Portsmouth Hospitals University NHS Trust

Standard Operating Procedure (SOP) for Delegation of Roles & Responsibilities

For Completion by SOP Author	
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For Completion by Research Dept., SOP Controller	
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The definitive versions of all Portsmouth Hospitals University Trust SOPs, Templates and Forms for Research are online at SOPs and Templates (porthosp.nhs.uk)

If you are reading this SOP in printed form then you are reading an uncontrolled document. You must therefore verify that the version number and date given below are the most recent, by cross-checking with the Trust research website before proceeding with implementation.

Portsmouth Hospitals University NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This SOP has been assessed accordingly.

CONTENTS

1. INTRODUCTION

This document has been produced in accordance with the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004 in conjunction with the Amendment Regulations 2006, the UK Policy Framework for Health and Social Care Research and ICH GCP Guidelines. These regulations will be referred to in this document as the Regulations.

The need for clarity about roles and responsibilities is fundamental to the conduct of research. The Regulations clearly place the responsibility for clinical trials on the sponsor including initiation, management, financing, conduct, monitoring and reporting of data. The legal responsibilities of the sponsor are outlined in the Regulations and summarised in the recent Good Clinical Practice Guide (ISBM 978 0 11 708107 9) published by the MHRA in 2012. The three main responsibility areas are:

- Authorisation for clinical trials and research ethics committee opinion
- GCP and the conduct of the clinical trials
- Pharmacovigilance

The Regulations state that *"prior to initiating a trial the sponsor should define, establish and allocate all trial-related duties and functions"* (ICH GCP). Further *"A person who is 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".* As such the Sponsor can delegate responsibilities but remains accountable. It is therefore critical that the sponsor implements procedures to ensure oversight of all delegated roles and responsibilities at the level of organisations and individual- *"…should ensure that there are formal processes in place to allow them to maintain oversight of delegated functions. This usually consists of some form of audit and monitoring activities to detect and rectify poor compliance"* (MHRA GCP Guide). Sponsor oversight is required for:

- Approvals such as ethical review and clinical trial authorization
- Trial documentation
- Trial data
- Trial interventions/medication
- Pharmacovigilance
- Monitoring/audit

Table 1.1 in the recent GCP guide (ISBM 978 0 11 708107 9) published by the MHRA outline and discusses these in more detail (the PHU Research Office has physical copies of this guide for reference).

2. PURPOSE

The purpose of this document is to describe the standard operating procedure for the allocation of roles and responsibilities within a research study and must be used when setting up and delivering all clinical research at PHU that is sponsored, co-sponsored or hosted.

3. SCOPE

This Standard Operating Procedure applies to:

- All clinical research activity conducted at PHU
- All clinical research activity for which PHU is responsible as Sponsor or Host

Who should follow this SOP?

- All staff involved in research at PHU.

The Trust recognises that some external sponsors, networks, funders and employers may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the Portsmouth Hospitals University Trust user (including those individuals contracted to work on behalf of the Trust), to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts the Trust's procedure then approval must be sought in writing from the Director of Research.

In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety

4. ABBREVIATIONS & DEFINITIONS

4.1. Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trials of an Investigational Medicinal Product
CTU	Clinical Trials Unit
CRO	Clinical Research Organisation
ICH GCP	International Conference on Harmonisation Good Clinical Practice
ISF	Investigator Site File
GCP	Good Clinical Practice
MHRA	Medicines and Healthcare Products Regulatory Agency
PHU	Portsmouth Hospitals University Trust
PI	Principal Investigator
SOP	Standard Operating Procedure
TMF	Trial Master File

4.2. Definitions (*based on the definitions proved in the MHRA Good Clinical Practice Guide, 2012)*

Sponsor

- Any individual, company, institution or organisation which takes responsibility for the initiation, management and financing (or arranging the financing) of a clinical trial.

Hosting organisation (host)

- An organisation selected by the sponsor to undertake clinical research activities, usually considered to be an investigator site.

