# Standard Operating Procedure

| S?? – SOP TITLE<br>Version No? | |
|---|---|
| Post holder responsible for Procedural Document | Helen Quinn, Director of Research & Development |
| Author of Standard Operating Procedure | |
| Division/ Department responsible for Procedural Document | Research & Development |
| Contact details | *Include email address(es)* |
| Date of original policy / strategy/ standard operating procedure/ guideline | dd/ mm/ yyyy<br>*the first ever version of the procedural document.* |
| Approving body and date approved | *dd/mm/yyyy*<br>*Governance Oversight Group (GOG)* |
| Effective date and version number | |
| Review date (and frequency of further reviews) | *Review date should be at least 3 months prior to expiry date.* |
| Expiry date | *Up to 3 years from the date the document became live.* |

| **Author & Position** | |
|---|---|
| Signature | |
| Date | |
| **Approver & Position** | |
| Signature | |
| Date | |

**Controlled document**

This document has been created following the Royal Devon University Healthcare NHS Foundation Trust Policy for the Development, Ratification & Management of Procedural Documents. It must not be altered in any way without the express permission of the author or their representative.

It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

## DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

**Once printed this is an uncontrolled document**

| Full History | | | |
|---|---|---|---|
| **Version** *Final version (use a whole number- 1; 2; 3 etc., rather than 1.1; 1.2; 1.3), from the first published SOP for which you have records. Draft versions of the current revision may be listed if helpful* | **Date** | **Reviewed By** | **Reason** |
| *1.0* | | | *e.g. New Policy, to meet … standards* |
| 2.0 | | | *e.g. Revision to reflect…* |
| | | | |
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|---|---|
| **Associated Trust Policies/ Procedural documents:** | *List of all Trust procedural documents mentioned in the document and any associated Trust procedural documents not mentioned. Hyperlink to their location on the intranet.* |
| **Key Words:** | *List all key words relating to document (e.g. medicine; management; etc.). This ensures that the document will be searchable under these terms on the intranet.* |
| **In consultation with:** Reference key roles or groups who have been involved in drafting or reviewing the SOP e.g. Governance Oversight Group, Team Leads, QA Team | |

# Contents

## KEY POINTS OF THIS PROCEDURAL DOCUMENT:

*This is a new section on the template and is aimed to provide staff with the key points only or summary of the policy that follows i.e. a policy on a page*

*Please consider the use of flow charts to describe processes where possible*

## 1. INTRODUCTION

*This may include a statement of intent; may provide an overview and background or context.*

## 2. PURPOSE

*Will explain why the document has been written/what are its aims and objectives (for example: to guide/ensure compliance/ meet legislative requirements/ improve/ explain etc.).*

## 3. SCOPE

*Explain who this SOP applies to e.g. all members of the Clinical Trials Pharmacy team*.

## 4. DEFINITIONS & ABBREVIATIONS

*Add or remove as applicable*

| | |
|---|---|
| CI | Chief Investigator |
| CIMD | Clinical Investigation of a Medical Device |
| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| CTU | Clinical Trials Unit |
| GCP | Good Clinical Practice |
| GOG | R&D Governance Oversight Group |
| HRA | Health Research Authority |
| IMP | Investigational Medicinal Product |
| IRAS | Integrated Research Application System |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| PI | Principal Investigator |
| R&D | Research & Development |
| REC | Research Ethics Committee |
| SOP | Standard Operating Procedure |
| Sponsor | An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate |
| TMF | Trial Master File |

## 5. DUTIES AND RESPONSIBILITIES OF STAFF

*This section will explain the duties and responsibilities of individual staff members and staff groups, broken down by job title, beginning at the highest (executive) level, where this is appropriate (e.g. for Trust policies and strategies). This is to ensure that each member of staff knows what is expected of him/ her, and that he/ she may be held to account. As in the Definitions section, the job title/ staff group should be in bold, followed, in standard text, by the description of the duties and responsibilities. Individual staff members should be listed first, followed by Groups/ Committees (again, with name in bold).*

## 6. PROCEDURES

*This section may be divided into as many sections as are suitable, and will generally-comprise a number of main sections and possibly subsections.*

| |
|---|
| **6.1 Sub Heading** |
| 6.1.1 |
| 6.1.2 |
| **6.2 Sub Heading** |
| 6.2.1 |
| **6.3 Sub Heading** |
| 6.3.1 |
| **6.4 Sub Heading** |
| 6.4.1 |
| **6.5 Sub Heading** |
| 6.5.1 |
| **6.6 Sub Heading** |
| 6.6.1 |
| **6.7 Sub Heading** |
| 6.7.1 |
| **6.8 Sub Heading** |
| 6.8.1 |

## 7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the Royal Devon website shortly after having been released.

7.2 All staff whose activities are subject to this SOP must ensure that they take time to read and understand the content of this SOP.

7.3 If applicable, a training log within the Investigator Site File/Trial Master File must be completed to document that members of staff have read and understood the contents of this SOP.

## 8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

| No | Minimum Requirements | Evidenced by |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

## 9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Royal Devon website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format must be retained indefinitely.

## 10. REFERENCES

*Hyperlink references to all external documents (legislation, journals etc.) where they are mentioned in the document. References throughout the document and in the References section list should be based on the principles of Harvard-style. Please contact the QA Manager for guidance if you have problems.*

*Please list all references that are mentioned in the body of the text in the References Section.*

*Any further references not mentioned but which were consulted can be included in a second list titled "Bibliography" or "Works Consulted". The References section should take the form of a hyperlinked list, without bullets.*