




SOP Number 001
 SOP Title Generation, Issue and Control of Standard Operating Procedures

	Name	Title	Signature	Date
Author on behalf of the QA Focus Group	Clare Riddle	Senior QA and Compliance Manager, Clinical Trials and Research Governance		23-OCT-2017
Reviewer on behalf of the QA Focus Group	Elaine Chick	Deputy Head of Clinical Trials and Research Governance		24 OCT 2017
Authoriser	Heather House	Head of Clinical Trials and Research Governance		24/10/2017

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for creation, approval, issue, review and control of SOPs to ensure that they are consistent, current and effective.

2. INTRODUCTION

SOPs are controlled documents which describe the procedures that must be followed to achieve uniformity in the performance of specific functions. They should be clear, concise and must be adopted by the users.

Staff performing the activity must be trained in the process described within the SOP.

The term 'SOP' is used throughout this document but incorporates all dependent lower level controlled documents (such as Work Instructions) that are used to maintain the conduct and quality of clinical research. The control of lower level documents will be described in local procedures, but must be subject to the principles of this SOP.

3. SCOPE

This SOP applies to all SOPs, including University of Oxford Core SOPs and those produced by units within the University of Oxford, for the management of clinical research, but may also be used for other research studies at the discretion of the unit and the Sponsor.

4. DEFINITIONS

Standard Operating Procedures (SOPs)

Detailed, written instructions to achieve uniformity of the performance of a specific function, communicate procedures to those who will undertake them, underpin training, and form a permanent record of the methodology employed.

University of Oxford Core SOP

Generic SOPs issued by the University, and reviewed by an SOP Committee which represents trial units, for use in clinical research operating under the auspices of the University of Oxford. These SOPs must be followed where the University is Sponsor for such research, and may also be used where the University of Oxford acts as the host institution.

Unit SOP

SOPs generated and issued by individual units within Oxford University that provide instruction that is specific to the unit's operations.

Work Instruction

A Work Instruction is a controlled document to be used when an SOP is not sufficiently detailed, e.g. for a specific role.

Author

Individual who prepares and writes the SOP. The author should be an individual who is appropriately qualified and experienced to ensure that it is a workable record of what actually happens.

Reviewer

A person who is appropriately qualified and experienced to provide constructive, critical review and help ensure the SOP is fit for purpose.

Authoriser

A senior individual with designated experience and authority to approve the SOP for use.

Quality Assurance (QA) Manager (or equivalent)

A person designated to oversee the document control and quality management systems.

Must/required/shall refers to a process that is a legislative requirement. The process has to be performed/documented to comply with a particular regulation.

Should refers to guidance related practices.

Recommended/Suggested refers to activity that is considered best practice.

5. RESPONSIBILITIES

Author

Generates the draft SOP using the approved template.

Ensures that appropriate individuals review the SOP.

Ensures that review comments are incorporated into the SOP as appropriate.

Receives comments from users of the SOP and assesses the need for revision.

Reviewer

Provides expert input into the SOP and supports the author as necessary to ensure that the SOP delivers accurate, clear, concise and feasible instructions to the intended users.

The reviewer of the first version of the SOP must be independent from the author. Subsequent reviews may be performed by the author.

Authoriser

Authorises the SOP for issue and use.

The authoriser may also be a reviewer or author, however, at least two individuals must have input into producing or updating the SOP.

Quality Assurance Manager (or equivalent)

Assesses the need for the specific SOPs when identified.

Provides support in the development and issue of SOPs.

Ensures that SOP is finalised, approved and signed off by the author, reviewer (where appropriate), and approver.

Ensures the document is correctly formatted, issues controlled reference number and version number.

Ensures that the SOP complies with relevant applicable University of Oxford Core SOPs where applicable, and submits SOPs related to Core SOP procedures to Clinical Trials and Research Governance (CTRG) for review.

Controls documents and ensures timely review.

CTRG

Generates and coordinates review of updates of University of Oxford Core SOPs.

Reviews SOPs submitted by units for compliance with the University of Oxford Core SOPs.

All staff

Follow the procedure described in the SOP

Inform the author or QA manager if errors or deviations from current/best practice are identified within the SOP that will require a review to be undertaken.

Comply with the Core and unit's SOP training and implementation instructions.

6. SPECIFIC PROCEDURE

6.1 Identification of Need

All procedures for the conduct and quality of clinical research must be defined within an SOP or similar, controlled document.

Any member of staff may identify procedures for inclusion within an SOP and should notify the person responsible. Such requests must be assessed to determine whether the process is already covered in existing procedures or is required to be included in an SOP.

If an SOP is required, an author must be assigned to draft the new procedure.

