Queen's University Belfast

**Research and Enterprise**

# Standard Operating Procedure
# Research Governance

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|---|---|---|---|
| **Title:** | **Delegation of Responsibilities** | | |
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| | Name and Position | Signature | Date |
|---|---|---|---|
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**When using this document please ensure that the version is the most up to date by checking the Research Governance Website**

Revision Log

| Previous Version number | Date of Review/Modification | Reason for Review/Modification | New Version Number |
|---|---|---|---|
| Final v 1.0 | 10/11/09 | Annual Review | Draft v 2.0 |
| Draft v 2.0 | 10/11/10 | Annual Review/ Update following MHRA GCP Inspection | Final v 2.0 |
| Final v 2.0 | 17/8/2012 | Periodic Review | Final v 3.0 |
| Final v 3.0 | 21/10/14 | Periodic Review | Final v 4.0 |
| Final v 4.0 | 07/09/2016 | Periodic Review | Final v 5.0 |

## 1. Purpose

This Standard Operating Procedure (SOP) describes how responsibility and accountability can be delegated among members of the research team.

## 2. Introduction

To ensure the smooth and accurate conduct of research studies, appropriately qualified personnel are required. This may include staff directly involved in the conduct of the research (e.g. Chief Investigator, co-investigators, research staff) and those staff who may be associated with, but not directly involved in the research trial (e.g. clinicians, pharmacists, laboratory staff).

For a study to run safely it is essential that all staff involved are aware of the anticipated extent of their involvement and the limits to their authority.

## 3. Scope

This SOP applies to all studies where the University is acting in the capacity of Sponsor, or Co-Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff, and students who are conducting research within or on behalf of the University.

## 4. Responsibilities

### 4.1 Chief Investigator

Each study will have a Chief Investigator (CI), who has overall responsibility for:

- The welfare of research participants;
- Conduct of the study in compliance with the protocol;
- Obtaining the necessary approvals and continued communication with approval/regulatory bodies (i.e. the Sponsor, Ethics, MHRA, Trust, Funding source);
- Informed consent;
- Safety Reporting;
- Where applicable, the administration and management storage of investigational product as appropriate;
- Accurate and timely completion of trial data;
- Archiving.

Additionally the CI must ensure that the study is logged onto the Insurance Database and that the correct level of risk is designated to the proposed research. The risk levels are detailed in the following table.

| Risk | Descriptor |
|---|---|
| Level 1 | Those projects which although involving human subjects are in no way associated with a medicinal purpose or do not involve issues such as alcohol and illicit drug use or higher risk sexual behaviour. Level 1 projects essentially involve research into, for example, behaviour, attitudes, rights and education issues. These projects do not include an intervention[1]. |
| Level 2 | Those projects that have more relevance to healthcare and include, for example, survey work on access to health care or issues, such as alcohol and illicit drug use or higher risk sexual behaviour. These projects do not include an intervention. |
| Level 3 | These projects essentially involve research involving collecting data (including risk factor data) in human subjects and correlating this with, for example, health status, and advances in diagnostics. The projects do not involve altering treatment regimens or the standard of routine care that these individuals receive. These projects do not include an intervention. |
| Level 4 | These studies generally either involve an intervention which has the aim of changing health status or behaviour or involve procedures that are generally more invasive in nature, but do not have the attributes/characteristics of Level 4b studies. |
| Level 4b | These studies involve Clinical trials of Investigational Medicinal Products or clinical trials into medical devices or involve procedures which aim to induce illness or other conditions (eg inflammation) in study subjects for the purpose of testing the efficacy of new treatment approaches. |

The Insurance Database will be audited by Senior Staff at the University annually and any discrepancies will be reported back to CIs.

## 5. Procedure

- As part of the University's Research Governance arrangements, all researchers are aware of their research responsibilities, as outlined in the University's Regulations for Research Involving Human Participants. When the University is acting in the capacity of Sponsor with a Health and Social Care (HSC) Trust, and then the researcher is reminded of their responsibilities, under the Research Governance Framework for Health and Social Care, as necessary.
- The CI, will discuss and agree the allocation of tasks with other members of the research project, as outlined in Appendix 1.
- The allocation of tasks to appropriately qualified persons should be recorded on a Study Delegation Log (SDL), as exampled in Appendix 1. The SDL will:
  i List the names of staff and the procedures that have been delegated to them.
  ii Be signed and dated by the CI/PI and filed appropriately within the Trial Master File.
  iii Be updated when new staff are recruited, but superseded versions must not be destroyed in order to provide for an audit trial.

  The SDL should be reviewed at appropriate intervals to ensure that it is kept up to date.
- For projects sponsored by the University, Sponsors responsibilities will be delegated to the CI.
- For multi-centre studies the CI should specify the responsibilities delegated to a site Principal Investigator.
- Where the University is operating as a co-sponsor with another organisation (e.g. Health and Social Care Trust), signatures will be required on the co-sponsorship agreement,

[1] An intervention is classed as a change directly related to the study that may alter the research subject's health, physically or mentally and includes any potential to alter behaviour as a result of participation.

attached as Appendix 2, and retained in the University's Research Governance Project File.

## 6. References

National Cancer Research Network, Standard Operating Procedure: Definition of Responsibilities.

Belfast Health and Social Care Trust, SOP, Delegated Responsibilities in Research Projects, September 2007.

## 7. Appendices

Appendix 1 - Study Delegation Log.
Appendix 2 - Clinical Trial Study Sponsorship: Roles and Responsibilities.

# Delegation and Staff Signature Log

| | |
|---|---|
| **Study Title:** | **Protocol No:** |
| **Chief Investigator:** | **EUDRACT No:** |
| **REC Reference Number:** | **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: ……... | |

*NB: This is not an exhaustive list and will require annotating at a local level.

Appendix 2

**Sponsorship Framework**

**Insert logo of lead sponsor** **Insert logo of Co-sponsor**

# Clinical Trial Study Sponsorship: Roles and Responsibilities

| **Project Details** | | | |
|---|---|---|---|
| **Full Research Title:** | | | |
| **Chief Investigator:** | | | |
| **Lead Sponsor:** | | **Co-sponsor:** | |
| **Funder:** | | **Financial Management:** | |
| **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 (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 approvals in place and start certificate issued. | | |
| 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) | | * |
| 5.6 | Maintain Trial Master File in accordance with Regulation 31a | | |
| 5.7 | Archive the Trial Master File (Reg. 31a) | | # |
| 5.8 | Ensure medical files of trial subjects retained for 5 years after conclusion of trial (Reg. 31a) | | |
| 5.9 | Approving and recording transfer of ownership of data or documents used in a clinical trial (Reg. 31a) | | * |
| 5.10 | Take the lead when investigating any complaint arising from clinical trial (GCP) | | |
| 5.11 | Lead any Misconduct in Research Allegation | | |
| ***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 | Ensure all SUSARs are entered into the European database. (GCP) | | |
| 6.8 | 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 | Ensure high quality data analysis (GCP) | | |
| 7.5 | 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***<br>*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.