Standard Operating Procedures & Work Instructions – Preparation, Review & Approval

NJRO-GEN-SOP-020

Contents

1. Background/Introduction

Standard Operating Procedures (SOPs) are written, detailed instructions designed to ensure uniformity in the performance of a specific procedure. SOPs must be clear, concise and of the same style and format. Work Instructions (WI) are a written description of a process. Both documents must also be available where needed and subject to rigorous document control

2. Purpose

This SOP has been written to provide guidance for all research staff developing SOPs and WIs for use in specific areas.

The procedure details the process for the preparation, review, approval and implementation of clinical research SOPs and WIs. This will ensure consistency in the content and format of these documents.

3. Scope of Document

This SOP describes the preparation, review, approval and implementation of SOPs and WIs as part of the document lifecycle or as a result of changes to practice or regulations.

This SOP is applicable to all staff who are involved in preparing, reviewing or controlling SOPs and WI in clinical research, including those operating under Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and the Human Tissue Act (2004).

This SOP does not detail individual research group's procedures for how they manage documents within their local environment. This must be documented locally in line with this procedure.

For information on the process adopted in the NJRO in accordance with this SOP, please refer to NJRO-GEN-SOP-001 "Document Control in the NJRO".

4. Definitions

GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
NJRO	Newcastle Joint Research Office
QMS	Quality Management System
SOP	Standard Operating Procedure
WI	Work Instruction

5. Roles & Responsibilities

It is the responsibility of staff to document their local procedures for document management in line with this SOP.

Staff must decide within local environments, who are the most appropriate persons within their individual teams to take responsibility for each step of the process, dependant on experience and/or competency.

It is the responsibility of the SOP/WI author to review the SOP/WI in advance of the review date.

Note: The author and approver of an SOP/WI cannot be the same person.

It is the responsibility of the NJRO Quality Management team to assess compliance with this procedure.

6. Procedures

The following procedure describes the key steps for managing SOPs/WIs throughout their lifecycle, as set out in Figure 1.

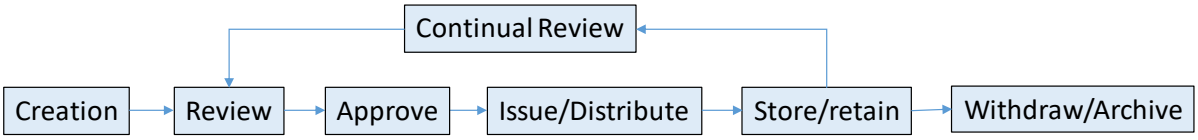

Figure 1: Lifecycle of SOPs and Policies

6.1. Creation of an SOP/WI

A SOP/WI should be written as soon as the need for a standard written procedure for an activity is identified.

Where applicable, SOPs/WIs must align with organisational policies and reference the specific policy/policies and/or SOPs.

The SOP/WI should be written by a member of staff with experience and knowledge of the procedure to be documented (referred to as the "SOP/WI author"). This may mean that a SOP/WI has more than one author.

Example templates are provided on the NJRO website.

NJRO-GEN-T-021 – Generic SOP template
NJRO-GEN-T-022 – Generic WI template

In addition, for groups using electronic systems (e.g. QPulse) reference may be made to the NJRO SOP and WI templates, which may be adapted as required (NJRO-GEN-T-001 and NJRO-GEN-T-002).

The following general guidance must be followed:

- Headers or Footers will include:
  - Version number
  - SOP/WI reference number
  - Page number in the format "x of y"
- Use standard font and size - Arial, font size 11
- Format text to left indent
- Use Bold for titles and sub-headings
- Include a revision history

The SOP template should include the following sections:

Front Page: This should contain:-

- SOP/WI Number
- SOP/WI Full Title
- Date Effective From
- Review Date
- Signature of Author
- Signature of Approver

If using an electronic quality management system such as Q-Pulse some of these requirements will be found in the document details screen.

Background/Introduction

Includes relevant supporting information and should include regulatory requirements (appropriately referenced).

Purpose
Describes the reason why the SOP/WI has been written.

Scope
Should define the boundaries of the SOP/WI i.e. which particularly aspects of a process it applies to. There may be occasions where it is appropriate to have more than one SOP/WI to describe an activity.

Responsibilities
Defines who will be responsible for each aspect of the procedure

Procedure
A step-by-step description of the activity, where appropriate sub-divided to aid clarity.

