor.

4. PROCEDURE

4.1. For all Trust Sponsored Multi-centre Research Studies

As part of the Research Governance Permission process a Sponsorship Delegation Framework (Appendix 1) is put in place between the sponsor (SEHSCT), chief investigator and any other applicable parties, prior to the granting of Research Permission that outlines responsibilities allocated to the sponsor, the Chief Investigator and participating sites.

When applicable, agreements are also put in place with participating sites, using the Model Non-commercial Agreement template, which allocates the responsibilities of the participating site.

Where the Trust is acting as co-sponsor with another organisation, a Co-sponsorship Agreement is put in place and signatures are required from representatives of each party. This is covered in SOP 24.

Original agreements are signed by all parties. An original signed copy is held by the Research Office in the project file.

4.2 For all Trust Sponsored Single-centre Research Studies

As part of the Research Governance Permission process a Sponsorship Delegation Framework (Appendix 1) is put in place between the sponsor (SEHSCT), chief investigator and any other applicable parties, prior to the granting of Research Permission that outlines responsibilities allocated to the sponsor and the Chief Investigator.

When the Trust is acting as co-sponsor with another organisation, a Co-sponsorship Agreement is put in place and signatures are required from representatives of each party. This is covered in SOP 24.

Original agreements are signed by all parties. An original signed copy is held by the Research Office in the project file.

4.3 For other Research Studies

The investigator is provided with information regarding responsibilities of Principal Investigators under the terms of the Research Governance Framework, as an appendix to the Research Final Permission Letter.

4.4 Delegation Logs

For CTIMPs, a delegation log specific to each site should also be used to clearly outline each team member's responsibilities (Appendix 2).

At the trial set-up meeting, the Delegation log should be given to the Principal Investigator (PI) to be placed in the Investigator Site File.

The PI allocates trial-related duties to each staff member working on the trial. These are recorded on the delegation log, along with the dated signature of the PI and the signature of the staff member.

A review date should be set to ensure that the delegation log is kept up to date.

5. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKS etc.

ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice E6(R1) 1996

Linked to: SOP 24 Sponsorship and Insurance Approval

6. APPENDICES

6.1 Appendix 1 Sponsorship Delegation Framework

6.2 Appendix 2 Delegation Log

Belfast Health and Social Care Trust

Sponsorship Delegation Framework

Project Details			
Full Research Title:			
Chief Investigator:			
Sponsor:			
Clinical Trials Unit:			
Funder:		**Financial Management:**	

Completion notes	
1.	All persons or organisations sponsoring the research are jointly responsible for the first five responsibilities.
2.	The Sponsoring organisation(s) must indicate which of the responsibilities they are going to assume in the "Sponsor" column and identify which of those responsibilities are being delegated to the Chief Investigator or other party in the "Delegated to" column.

Description		**Sponsor**	**Delegated to**
1. Responsibility			
1.1	The research respects the dignity, rights, safety and well being of all participants.	All	All
1.2	The work is consistent with the Research Governance Framework.	All	All
1.3	Everybody involved in the research agrees the division of responsibilities.	All	All
1.4	All scientific judgements are based on independent and expert advice.	All	All
1.5	Assistance is provided to any enquiry, audit or investigation.	All	All
2. Study preparation:			
2.1	Design of the protocol and associated documents (GCP)		
2.2	Ensure statistical review (GCP)		
2.3	Ensure Independent scientific review		
2.4	Design Investigators Brochure (Reg. 3)		
2.5	Annually review Investigators Brochure (Reg. 3)		
2.6	Secure study funding and secure agreement between Sponsor and Investigator/Institution were required. (GCP)		
2.7	Researchers have the experience and expertise and access to the resources needed for the research. (GCP)		
2.8	Identify, develop and secure third party contracts (GCP)		
2.9	Ensure necessary indemnity arrangements in place (GCP)		
2.10	Ensure all management approvals in place and research management permission granted		
2.11	Ensure appropriate employment/honorary contracts in place for investigators		
2.12	Risk assess the Trial		

