South Eastern Health and Social Care Trust

Standard Operating Procedure
(SOP)
Research and Development Office

Title of SOP:	Sponsorship and Indemnity
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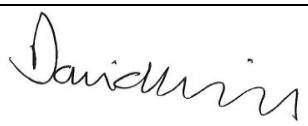
Author:	Alison Murphy, Research Manager
Approved by:	Endorsed by Paul Carlin
Signed:	
Date:	01 August 2013

Version History:

Version No.	Date	Author	Reason for Change
1.0	Sept 2007	Katrina Hughes	N/A
2.0	Aug 2011	Alison Murphy	Updated to new SOP format. Revised title. Revised guidance in line with revised permission process and IRAS application. Added appendices.

Table of Contents

1. INTRODUCTION

Since April 2004 it has been a requirement for all research to have a sponsor. Under the Research Governance Framework for Health and Social Care all clinical research conducted in the NHS/HSC must have a Sponsor in the UK.

In addition, under the Medicines for Human Use Clinical Trials Regulations 2004 and the Amendments Regulations 2006, it is a legal requirement for all Clinical Trials of Investigational Medicinal Products (CTIMPs) to have a Sponsor in the European Economic Union (EEU).

Any research requiring the collaboration of the South Eastern Trust must have an individual or organisation willing and able to undertake the responsibilities of the research sponsor/co-sponsor. The sponsor takes responsibility for the initiation, management and financing (or arranging the financing of that research study). This involves ensuring the design of the study meets the required standards and that arrangements are in place to ensure appropriate conduct and reporting.

Where an external sponsor cannot be secured for a project, an application may be made to the Trust Research Office to sponsor/co-sponsor a project.

2. OBJECTIVE

The objective of this SOP is to describe the processes involved for securing Trust sponsorship for research projects that fall under the Research Governance Framework, February 2007 and the Medicines for Human Use (Clinical Trials) Regulations 2004.

3. SCOPE

This SOP applies to all research projects requiring sponsorship from the South Eastern Trust.

4. PROCESS

4.1 When to apply for Trust Sponsorship

Application for Trust sponsorship should occur **prior** to the submission of any study approvals through the Integrated Research Application System (IRAS) (REC, R&D, MHRA etc) and, in any case, **before** project initiation.

4.2 How to apply for Trust Sponsorship

When making a sponsorship/co-sponsorship application to the Trust Research Office the following should be submitted:

- Draft IRAS NHS R&D Form and IRAS SSI Form

At this stage, the IRAS form does not need to be fully completed but should contain as much information as available at the time of sponsor request

- Research Protocol (version control and date)
- External Referees or other scientific critique report (if available) or Funding Confirmation letter from a recognised funder completing peer review
- Peer review nominations (if external scientific critique not available)

4.3 Review by the Trust Research Office

The Trust Research Office will review your project, complete a peer review, if required, assess the appropriate sponsorship/co-sponsorship arrangements, initiate sponsorship/co-sponsorship agreements and negotiate contracts. Research Office staff are happy to meet with investigators or other research staff to assist with this.

4.3.1 Assess suitable sponsorship/co-sponsorship arrangements

In order for the Trust to act as the research sponsor, the research office will assess your project for risk to Trust and subjects and review the arrangements for the initiation, management and financing of the study. Co-sponsorship maybe considered, for example with a university, if there is involvement of another organisation and the Research Office will discuss and agree arrangements with the other parties.

4.3.2 Peer Review

The sponsor of the research is responsible for the scrutiny of the hypothesis, design, methodology and analysis of a proposed research study. If the Trust is sponsoring the project it must ensure that it is of appropriate scientific quality. If the study has been, or will be reviewed for scientific quality by an external funder it may not need further review. If the study will not be reviewed by an external funder, the Research Office will facilitate the peer review of the project. Arrangements for peer review should be commensurate with the scale of the research and the potential risks or burdens involved for participants.

4.3.3 Assess and confirm insurance cover

It is extremely important that appropriate insurance is in place for each research project you undertake in order to cover against two types of possible harm to a research participant: negligent and non-negligent.

