Portsmouth Hospitals University NHS Trust

Standard Operating Procedure (SOP) for the Development, Management & Control of Research-Related SOPs

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 NHS Trust SOPs for Research are online at https://www.porthosp.nhs.uk/research/

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

Standard Operating Procedures are an essential part of quality management; setting out written procedures by which quality activity is attained. The Trust has responsibilities for the good governance of all research activities but ICH guideline E6 for GCP states specifically our obligations as Sponsor of clinical research:

"The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)."

The Medicines for Human Use (Clinical Trials) Regulations 2004 in conjunction with the Amendment Regulations 2006 (collectively referred to hereafter as "the Regulations"), stipulate the legal requirement for all research Sponsor organisations of Clinical Trials of Investigational Medicinal Products(CTIMPs) to, "*put and keep in place arrangements for the purpose of ensuring that with regard to that trial the conditions and principles of good clinical practice are satisfied or adhered to"* (28, (2)).

2. PURPOSE

The purpose of this SOP is to describe the Standard Operating Procedures for the development; management and control of research-related SOPs.

3. SCOPE

This SOP applies to:

- All Trust staff or contracted individuals, who may develop a SOP on behalf of Portsmouth Hospitals University NHS Trust, where the SOP is principally intended to govern Trust research activities.
- Trust Research staff who will manage and control research-related SOPs on behalf of the Trust.

This SOP does not apply to research-related work instructions, which may be developed for internal use by departments, to document detailed departmental processes. (1)

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 NHS 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 Trust procedures, then approval must be sought from a senior manager within the research & innovation department.

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.

(1) **Note:** Work instructions should be version controlled but may range from a detailed document to a simple flow diagram or process map. Please seek advice from the R&I Office if required.

4. ABBREVIATIONS & DEFINITIONS

Abbreviation	Meaning
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
ISF	Investigator Site File
MHRA	Medicines and Healthcare Products Regulatory Agency
NRES	National Research Ethics Service
R&I	Research & Innovation
REC	Research Ethics Committee
PHU	Portsmouth Hospitals University NHS Trust
PI	Principal Investigator
SOP	Standard Operating Procedure
TMF	Trial Master File

Definitions

Term	Definition
Minor Amendment	Minor Amendments to a SOP means an administrative change or a change that does not significantly affect the roles, responsibilities or procedures.
Substantial Amendments	Substantial Amendments to an SOP means a significant change to the roles and responsibilities or to procedures. Any change in legislation or accepted standards of good practice that affects a change in a SOP, shall generally be considered to be substantial.
PHU Research	PHU Research means all research activity for which Portsmouth Hospitals University NHS Trust is responsible either as a Sponsor organisation (including participating sites for multi-site studies) or as a host site.
Senior Research Management Team Members	Senior Research Management Team Members for the purpose of this SOP are the Executive Director of Research, Deputy Director of Research, Lead Research Nurse, Head of Research Operations, R&D Manager, Research Manager, Research Finance Manager and the Research Facilitators.

5. DUTIES AND RESPONSIBILITIES

Role	Responsibilities
SOP Author	is a named individual responsible for driving and developing SOP content.
SOP Controller	is a member of the Trust's research office, responsible for: • Formally registering the SOP on the PHU Research SOP register. • Facilitating the review and approval of the SOP. • Ensure all SOPs are compliant with the current and approved SOP template. • Changing versions, footers, watermarks and populating the SOP template details as appropriate. • Ensuring the routine review and amendment of approved SOPS. • Maintaining the SOP register and ensuring up-to-date, approved and controlled documents are uploaded onto the Trust's research website.

	• Ensuring notice of updated SOPs is communicated in research communications.
SOP Reviewer	is responsible for reviewing a SOP for quality and compliance with: • PHU process; and • The Regulations or standards of good practice.
PHU Research Department Senior Management Team	is responsible for: • Accepting proposed SOPs onto the PHU Research SOP register. • Nominating and approving SOP authors and reviewers. • Advice and decision making where issues are unclear, and for escalating decisions onto the Research Delivery Meeting or Research Governance and Risk Group. • Submitting substantial amendments for review and committee approval.
Research Delivery Meeting or Research Governance and Risk Group	is responsible for: • Oversight and ratification of all SOPs and substantial amendments. • Advice and final decision making where issues are escalated. • Approving the review process for each SOP. • Agreeing the proposed SOP implementation date and training plan.

6. PROCESS

6.1. Development of a SOP

- Once the requirement for a SOP has been identified it should be proposed to the Research Department SOP Controller who will seek agreement from a member of the Senior Research Management Team to formally register the draft title of the SOP.

- The SOP Controller will document the title on the SOP register and issue a reference number. Prior to 2020, the reference number began with the pre-fix PHT/RDSOP/__ and have a unique identifying number. Following the publication of this SOP, reference numbers will change to the pre-fix PHU/RDSOP/___ for newly written SOPs. For pre-existing SOPs, their reference number will be updated to 'PHU' the next time they are updated, following the publication of this SOP.

- The SOP controller will consult the SOP proposer and Senior Research Management Team to nominate and agree an appropriate SOP author and timeline for completion.

- The SOP author should be an individual who is appropriately qualified or experienced in, and familiar with, the procedures to be described in the SOP.

- The SOP controller will ensure the SOP author has a copy of the SOP template, SOP unique reference number, SOP review form and this procedure. [(2)]

- The SOP author should ensure that the draft documents are clearly version controlled at all times with a sequential draft version number, including a date of the last documented change in the footer of each page.

- The template will be issued with a "draft" watermark until the SOP is approved and issued.