3. Authorisation and ongoing Management of Clinical Trials			
3.1	Apply for EudraCT No		
3.2	Register study on Clinical Trial database		
3.3	Request authorisation to conduct Clinical Trial (Reg. 12)		
3.4	Request permission from licensing authority for substantial amendment (Reg. 22)		
3.5	Address amendments requested by the licensing authority (Reg. 23)		
3.6	Give notice of conclusion to licensing authority (Reg. 27)		
3.7	Notify licensing authority of serious breaches (Reg. 29a)		
4. Ethics Committee Opinion			
4.1	Apply to Ethics Committee for approval (Reg. 14)		
4.2	Request permission from ethics committee for substantial amendment (Reg. 24)		
4.3	Submit annual progress report (Reg. 29)		
4.4	Submit end of study report (Reg. 27)		
4.5	Submit Final report within one year of trial end		
5. Good Clinical Practice			
5.1	Ensure trial conducted in accordance with protocol (Reg. 29)		
5.2	Development of Trial specific SOPs to maintain clinical trial quality control (GCP)		
5.3	Supply IMP / Medical Device free of charge (Reg. 28)		
5.4	Suspend or terminate clinical trial (Reg. 31)		
5.5	Maintain Trial Master File in accordance with Regulation 31a		
5.6	Archive the Trial Master File (Reg. 31a)		
5.7	Ensure medical files of trial subjects retained for 5 years after conclusion of trial (Reg. 31a)		
5.8	Approving and recording transfer of ownership of data or documents used in a clinical trial (Reg. 31a)		
5.9	Take the lead when investigating any complaint arising from clinical trial (GCP)		
5.10	Lead any Misconduct in Research Allegation		
5.11	Take appropriate urgent safety measures		
5.12	Notify licensing authority & Ethics Committee of urgent safety measures		
6. Pharmacovigilance			
6.1	Keep records of all adverse events reported by the investigators. (Reg. 32)		
6.2	Assess Serious Adverse Events not identified in trial protocol for expedited reporting to licensing authority/ethics committee (Reg. 32)		
6.3	Ensure SAEs are reviewed by an appropriate committee for monitoring trial safety (GCP)		
6.4	Ensure recording and prompt reporting of suspected unexpected serious adverse reactions, (SUSARs) (Reg. 33)		
6.5	Onward reporting of SUSAR to licensing authority/ethics committee (Reg. 32)		

6.6	Ensure investigators are informed of SUSARs. (GCP)		
6.7	Provide annual list of SSARs and a safety report to ethics committee and relevant licensing authority (Reg. 35)		
7. Data Management			
7.1	Design of case report forms (GCP)		
7.2	Design of database (GCP)		
7.3	Collect high quality and accurate data from research subject (GCP)		
7.4	Analyse high quality laboratory data		
7.5	Ensure high quality data analysis (GCP)		
7.6	Comply with Data Protection Act (GCP)		
8. IMP Management			
8.1	Liaise with site pharmacists regarding the provision and accountability of the drugs.		
8.2	Ensure that the IMP is not used for any purposes other than the conduct of the study and is used in strict accordance with the protocol. (Reg. 13)		
8.3	Ensure necessary agreements are in place with IMP provider		
8.4	Ensure IMP is provided and labelled in accordance with the Regulations (Reg 46)		
8.5	Ensure that IMP is stored in appropriate and secure conditions and that detailed records are maintained regarding its movement from delivery to return/destruction.		
9. Monitoring and Audit			
9.1	Conduct on site monitoring in accordance with monitoring plan		
9.2	Development and execution of audit plan (GCP)		
10. Intellectual Property and Dissemination of Results			
10.1	Engage with HSC Innovations and Knowledge Transfer/Exploitation Units to ensure Intellectual property rights and their management are appropriately addressed. (RGF)		
10.2	At the conclusion of the study, plans are in place for disseminating the findings. (GCP)		

Declaration: **I agree to the responsibilities set in this document** **Signatures** *Add additional rows below if necessary.*		
Signatory *please print relevant person's name*	***Signature***	***Date***
Sponsor:		
Chief Investigator:		
[Add any additional parties to agreement]:		

* Where sponsor responsibilities are delegated to the CI – the CI must seek approval of the sponsor BEFORE acting with delegated responsibility.

\# Where sponsor responsibilities are delegated to the CI – the CI must send a copy to the sponsor.

6.2 Delegation Log

Belfast Health and Social Care Trust

Delegation and Staff Signature Log

Study Title:	**Protocol No:**
Chief/Principal Investigator:	**EUDRACT No:**
SEHSCT Research Office Reference No:	**Sponsor:**

Staff signature and site delegation of tasks

Name	Initials	Study Role	Key Delegated study Task(s)*	Duration From:	To:	Signature	CI/PI Signature

***Key for list of delegated study task(s)**

1. Obtain informed consent	6. Drug Dispensing	11. Data Query Signature	16. Archiving	21. Other: ……..
2. Physical Exam/ Clinical Evaluations	7. Drug Accountability	12. Resolving data queries	17. Other:	22. Other: ……..
3. Source document entry (i.e. Medical notes)	8. Case Report Form Completion	13. Reviewing and Reporting Adverse Events	18. Other: ……..	23. Other: ……..
4. Inclusion/ Exclusion Assessment	9. Case Report Form Signature	14 Medical Prescriptions	19. Other: ……..	24. Other: ……..
5. Investigational Product Accountability	10. Data Query Completion	15.Maintaining Trial Master File (TMF)	20. Other: ……..	