Negligent Harm: Any action or process that is held by a court to have caused harm as a result of lack of due diligence, lack of care, omission of duty or an act of carelessness towards a participant in a research project.

Non-Negligent Harm: Circumstances where there is no specifically identified causative factor relating to the harm of a participant in a research project, but harm is likely, on the balance of probabilities, to have arisen from the participant taking part in the research.

Not all projects will need cover against both types of harm. However, it is the responsibility of the Trust Research Office to determine what insurance is relevant to your research project.

The South Eastern Health and Social Care Trust provides indemnity for negligent harm that may arise as a result of this study, according to the regulations given by the Department of Health in Northern Ireland.

In relation to non-negligent harm, in NHS Indemnity: 'Arrangements for Clinical Negligence Claims in the NHS' (DoH, 1996), paragraph 16 in Annex A states "Apart from liability for defective products, legal liability does not arise where a person is harmed but no one has acted negligently. An example of this would be unexpected side-effects of drugs during clinical trials. In exceptional circumstances (and within the delegated limit of £50,000) NHS bodies may consider whether an ex-gratia payment could be offered. NHS bodies may not offer advance indemnities or take out commercial insurance for non-negligent harm".

It is therefore, only on this basis that indemnity for research projects will be provided by the South Eastern Health and Social Care Trust.

Importantly, you will be required to explain what arrangements are in place for negligent and/or non-negligent harm in any IRAS application (Question A76), for the design, management and conduct of the research. The Trust Research Office will provide guidance on this during the sponsorship review.

4.3.4 Initiate Sponsorship/co-sponsorship Agreements

If the Trust is to co-sponsor a research project with another organisation the Research Office will initiate an agreement which will allocate the responsibilities of the sponsor to the relevant organisations, delegating where appropriate to the CI/PI. See appendix 2 & 3. If no co-sponsorship arrangements are required a Sponsorship Delegation Framework will be initiated, see appendix 4, setting out any responsibilities delegated to the CI/PI and any other involved parties.

4.4 Outcome of Sponsorship Application

The Research Office will confirm South Eastern Trust sponsorship in writing via a signed letter. You must not assume that the Trust will sponsor your project until you have received this confirmation.

Once the sponsor is agreed, it is a formal requirement to have the sponsor:

- Sign / electronically authorise the "Declaration by the sponsor's representative" part of the IRAS application; and
- Enclose a letter confirming their agreement to the "Declaration by the sponsor's representative" part of the IRAS application

The Research Office will agree and execute the signing of co-sponsorship agreements or sponsorship delegation framework, ensuring that each party receives a copy and is aware of their responsibilities.

5. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKS ETC

Research Governance Framework for Health and Social Care (2007)

EU Directive 2001/20/EU http://www.dh.gov.uk/assetRoot/04/10/89/0418965.pdf

6. APPENDICES

6.1 Appendix 1 Guide to who should take on sponsorship role

6.2 Appendix 2 Co-sponsorship Agreement

6.3 Appendix 3 Co-sponsorship Agreement – Clinical Trials

6.4 Appendix 4 Sponsorship Delegation Framework

6.1 Guide to who should take on sponsorship role

	Source of Funding		
Who developed the project?	Commercial	Non-Commercial	None
University Employee	University	University	University
Trust Employee with Honorary Contract at University (funds would go through University)	Trust	Trust/University	Trust
Trust Employee without Honorary Contract at University	Trust	Trust	Trust
Commercial company	Company	n/a	n/a
Other, eg employee of another Trust	Other	Other	n/a

6.2 Co-sponsorship Agreement

Insert HSC Logo **Insert University Logo**

Sponsorship:
Roles and Responsibilities

Sponsorship Framework

Project Details			
Full Research Title:			
Chief Investigator:			
Lead Sponsor:		**Co-sponsor:**	
Sponsor's Ref. No.		**Co-sponsor's Ref. No.**	
Funder:		**Financial Management:**	
Care Organisation(s):			
Investigator(s)		**Role**	**Employer**

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 in the "Delegated to" column. Where responsibilities are shared equally, the lead sponsor is named first.
3.	A Project is not fully sponsored until the sponsor for **all** responsibilities has been assigned.

