UNIVERSITY OF SUSSEX

Standard Operating Procedures for Delegation of Roles & Responsibilities

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[1] http://www.sussex.ac.uk/staff/research/governance

Acknowledgement , University of Keele

1. Purpose & Scope

1.1 The EU Good Clinical Practice (GCP) Directive 2001/20/EC was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union. It was transposed into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) which came into force on 1st May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments will be referred to as the Regulations in the rest of this document[2].

1.2 This Standard Operating Procedure (SOP) sets out the delegation of sponsor functions to different members of staff, for research studies sponsored by the University of Sussex (US).

1.3 The scope of the document is for all schools at the University of Sussex, all members of staff with substantive employment and students registered at the University (including Brighton and Sussex Medical School).

2. Introduction

2.1 The Regulations and the UK Policy Framework for Health and Social Care[2] place the overall responsibility for a research study firmly on the Sponsor.

2.2 US as a sponsor can delegate but it is the organisation that still remains responsible and must therefore ensure that delegated tasks are carried out properly. ICH-GCP guidelines stipulate that 'prior to initiating a study, the sponsor should define, establish, and allocate all study-related duties and functions. '

2.3 The Regulations, in relation to delegation state:
"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".[3]

2.4 The need for clear allocation of responsibility arises at organisational as well as individual level. There needs to be clarity prior to initiating studies how these functions will be allocated.

3. Responsibilities

CI (Chief Investigator)

3.1 It is the responsibility of the Cl to ensure this SOP is followed and the duties expected to be conducted by them, are performed.

[2] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
[3] http://www.legislation.gov.uk/uksi/2006/1928/made?view=plain

3.2 The Cl must also ensure that the Principal Investigators at each participating research site undertake their duties or delegate them appropriately.

US Research Ethics, Integrity and Governance Office (REIGO)
3.3 The US Office Research Ethics, Integrity and Governance Office is responsible for ensuring this SOP is followed and the duties expected to be conducted by the department, are performed.

4. Procedure

4.1 Appendix 1 below provides a template to outline the delegation of responsibilities for US sponsored research studies. Departures from this may be made if the arrangement is clearly documented in the study documentation.

4.2 Each individual involved in conducting a research study shall be qualified by education, training and experience to perform their tasks. It is the responsibility of anyone authorising onward delegation of tasks to ensure that the delegate is appropriately qualified for that task.

All relevant elements should be considered — not only professional qualifications but also GCP training and familiarity with the protocol.

Study Oversight Roles and Responsibilities

4.3 The following table outlines the responsibilities delegated by US (the sponsor) to (Research Governance Office), the CI (Chief Investigator), the PI (Principal Investigator), the CTU and any other relevant parties. In some cases, roles may be delegated by the Cl to the Research Ethics, Integrity and Governance team (REIGO). This must be documented at the start of the study, where applicable.

Responsibility/Role	REIGO	CTU	CI	PI	Other
Setting up a research study					
Establishment of research type		X			
Ensuring sufficient resources for conduct of research			X	X	
Preparation of protocol, PIS, Consent Form, Case Report Form and other associated study documents			X		
Support in preparation of study documents		X			

Responsibility/Role	**REIGO**	**CTU**	**CI**	**PI**	**Other**
Submission of study documents to Sponsor (SOPRG01a)			X		
Risk assessment of research study and implementation of mitigation measures (SOPRG04)	X				
Completion and submission of documents to REC, MHRA, HRA and any other relevant agencies once sponsorship has been granted			X		
Database set up for research study		X	X		
Set up Investigator Site File and Trial Master File		X	X		
Set up of study specific procedures (e.g. Pharmacy manual, Lab manual etc.)					
Release of IMP					
Registering study on public database		X			
Organising & conducting the site initiation meeting					
During the research study					
Preparation & submission of amendments to relevant agencies		X			
Review of amendments prior to submission (SOPRG16)	X				
Maintenance of ISF				X	
Maintenance of TMF		X	X		
Study conduct in accordance with SOPs, regulations and guidelines					