Chief Investigator (CI)

- A CI is the authorised health care professional, whether or not they are an investigator at any particular site, who takes primary responsibility for the conduct of the clinical research at all sites involved in the study.

Principal Investigator (PI)

- The PI is the authorised health care professional responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator.

5. DUTIES AND RESPONSIBILITIES

The following parties are responsible as outlined below:

Research Office:

- Providing a delegation matrix for Sponsored studies and agreeing the onward delegation of Sponsor responsibilities on behalf of the Trust.
- Agreeing, ensuring and contracting with collaborators and sub contractors their roles and responsibilities in PHU Sponsored studies.
- Providing a template delegation log for use in hosted studies, if not provided by the Sponsor.
- Providing advice/oversight where appropriate of best practice for the delegation of roles and responsibilities in clinical research studies at sponsor or site level.

Research Team:

- Ensuring all delegated roles and responsibilities are appropriately recorded and undertaken.
- Ensuring all clinical research studies have a completed delegation log held within the Investigator Site File (ISF).
- Using the PHU delegation log template if an appropriate log has not been provided by the Sponsor.
- Ensuring they themselves are fully qualified, competent and confident to undertake any roles and responsibilities delegated to them.
- Seeking appropriate advice/support in regards to the delegation of roles/responsibilities if required (from the PI, Sponsor, Research Office etc.).

Principal Investigator:

- Ensuring overall responsibility and oversight for the appropriate delegation of roles within a hosted study at PHU as a site or at a site sponsored by PHU.
- Ensuring that roles and responsibilities are delegated to those who are suitably qualified and experienced to undertake them, consummate to their job roles.

Chief Investigators in PHU Sponsored studies

- Ensuring all delegated Sponsor responsibilities are met as agreed and recorded in the delegation of responsibilities matrix.

Different levels of responsibility can be delegated by the Sponsor to participating organisations and/or individuals. In order to appropriately capture delegated responsibilities two templates have been created in association with this SOP.

They are:

1. Delegation of roles and responsibilities matrix.
2. Template delegation log, where this is not provided by the Sponsor.

Templates are to be adapted to define, establish and allocate all study-related duties and functions.

5.1. Sponsor Delegated Roles and Responsibilities Matrix

For template see controlled documents on the Research Website - SOPs and Templates (porthosp.nhs.uk)

This template is to be used when PHU is the Sponsor and may delegate responsibilities for example to the:

- The Chief Investigator.
- The Principal investigator (when multisite).
- The research fellow leading the study.
- Subcontractor (for e.g a CTU).
- Collaborator.

This document will be final and is to be included in relevant contract(s) and should be signed off by the CI upon sponsorship agreement.

5.2. Delegation Log

For template see controlled documents on the Research Website - SOPs and Templates (porthosp.nhs.uk)

This log is to be used when the PI of a Hosted study or CI of a Sponsored study onward delegates to individuals in the local research team of the study. The PI can delegate duties, but never the responsibility for the study at the site. The PHU specific template should be used in the event that the Sponsor has not issued their own log or where PHU is the Sponsor.

Where EDGE is intended to be used as a electronic delegation log for a study this is possible with agreement from the Research Office/Sponsor. Guidelines on how to utilise this method are available, via the Wessex Research Hub Group, on request from the R&D Manager or Trust Lead Research Nurse.

6. PROCESS

Documentation of delegated duties is an on-going process as circumstances may change, e.g. different members of staff may become involved in the study.

The log must:

- List the names and roles of all staff involved and outline which duties have been delegated to them.
- Confirm the start and end dates for each member of staff performing their delegated duties.
- Be signed and dated by the PI–The PI should sign off each individual member of staff, considering their evidence of training, education and experience prior to the staff member carrying out any duties for the study. By delegating duties, the PI confirms that the team member is appropriate for their delegated duties and retains the responsibility from compliant delivery of said duties. Therefore, active involvement in the study is not permitted for staff until they have been signed off by the PI.
- Be updated throughout the study. This may include new staff being added and staff who leave removed. Superseded versions must not be destroyed to ensure an accurate audit trail of who was performing which duties at any time point in the conduct of the study. Other

changes that may require an update to the log would be a change in study procedures following an amendment to the study.
- Be filed appropriately in the Investigator Site File.
- Be supplied to the sponsor as requested, with updated versions being supplied when updated.