6.2. Review of a SOP

- Once the SOP author is ready for the draft SOP to be reviewed, they should submit it to the SOP Controller, nominating appropriate SOP reviewer(s).

- The SOP controller will agree the SOP reviewer(s) with a member of the Senior Research Management Team. Reviewers should be suitably qualified or experienced in, and familiar with, some or all the procedures and subject matter to be described in the SOP. Reviewers may be members of the Research Delivery Meeting or internal Research Department Staff, or external to the Trust.

- The SOP author will send the draft SOP to the reviewer(s) and address comments until a final draft has been agreed.

- If there is any disagreement or uncertainty on the content of a SOP, then these shall be escalated to a senior manager within the research department or the Research Delivery Meeting or Research Governance & Risk Group for a final decision. These discussions will be recorded. Any decisions made outside of the Research Delivery Meeting or Research Governance & Risk Group will be reviewed and recorded at the next meeting.

6.3. Approval and Issue of a SOP

- All reviewed SOPs will be formally submitted to the next available Research Delivery Meeting or Research Governance & Risk Group for final ratification before full issue and implementation

- Once ratified by the Committee the SOP controller shall prepare the SOP for issue by:
  (a) Replacing the draft version numbers [dates] with “Issued” Version 1.0 and [date].
  (b) Documenting the implementation date.
  (c) Changing the “draft” watermark to “uncontrolled document”.
  (d) Populating the SOP training log template at the back of the SOP.
  (e) Recording and uploading the issued SOP onto the Research Website.
  (f) Updating the Research SOP register.

6.4. SOP Implementation and Training Period

- Once the SOP is issued on the Trust website the SOP controller must send “notice” to all individuals with responsibilities defined in the SOP.

- This notice may be via specific email or through general Trust or Research & Innovation Department communications but must give reasonable time for training to occur before the final implementation date (4 weeks is recommended).Specific training requirements for each SOP will be specified in *Section 7* of the SOP template. A SOP training log template is provided for investigators to sign to demonstrate their understanding of the SOP and to keep in their files.

6.5. SOP Amendments and Review

- Any minor amendments to a SOP will not require review or ratification from the Research Delivery Meeting or Research Governance & Risk Group. The SOP controller may agree administrative changes but must escalate more substantive issues to a member of the Senior Research Management team.

- Minor amendments will necessitate a change in version number usually documented as a decimal increment, for example from version 1.0, version 1.1, 1.2 etc; and must be recorded on the SOP register.

- Substantial amendments to a SOP will be required to receive formal review by a SOP reviewer, and will be submitted for ratification to the Research Delivery Meeting or Research Governance & Risk Group.

- Substantial amendments to a SOP will necessitate a change in version number usually documented as a whole number increment, for example from version 1.0, to version 2.0, 3.0 etc; and must be recorded on the SOP register.

- All SOPs must be periodically reviewed for continued compliance with The Regulations and standards of good practice. A review period of 3 years will be recorded unless otherwise decided by the Research Delivery Meeting or Research Governance Group.

- All SOPs due for periodic review should be sent to the SOP author or other nominated SOP reviewer for assessment of any changes in legislation, procedures or standards of good practice. Any changes to the SOP following this review should be managed as an amendment. The periodic review will be recorded by the SOP controller on the SOP register.

7. TRAINING REQUIREMENTS

- Only Research & Innovation Office staff involved in writing SOPs are required to be trained in this SOP. Staff who are delegated the role of SOP Controller will receive training specific in their roles and responsibilities by a senior manager within the research department. Training for new research office staff shall occur as soon as possible after their induction to the department. Existing staff shall be trained before the SOP implementation date and requirements for any training updates shall be reviewed at appraisal.

- The Research & Innovation Department will endeavour to notify staff of SOP developments that may be relevant to them. SOPs are available on the Research & Innovation Department website. Updates on SOPs will feature in research huddles and/or communications. It is the responsibility of all research active staff to ensure that they read the issued updates, that are 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 template is provided to support this process. A study specific SOP training plan will be developed for investigators on high risk PHU 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 which will normally be between 2-6 weeks after publication.

- All staff are responsible for maintaining their own SOP training records and copies must be made available to line managers, the SOP controller or study monitors on request.

8. REFERENCES AND ASSOCIATED DOCUMENTATION

Associated documents:

- Template for Research Related SOPs

Reference:

- The Medicines for Human Use (Clinical Trials) Regulations 2004 in conjunction with the Amendment Regulations 2006
- Guideline for Good Clinical Practice ICH Harmonised Tripartite Guideline E6 (R1)
- Research Support Services Framework, *NIHR,* 2011

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	01/07/2012	N/A
1.1	07/04/2016	Additional information regarding SOP training added
2.0	TBC	Reformatting in section 4 and 5. Removal of the use of a review form when reviewing SOPs. SOP author, rather than the SOP controller, will send SOP to reviewers. Removal of requirement for senior management team to advise on appropriate means of

		SOP notification. Update to the groups who can ratify a SOP and to the name of some departments. Update to members of the senior management team.

10. APPENDICES

10.1. Training Record

Portsmouth Hospitals University NHS Trust

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. The research department or your line manager may request copies to verify your training. 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	
Title of SOP	Standard Operating Procedure (SOP) for the Development, Management & Control of Research-Related SOPS
Reference Number	PHU/RDSOP/001
Version	2.0
Issue Date	29 March 2023
Implementation Date	insert

Personnel Details	
Name	
Job Title & Research Role	
Date of Training	
Nature of Training	Self Directed/Delivered by etc
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 …….