Responsibility/Role	**REIGO**	**CTU**	**CI**	**PI**	**Other**
Documented study specific delegation of duties by the PI to the research team				X	
Adequate training provided and documented to research team			X	X	
Reporting serious adverse reactions to the REC			X		
Adequate training provided & documented to research			X	X	
Reporting serious adverse reactions to the REC			X		
Monitoring the research study (SOPRG05A)	X				
Data Management (data entry, query resolution etc.)			X		
Preparation and submission of Annual Progress Reports			X		
Communication of study developments to participating sites			X		
IMP Management			X		
Reporting serious adverse events/ reaction to the MHRA (SOPRG21)		X	X		
Notifying SUSARs (Suspected Unexpected Serious Adverse Reactions) to other investigators		X	X		
Preparation and submission of Development Safety Update Reports to MHRA			X		

Responsibility/Role	**REIGO**	**CTU**	**CI**	**PI**	**Other**
Reporting of Serious Breaches & Urgent Safety Measures to REIGO (SOPRG03 and SOPRG16)			X		
Reporting of Serious Breaches & Urgent Safety Measures to MHRA & REC			X		
Reference Safety Information check			X		
End of the research study					
Notification of the end of the study to REC, Research Governance Office and MHRA when applicable (SOPRG09a)			X		
Submission of the clinical study report within one year of the end if study to the MHRA			X		
Publications of results on the public database within 12 months of the end of the study (SOPRG35)			X		
Archiving of the research sites study documentation (SOPRG33)			X		
Archiving of the TMF				X	
Notifying research teams when documents can be destroyed		X	X		

Clinical Research Staff Roles and Responsibilities

4.5 For multi-centred, US sponsored studies, a clinical trial agreement will be executed prior to the study commencing at that research site. This will detail the duties being delegated from the sponsor to the PI and hosting research site.

4.6 At each research site, whether multi or single centred, the delegation of duties from the PI to other members of the clinical research team must be documented on a delegation log. This log must be

signed by the delegate and by the PI to demonstrate that both parties are aware and comfortable with the duties delegated to them (see Appendix 1). All research staff on the delegation log must have had GCP training within the last 2 years. A copy of this certificate should be filed in the site file. A signed & dated research CV within the last year should also be filed. There must also be documented evidence that those on the delegation log are qualified for the delegated task (e.g. Professional registration documented in CV), and that they have been trained in the relevant study procedures. If any of this information is stored outside of the investigator site file (ISF), then a file note should be stored in the site file indicating where this information can be found.

5. Training

5.1 This is a 'read and understand' SOP. Please note that REIGO department discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the University website.

6. Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational or Medicinal Product
CTU	Clinical Trials Unit
CV	Curriculum Vitae
EU	European Union
GCP	Good Clinical Practice
HRA	Health Research Authority
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IMP	Investigational or Medicinal Product
ISF	Investigative Site File
MHRA	Medicine and Healthcare Products Regulatory Agency
PI	Principal Investigator
PIS	Patient Information Sheet
REC	Research Ethics Committee
REIGO	Research Ethics ,Integrity and Governance Office
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reactions)
TMF	Trial Master File
US	University of Sussex

7. Cross Referenced SOPs

- SOPRG01A Sponsorship Approval CTIMPs
- SOPRG03 Notification of Serious Breach of Good Clinical Practice or the Protocol
- SOPRG04 Risk Assessment
- SOPRRG33 Archiving Paper Trial Documents (for University of Sussex as a Sponsor)
- SOPRD05A Monitoring CTIMP Research Projects

- SOPRG21 Adverse Events in CTIMPS
- SOPRG9A Procedures for Close out of a CTIMP
- SOPRG16 Amendments, Urgent Safety Measures and Temporary Halt to a Trial

8. References

Clinical Trials Regulations 2004 (SI 2004/1031)
http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

Clinical Trials Regulations 2006 (SI 2006/1928)
http://www.legislation.gov.uk/uksi/2006/1928/pdfs/uksi_20061928_en.pdf

UK Policy Framework for Health and Social Care Research

https://www.hra.nhs.uk/planning-and-improving-research/policies-standardslegislation/ukpolicy-framework-health-social-care-research/

International Conference on Harmonisation Good Clinical Practice Guidelines E6

Good Clinical Practice, International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use
http://ichgcp.net/

MHRA Good Clinical Practice Guide, The Stationery Office: London, (2012)