Review and Monitoring of the Document

- Record the review frequency for the document. GCP recommends documents must be reviewed every two years as a minimum. The Human Tissue Act (2004) does not stipulate a frequency, however to ensure best practice it is advised to align this with GCP requirements.
- If the SOP/WI describes a non-critical GCP activity then a longer review period can be assigned (maximum 3 years)
- More frequent reviews may be required due to changes in legislation or practice.
- If using an electronic quality management system such as Q-Pulse these requirements will be found in the document details screen.

References
A list of any reference documents including year of publication

Document revision history
A table should be populated to concisely document the changes to the previous version of the document, including the sections affected, description of the change and reason. If there have been no changes from the previous document, this should be stated.

Appendices
A list of any supporting documents not included in the main body of the SOP. Any appendices should be cross-referenced to the main document e.g. NJRO-GEN-T-020

6.2. Review

Once an SOP/WI has been drafted the author will send the SOP/WI to the reviewer.

The reviewer will check the document for consistency with the document template and referencing to other relevant SOPs/WIs or policies.

Care should be taken to check references to other documents are current and key information e.g. effective date, review date and version control are correct.

The SOP/WI author can decide to incorporate or reject the comments in consultation with the reviewer.

6.3. Approval

Once a draft has been reviewed and deemed suitable, it must be authorised as an approved version prior to implementation. Authorisation must be conducted by the appropriate personnel as per organisation/ team structure.

An SOP/WI reference number will be issued and documented in the document record system

Once the authorisation process is complete the final version will be implemented for use.

6.4. Issue/Distribute

All staff that must follow the SOP/WI must be informed of the new/updated document.

The message should include a reminder of the need to review relevant SOPs/WI and document the review appropriately.

If using an electronic quality management system such as Q-Pulse the system will issue the above reminders automatically.

All staff are responsible for recording training (e.g. read and understood register). If an electronic system is used (e.g. Q-Pulse) this may be conducted electronically.

A log of all SOPs/WIs relating to a groups operational activities should be maintained, and used to facilitate staff induction, by enabling all key documents that must be followed to be easily identified. This list should be made readily available for audit.

6.5. Store/Retain

The superseded master copy must be clearly identified and all other paper and electronic copies of the document will be destroyed.

If using an electronic quality management system such as Q-Pulse the superseded electronic copies are marked as obsolete but can still be viewed if necessary.

The signed copy of the new master document must be filed in the master SOP/WI file.

If using an electronic quality management system such as Q-Pulse the documents will have an electronic signature and all SOPs/WIs are held within the system rather than a file.

Where documents are stored electronically for everyday use but outside an electronic system (e.g. on shared drive/intranet) it must be ensured that documents are locked to editing to prevent any unauthorised changes being made e.g. as an ISO 19005-1 compliant PDF file.

6.6. Continual Review of a SOP/WI

Reviews can take place as part of the document lifecycle or as a result of changes in practice and/or regulations. Critical SOPs/WIs should be reviewed, as detailed in section 6.2 to 6.5, after 2 years (in line with GCP regulations) unless changes to legislation or practice dictate otherwise. Non-critical documents may be assigned an extended review period, provided this is justified in research teams Document Control documentation.

If the original SOP/WI author is no longer in post, a new author will be appointed by an appropriate person within the team.

The responsible person must send out a SOP/WI Review Notification to the author a minimum of one month before the review date. If using an electronic quality management system such as Q-Pulse the system will issue review reminders automatically.

The updated document must be sent to reviewers with a description of the changes to the document (e.g. as a table, or tracked changes in Microsoft Word).

Once approved, changes to the document must be recorded as revision history within the document (e.g. as a table on the front page or as an appendix). If using an electronic document management system such as Q-Pulse the revision history will be held in the document details screen.

Updated documents must be re-issued with a new ascending version number e.g. v1, 2, 3.

If there are no changes to be made, this must be acknowledged in the SOP/WI Revision History and a new version number created as above.

Updated documents must follow the approval and distribution process as per steps 6.3 and 6.4. Superseding of previous versions must follow step 6.5.

If there is a delay in the approval of documents which exceeds the review date, justification must be documented through a method such as a file note. This must be communicated to document users to ensure there is no confusion regarding which procedure must be followed.

7. References

- NJRO Website – SOP Template (https://newcastlejro.com/).
- Human Tissue Authority Code of Practice E "Research" Standards and Guidance https://www.hta.gov.uk/