The delegation of roles and responsibilities should be discussed early and, in the case of a sponsored study, be of consideration when applying for funding e.g. support from Clinical Trial Unit (CTU) or Clinical Research Organisation.

For a sponsored study, the facilitator of the research project will discuss the delegation of responsibilities with the researchers ahead of R&D sponsorship and the matrix should be completed upon PHU confirmation of capacity and capability/green light. It is the responsibility of the CI/PI to assure that they have an appropriate study team to support the study and maintain study oversight.

As opposed to the matrix, the delegation log is a live document used by the CI/PI to clearly document delegated research responsibilities throughout the study.

7. TRAINING REQUIREMENTS

All researchers and research department staff should be trained in this procedure. Evidence of training shall be required for all Chief Investigators and individual's delegated specific roles and responsibilities in Trust Sponsored studies

The Research Department will endeavor to notify staff of SOP developments that may be relevant to them. Updates on SOPs will feature in Research news bulletins and communications. It is the responsibility of all research active staff to ensure that they read the Issued updates that may be relevant to them.

When a new SOP is authorised, or when an existing SOP is revised, self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record. A study specific SOP training plan will be developed for investigators on high risk PHT Sponsored studies.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the trainee should approach their line manager and the SOP Controller who will arrange additional training. All staff should complete their training prior to the published implementation date.

All staff are responsible for maintaining their own SOP Training Logs and copies must be made available to line managers, the SOP Controller or study monitors on request.

8. REFERENCES AND ASSOCIATED DOCUMENTATION

- The Medicines for Human Use (Clinical Trial) Regulations 2004 and the Medicines for Human Use (Clinical Trial) Amendment Regulations 2006, the Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006, the Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008, and the Medicines for Human Use (Miscellaneous Amendments) Regulations 2009.
  http://www.legislation.gov.uk/uksi/2004/1031/contents

- Health Research Authority (Last accessed May 2023) Health Research Authority (hra.nhs.uk)

- UK policy framework for health and social care research, Dept Health & Social Care, 2017(Last accessed May 2023). UK Policy Framework for health and social care research

- ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (R1), Key Requirements Affecting Clinical Trials in Europe, Canary, 2010

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Good Clinical Practice. http://www.ichgcp.net

- The Good Clinical Practice Guide, MHRA ISBM 978 0 11 708107 9

9. 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	18/12/2014	New document
1.1	07/04/2016	Additional information regarding SOP training added
2.0	05/12/2023	Updated Trust naming convention Web links updated throughout Updated references and further information in the introduction Update to definitions Additional clarity added to duties and responsibilities Contemporaneous updates and further information provided to process section References updated

10. APPENDICES

Appendix 1: Confirmation of SOP Training Record

CONFIRMATION OF SOP TRAINING RECORD

A copy of this record may be kept in your personal training file to confirm your training in a specific SOP. If required by a study Sponsor a record may also need to be kept in the Trial Master Files (TMF) or Investigator Site Files (ISF)

SOP Details: To be completed by the SOP Controller	
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Personnel Details	
Name	
Job Title & Research Role	
Date of Training	
Nature of Training	Self Directed
Records of any meetings to clarify details in SOP	

Signatures
I confirm that I have read and consider myself to be sufficiently trained in the above Standard Operating Procedure with regards to my individual roles and responsibilities Signature of Trainee …… Date ……
I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities Signature of Trainer …… Date ……
Additional Notes & Signatures

Signature of Trainer (where appropriate)

I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities

Signature of Trainer …… Date ……