Appendix 1

HRA Delegation Log Template - Non-Commercial

STAFF SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

Study Sponsor: _____ **IRAS Project ID:** _____

Protocol / Study Number: _____ **Principal Investigator:** _____

Protocol / Study Short Title: _____

Participating Organisation No.: _____ **Participating Organisation:** _____

I confirm/ acknowledge that the information in this form is correct and that;

- I will remain responsible for the conduct of the study and reported data at this participating organisation.
- I will oversee the study at this participating organisation.
- I will authorise tasks to be delegated to people listed in this form.
- I will only delegate tasks to people who are appropriately skilled and trained to carry out those tasks.
- I will tell the people delegated tasks of their responsibilities in carrying out those tasks.
- I will make sure that no one who is to be delegated tasks will carry out those tasks before they have been delegated to them.
- I will make sure that no one who is to be delegated tasks will carry out those tasks before they have completed any training required to carry out the tasks.
- I will make sure that people delegated tasks receive the necessary information and training at the proper times.
- I will make sure that any and all changes to people delegated tasks, or the delegated tasks, are recorded on this form at the proper times.
- I acknowledge the 'Data Privacy Statement' attached to this log.

STAFF SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

Study Sponsor: _____ **IRAS Project ID:** _____

Protocol / Study Number: _____ **Principal Investigator:**

Key to tasks

1. Coordinate approval communications/ submissions
2. Screen/ recruit study participants
3. Obtain informed consent
4. Confirm eligibility (inclusion/ exclusion)
5. Obtain medical/ medication history
6. Perform medical examination
7. Conduct study visit procedures (e.g. vital signs, height, weight, ECG)
8. Conducts specialist study visit procedures (e.g. photography, audio recordings)
9. Perform study related assessments
10. Make study related medical decisions
11. Evaluate study related test results
12. Collect biological samples/ material
13. Process, store or ship biological samples/ material
14. Randomise study participants (with or without IWRS/ IVRS)
15. Make (e)CRF entries or corrections
16. Sign off (e)CRFs
17. Resolve data queries
18. Maintain essential documents
19. Manage IMP/ device receipt, storage and temperature monitoring
20. Prepare and/ or dispense IMP/ device
21. Managed IMP/ device accountability
22. Assesses AE/ SAE severity and causality
23. Report SAEs
24. Receive/ access safety notifications
25. Activities related to regulatory communications/ submissions
26. Activities related to randomisation code break
27. Other*
28. Other*

29. Other* _____
30. Other* _____

31. Other* _____
32. Other* _____

(*) Other tasks that are specific to the study, or are local regulatory requirements, identified by the sponsor.

Use the key of tasks to complete the Study Task column. For each person listed in the Name column, record the number(s) of the task(s) delegated to that person. Numbers can be recorded consecutively, or as a range, e.g. 3, 4, 5, 6, or 3-6; 8-11. Tasks should only be delegated to people who are suitably qualified by education, training and/or experience to carry out that task/role.

STAFF SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

Study Sponsor: _____ **IRAS Project ID:** _____

Protocol / Study Number: _____ **Principal Investigator:**

If there are any additional study specific tasks not listed, add these to the "Other*" sections of the key.

This log should include all people who routinely see study participants, who carry out study protocol related tasks, or who are responsible for data collection/interpretation. Add new or replacement people as appropriate.

NAME (Please print)	**SIGNATURE** My signature below indicates: - I accept to carry out the delegated task(s) - I acknowledge the Data Privacy Statement attached to this document	**INITIALS**	**STUDY TASK** (Select from the key)	**START OF TASK(S)** (dd/mmm/yyyy)	**PI SIGNATURE**	**END OF TASK(S)** (dd/mmm/yyyy)	**PI SIGNATURE**

Comments: Please initial the box if there are no comments ☐

(To be completed by the Principal Investigator at the end of the study).

STAFF SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

Study Sponsor: _____ **IRAS Project ID:** _____

Protocol / Study Number: _____ **Principal Investigator:**

I confirm that the information in this form is accurate and complete

STAFF SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

Study Sponsor: _____ **IRAS Project ID:** _____

Protocol / Study Number: _____ **Principal Investigator:** _____