SOP Number **Insert Number**

SOP Title **Document Control**

	NAME	TITLE	SIGNATURE	DATE
Author				
Reviewer				
Authoriser				

Effective Date:	

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

This SOP template has been written as an example which can be adapted for use in any department conducting clinical research where there are no SOPs in place. The contents of the SOP should be reviewed in conjunction with the procedures which take place within the department and the text should be altered accordingly.

Delete highlighted text before finalising the document.

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the standard procedures to be followed for the management of controlled documents related to clinical research sponsored by the University of Oxford.

2. INTRODUCTION

The Medicine and Healthcare Regulatory products Agency (MHRA) and the Research Ethics Committees (RECs) require that documents submitted to them be version controlled.

For other clinical research related documents, it is good practice and common expectations within the research community and from regulatory agencies that procedures must be in place to ensure the accountability, traceability, and consistency of these documents.

3. SCOPE

This SOP applies to clinical research where the University of Oxford has accepted the role of 'Sponsor', in the INSERT NAME department/ for the INSERT NAME/NUMBER trial/study.*

* delete as appropriate

This SOP does not apply to commercially sponsored research or research sponsored by an external non-commercial organisation.

Controlled documents related to clinical research are study protocol, participant information sheet, informed consent form, and where applicable, advertisements and GP letters. Others include but not limited to case report forms, subject diaries, departmental and study specific SOPs, organisation chart, training matrix and work flow instructions.

4. RESPONSIBILITIES

4.1 Chief/Principal Investigator

To ensure that controlled documents related to clinical research are appropriately managed. It is also the responsibility of the Chief/ Principal Investigator to determine which documents need to be controlled.

5. SPECIFIC PROCEDURE

5.1 Version control and naming convention

All controlled documents need to be dated and/or versioned. Some need to be named in a systematic way as well, especially if they belong to a series or set of documents e.g. SOPs.

See examples below:

Study protocol, participant information sheet and consent form

The first draft of the protocol should be labelled '**Draft version 0.1**' and dated. Further draft versions should be labelled '**Draft version 0.2, 0.3**' etc and dated.

The final original version of the protocol may be labelled '**Final Version 1.0'** and dated. This version will be submitted for the appropriate approvals.

If amendments are necessary following review of the protocol by the Ethics Committee or MHRA then subsequent versions of the protocol may be labelled '**Draft Version 1.1, 1.2'** whilst being drafted and reviewed and the version re-submitted for approval should be labelled '**Final Version 2.0'** and dated.

If the protocol is then amended again during the study then the version submitted for approval of the amendment will be labelled **'Final Version 3.0'** and so on.

Standard Operating Procedures

Start with an abbreviation of the topic covered e.g. CR for clinical research, followed by a number starting from 001, followed by a version number starting from V1 and date. For example the first SOP for clinical research will have the SOP number: **CR-001-V1** dated 1st Jan 2006. Draft versions should be handled the same way as the protocol.

5.2 Other considerations

Where appropriate, the following information should be on the document:

- Effective date and expiry date or next review date if applicable. It may be necessary to also include date issued and date printed.
- Pagination – It is recommended that pages are numbered as "Page X of Y"
- Confidential – If the document is confidential, mark "Confidential"
- Draft vs Final – State "Draft" or "Final" as appropriate
- Document identification e.g. a title, department name
- Approvals - It may be necessary to include signature and date of Author, Reviewer and Authorizer e.g. for SOPs, protocols. It may be more convenient to have a separate signature sheet. Include designation or title of signatories.
- Copyright of Insert as appropriate – Insert copyright information if necessary.
- Reason for Change – If it is a revision of the control document, state reason for change and list changes.
- Referencing - Wherever reference is made to another controlled document, you may use the instruction "see/refer insert Document Title". The version number may be excluded.

5.3 Storage and archiving

Controlled documents should be stored in an area or room restricted to authorized individuals only. If the controlled documents are part of essential documents, they should be part of the Trial/Research Master File (see SOP: Trial Master Files) and archived appropriately (see SOP: Archiving of Essential Documents).

Old versions of controlled documents must be archived as well.

6. FORMS/TEMPLATES TO BE USED

Where Forms/Templates are referenced in the text, the numbers and titles are listed under this section.

7. INTERNAL AND EXTERNAL REFERENCES

This section is used to list all controlled internal references (e.g. SOPs) and external references referred to within the text of the SOP only.

7.1 Internal References

7.2 External References

8. CHANGE HISTORY

Where the SOP is the initial version:

- SOP No: Record the SOP and version number
- Effective Date: Record effective date of the SOP or “see page 1”
- Significant Changes: State, “Initial version” or “new SOP”
- Previous SOP no.: State “NA”.
- Where replacing a previous SOP:
- SOP No: Record the SOP and new version number
- Effective Date: Record effective date of the SOP or “see page 1”
- Significant Changes: Record the main changes from previous SOP
- Previous SOP no.: Record SOP and previous version number

SOP no.	Effective Date	Significant Changes	Previous SOP no.