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		
2.2	Ensure statistical review		
2.3	Ensure Independent scientific review		

2.4	Secure study funding and secure agreement between Sponsor and Investigator/Institution where required.		
2.5	Researchers have the experience and expertise and access to the resources needed for the research.		
2.6	Identify, develop and secure third party contracts		
2.7	Ensure necessary indemnity arrangements in place		
2.8	Ensure all management approvals are in place and research management permissions given.		
2.9	Obtain Management (NHS R&D/University Governance) permission.		
2.10	Ensure appropriate employment/honorary contracts in place for investigators		
2.11	Risk assess the Study		
3. Ethics Committee Opinion			
3.1	Apply to Ethics Committee for approval		
3.2	Request permission from ethics committee for substantial amendment		
3.3	Submit annual progress report		
3.4	Submit end of study report		
3.5	Submit Final report within one year of study end		
4. Good Clinical Practice			
4.1	Ensure study conducted in accordance with protocol		
4.2	Ensure adherence to SOPs to maintain quality control		
4.3	Suspend or terminate study		
4.4	Maintain Trial Master File		
4.5	Take urgent safety measures		
4.6	Report urgent safety measures		
4.7	Archive the Trial Master File		
4.8	Take the lead when investigating any complaint arising from the study		
4.9	Lead any Misconduct in Research Allegation		
4.10	Keep records of all adverse events reported by the investigators		
5. Data Management			
5.1	Design of case report forms		
5.2	Design of database		
5.3	Collect high quality and accurate data from research subject		
5.4	Analyse laboratory data		
5.5	Ensure high quality data analysis		
5.6	Comply with Data Protection Act		
6. Monitoring and Audit:			
6.1	Development and execution of audit plan		
6.2	Sharing audit reports		
7. Intellectual Property and Dissemination of Results:			
7.1	Engage with HSC Innovations and Knowledge Transfer/Exploitation Units to ensure Intellectual property rights and their management are appropriately addressed.**		
7.2	At the conclusion of the study, plans are in place for disseminating the findings.		

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***
For Lead Sponsor:		
For Co-Sponsor:		
Chief Investigator:		
Site Principal Investigator:		

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

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

** Allocation of Intellectual Property will be addressed through a separate agreement.

Insert HSC Logo **Insert University Logo**

Clinical Trial Study
Sponsorship:
Roles and Responsibilities

Sponsorship Framework

Project Details			
Full Research Title:			
Chief Investigator:			
Lead Sponsor:		**Co-sponsor:**	
Sponsor's Ref. No.		**Co-sponsor's Ref. No.**	
Funder:		**Financial Management:**	
Care Organisations:			
Investigator(s)		**Role**	**Employer**

Completion notes	
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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 where 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 approvals in place and research management permissions given.		
2.11	Obtain Management (NHS R&D/University Governance) approval(s)		
2.12	Ensure appropriate employment/honorary contracts in place for investigators		
2.13	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	Take urgent safety measures (Reg. 30)		
5.6	Report urgent safety measures (Reg. 30)		

5.7	Maintain Trial Master File in accordance with Regulation 31a		
5.8	Archive the Trial Master File (Reg. 31a)		
5.9	Ensure medical files of trial subjects retained for 5 years after conclusion of trial (Reg. 31a)		
5.10	Approving and recording transfer of ownership of data or documents used in a clinical trial (Reg. 31a)		
5.11	Take the lead when investigating any complaint arising from clinical trial (GCP)		
5.12	Lead any allegation of Misconduct in Research		
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 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	Frequency of monitoring to be: *{insert frequency}*		
9.2	Securing monitors (GCP)		
9.3	Sharing monitors reports		
9.4	Development and execution of audit plan (GCP)		
9.5	Sharing audit reports		
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***
For Lead Sponsor:		
For Co-Sponsor:		
Chief Investigator:		
Site Principal Investigator:		

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6.4 Sponsorship Delegation Framework

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	
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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
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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)		
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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)		
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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)		
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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]:		

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