

**INSERT TITLE OF SOP**

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| **For Completion by SOP Author** | |
| Reference Number | Reference PHTRD/SOP\_\_  *[Number provided by SOP Controller on Registration of SOP]* |
| Version | Insert [Draft Version & Number] Please also Amend Footers.  *[Draft version will be changed to Issued Version by the SOP Controller on approval]* |
| Document Author(s) | Insert Author(s) and Job Title(s) |
| Document Reviewer(s) | Insert Document Reviewer (s) and Job Titles(s) |

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| **For Completion by Research Dept., SOP Controller** | |
| Name of Responsible Committee | Research Governance Group, [Insert Date Ratified] |
| Issue Date | Insert Date Issued  *(Change Version, Footers & Watermark)* |
| Implementation Date | Insert Agreed Date for Implementation. Must be after agreed training period (between 2-6 weeks from date issued) |
| Review date | Insert Agreed Review Date *(usually 3 years)* |
| Electronic location | Insert G Drive Location |

The definitive versions of all Portsmouth Hospitals Trust SOPs, Templates and Forms for Research are online at <http://www.porthosp.nhs.uk/research-department>

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 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

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# INTRODUCTION

Insert a brief introduction to the SOP. This may include a background summary and reference any legislation, standards or guidance which may have lead to its development.

Insert this standard text:

# PURPOSE

Insert a purpose using the following text:

*‘The purpose of this document is to describe the Standard Operating Procedures for…’*

# SCOPE

Describe one or more of the following:

* Who the SOP applies to (which staff members)
* The sorts of activity the SOP applies to
* The type of research the SOP applies to. (e.g. all research, hosted or Trust-Sponsored only, single or multi-site)

Insert the following standard text:

*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 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*

# ABBREVIATIONS & DEFINITIONS

Insert the meaning of any commonly used abbreviations (e.g. SOP = Standard Operating Procedure) and definitions.

**Abbreviation**  **Meaning**

PHT Portsmouth Hospitals NHS Trust

SOP Standard Operating Procedure

|  |  |
| --- | --- |
| **Term** | **Definition** |
| **PHT Sponsored Studies** | Studies which Portsmouth Hospitals NHS Trust have ultimate responsibility for the initiation, management of and financing for. They take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. |
| **Research Study Team** | The people involved in the conduct of a research project. There may be different research teams for the project at different sites. |

# DUTIES AND RESPONSIBILITIES

Summarise the duties and responsibilities of key staff involved in conforming to the SOP

|  |  |
| --- | --- |
| **Role** | **Responsibilities** |
| **Investigator** |  |
| **Research Study Team** |  |
| **PHT R&I Office** |  |

# PROCESS

Describe the procedure(s) to be followed. Wherever possible use a numbered list which can be followed step-by-step, or consider using a flowchart for more complicated procedures. In some cases it may be appropriate to have more than one procedure in which case you should create a new section for each procedure. Language should be clear and instructive

## This is an example of a second level heading.

# TRAINING REQUIREMENTS

Describe:

* Who is required to be trained in the SOP
* Who is going to provide the training and frequency of this training
* Specify if evidence of training in the SOP should be checked/verified at study initiation
* Insert the following standard text for Trust-wide SOPS :

*“The Research Dept., will endeavour to notify staff of SOP developments that may be relevant to them. SOPs are available on the Research department website. Updates on SOPs will feature in Research newsletters and communications and disseminate at local research meetings. 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 template is provided to support this process.* *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 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.”*

# REFERENCES AND ASSOCIATED DOCUMENTATION

**Associated Documents**

* Other related policies & procedures
* Associated templates or forms

**Reference**

* Texts or key documents referenced in the body of the SOP

# 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.

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| Version | **Date Implemented** | **Details of Significant Changes** |
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# APPENDICES

Insert each appendix as a new section.



**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)**

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| --- | --- |
| **SOP Details:** To be completed by the SOP Controller | |
| Title of SOP |  |
| Reference Number | Insert SOP Reference Number. PHT/RDSOP/\_\_ |
| Version | Insert Version |
| Issue Date | Insert Date Issued |
| Implementation Date | Insert Agreed Date for Implementation. |

|  |  |
| --- | --- |
| **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 |  |
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| **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 ………………………. |
|  |