6.2 Numbering, Version Control and Format

All SOPs must be developed using an approved template (for example see Core Form 001a – Core SOP template), and must follow a defined indexing and versioning system, so that each version of every SOP can be uniquely identified. This is described in the University of Oxford Core SOP 014 – Version Control.

The current status of each SOP should also be clearly marked (e.g. draft, authorised, superseded) in order to maintain a clear audit trail of versions.

6.3 Content / Authorship

SOPs should be written in a clear and concise manner and be as instructive as possible, so that any trained individual can complete the SOP activity effectively.

Content should not include reference to data that may change on a regular basis (e.g. phone numbers, addresses, staff names). All abbreviations and acronyms should be defined.

Wherever reference is made to an activity covered by another SOP, the SOP reference should be inserted. The version number should not be included.

Once the first draft of a new SOP has been written, a suitably qualified reviewer will be identified who will ensure that the SOP complies with all relevant regulations/guidelines, and is formatted/indexed correctly.

If the SOP is a unit SOP, and relates to a process covered by a Core SOP but it is considered that further detail is required at unit level, there are two options for preparation of the SOP:

- Request an editable version of the relevant Core SOP from CTRG in order to add further specific detail
- Write the unit SOP from scratch, maintaining compliance with the Core SOP

In either case, the SOP will be submitted to CTRG for review to ensure no points of conflict with the Core SOP.

6.4 Authorisation

Once the final version of the SOP has been produced, it must be authorised by a senior member of the department. The authoriser will sign and date to take overall responsibility for the SOP. University of Oxford Core SOPs must be authorised by a senior member of CTRG.

The effective date should be agreed with the relevant senior staff and will allow time for user notification, SOP training and implementation.

6.5 Notification and Training

SOP users must be trained as appropriate to ensure understanding and compliance prior to performing the activity. Training must be recorded, and appropriate training records maintained.

6.6 Storage and Access

Current SOPs must be readily available at point of use in electronic or paper format. Unauthorised copies must not be used as these may become outdated and lead to incorrect procedures being performed.

The University of Oxford Core SOPs published on the CTRG website are the only official version. Core SOPs copied or printed are uncontrolled. Units will institute a system to ensure that unit SOPs, if copied or distributed, are appropriately tracked.

The University will make relevant material (e.g. SOP listings, individual controlled documents, change history and archival records) easily available to authorised third parties for the purpose of confirming that clinical research is conducted in accordance with the principles of Good Clinical Practice and the applicable SOPs.

6.7 SOP Change Requests and Deviations

Unauthorised changes to a current SOP are not permitted. Any amendment requires a new version to be produced and issued.

Users will inform the author and/or QA manager without delay to request changes to an SOP. Examples might include changes to correct errors, prevent forced deviations, improve feasibility/effectiveness and ensure the SOP reflects current/best practice. Change requests will be reviewed as described below.

All deviations from and/or errors within the SOP must be reported to the QA manager who will document the error/deviation and ensure a review is performed, including implementation of any corrective/preventive actions.

6.8 Review of Issued SOPs

All SOPs must be current and fit for purpose and as such require regular review. A routine review of each SOP must be carried out at least every three years.

Earlier review may be necessary due to the introduction of new regulations or procedures, or in response to SOP change requests or deviations.

The reviewer will usually be the author or another suitably qualified and experienced individual.

If the SOP requires updating, a new version must be created and issued as above. If no change is required, the review date must be renewed.

If a new version is required, an editable copy of the SOP and current SOP template (if different) should be made available to the author for updating. Changes should be tracked and the significant changes recorded for ease of reference.

In case of amendment to unit SOPs, any revision, related to a process covered by a Core SOP will be submitted to CTRG for review to ensure no points of conflict with University of Oxford Core SOPs.

6.9 Archiving

Original versions of SOPs, relevant controlled documents and other related quality management records must be retained securely for as long as necessary to reconstruct the conduct of the dependent clinical research activities. This should be in line with University of Oxford Core SOP 005 – Archiving of the Trial Master File and Essential Documents and 014 – Version Control.

7. RELATED DOCUMENTS

Core Form 001a – Core SOP Template

University of Oxford Core SOP 005 - Archiving of Trial Master File and Essential Documents

University of Oxford Core SOP 014 – Version Control

8. REFERENCES

MHRA Good Clinical Practice Guide (2012)

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes	Previous Version No.
2.0	01/01/2014	Redrafting of Work Instruction section Addition of Core SOP template to Related Documents Additional instructions in Content/Authorship	1.0
3.0	24/06/2014	Amended wording in section 6.3 regarding use of Core SOPs	2.0
4.0	See page 1	Update to front page in line with changes to SOP template. Removal of sentence from section 6.8 on new SOPs and addition of archiving section 6.9.	3.0