NJRO Document Control using Q-Pulse

NJRO-GEN-SOP-001

Contents

1. Introduction

Document Control is designed to ensure the following:-

a) Only documents approved by members of the Document Control Group are released for use within the department
b) Documents are released and withdrawn systematically so that all changes are traceable and identifiable
c) All documents are identifiable by a unique reference number
d) Documents conform to a standard format that is familiar to staff for ease of navigation and is recognisable as an authorised document
e) The Newcastle Joint Research Office (NJRO) shall control all documents required by the Quality Management System and shall ensure that unintended use of any obsolete document is prevented
f) A full document register will be maintained
g) Only current, approved versions of applicable documents are available at point of use
h) Documents remain legible
i) Documents are periodically reviewed and updated at a frequency that ensures they remain fit for purpose
j) Obsolete controlled documents are dated and marked as obsolete
k) At least one copy of an obsolete document is retained for a specific time period

All documents are identified to include:

- A Title
- A Unique Identifier on each page
- The date of the current version and/or version number
- Page number to total number of pages (e.g. Page 1 of 15)
- Authority for use

2. Scope of the Document

This document describes the procedures used to produce and control internally generated documents (Standard Operating Procedures and Working Instructions) that form part of the NJRO Quality System. The format of Policies is governed by the Trust template.

3. Responsibilities

It is the responsibility of designated document authors to ensure that this SOP is followed when preparing Standard Operating Procedures, Working Instructions, Templates and Guidance Documents

4. Definitions

Standard Operating Procedure (SOP), Working Instructions (WI) and Templates (T), are generic terms used to describe the documents which fall within the scope of the NJRO Quality System. Where documentation does not fit into these categories it should be raised with the Q-Pulse System Manager

5. Procedure - Document Layout

5.1. Document Appearance

Style and format

Body text of documents will be produced using Arial font with a font size of 11 points and will be left justified

Numbering for the document will be outlined in the contents section and then followed through the document. Numbering will take the format of:

1. Background/Introduction
This document describes…

1.1. Title of Subsection
Body of Text…

2. Scope
Start here...

2.1. Title of Subsection
Body of Text…

All main section headings will be in bold Arial font, size 12 points with sub section headings in bold Arial font, size 11 points. Should a list be required, it should be in the form of either a bulleted or lettered list. Bold text will then commence after clear line spacing. The use of block capitals should be avoided. See appendix 1. **NJRO SOP Template (NJRO-GEN-T-001)**

5.2. Document Header

Every page of each document shall have a header in the following format;

(Numbers in italic superscript are for annotation purposes only and are not part of the header)

Newcastle Joint Research Office[1]

[2]

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[1] Section/Department name. Valid names are:-

- Newcastle Joint Research Office
- Research Delivery

[2] Departmental logos (Newcastle Upon Tyne Hospitals NHS Foundation Trust and Newcastle University)

5.3. Title Page

The title and unique identifier for each document shall be entered into a centred box towards the centre of the front page. The title shall be in bold Arial type with a font size of 18 points and the unique identifier below in bold Arial type with a font size of 12 points.

Information pertaining to:-

- **Author** – name of the person writing the document
- **Authorised by** – name of the person who has authorised/validated release of the document
- **Approved by** – name of the person who has approved release of the document
- **Date of issue** – date the current version was activated

Will be held on the Q-Pulse system and therefore has no need to be stated on the document itself

5.4. Document Footer

Every page of each document shall have a footer in the following format:-

Document Title – V1 XXX-YYY-ZZZ-A

Page x of y

This is a copy of a controlled electronic document embedded in the Q-Pulse System which has been verified and approved for use. It is the responsibility of the person referencing any printed copy of this document to ensure it is a copy of the current version displayed on the Q-Pulse System before use.

The full document title and version number shall be located justified left, with the unique identifier justified right. Page numbers will appear in the footer of all pages and will be in the form x of y, where y is the total number of pages.

5.5. The Unique Identifier

Documents are identified by a unique identifier. The unique identifier shall be in the format:

XXXX-YYY-ZZZ-A, where **XXXX** is the abbreviation for the department name, **YYY** is the area or suite within that department, **ZZZ** represents the document type and **A** the identifying number for that specific document. Q-Pulse will automatically assign the next available number to each document as they are uplifted onto the system.

Department abbreviations (XXXX) are as follows:-

NJRO – Newcastle Joint Research Office

DLV – Research Delivery

Areas within a department/suites (YYY) are as follows:-

GEN – General

QA – Quality Assurance

REG – Regulatory Compliance

GOV – Governance

G&C – Grants and Contracts

FD – Funding Development

INF – Informatics

TISS - Tissue

Document types (ZZZ) are as follows:-

SOP – Standard Operating Procedure

WI – Working Instruction

T – Template

GUIDE – Guidance document

e.g.

NJRO-GEN-SOP-001 is Newcastle Joint Research Office\General\Standard Operating Procedure\001

NJRO-QA-WI-002 is Newcastle Joint Research Office \Quality Assurance\Work Instruction\002

5.6. Procedure - Document Structure

The following elements should be incorporated into new strategies/policies/procedures or revisions of existing strategies/policies/procedures:-

- **Background/Introduction**
  This should inform the reader of the rationale for the strategy/policy/procedure

- **Purpose**
  This should detail the aim or objective of the strategy/policy/procedure

- **Scope of Document**
  This should detail to whom the strategy/policy/procedure relates and state the limitations of the strategy/policy/procedure application

- **Definitions**
  List and describe the meaning of the terms used in the context of the document

- **Roles & Responsibilities**
  States the roles and responsibilities of staff covered by the strategy/policy/procedure

- **Procedures**
  This section will include the main strategy/policy/procedure guidance in relation to the specific issue – all relevant information and steps in the process should be added in as many sub-sections as necessary. Where deemed appropriate, a separate 'work instruction' can be created to sit alongside the main procedural document and should be referenced accordingly in the main document.

- **References**
  References should be included within the strategy/policy/procedure. The preferred referencing methodology is the Harvard method. It is the authors responsibility to ensure that references cited within strategy/policy/procedure are the most recent available

- **Appendices**
  A list of supporting documents not included in the main body of the SOP. Appendices may be added to documents containing information related to that document. Appendices will use the same document header and footer and sit in line with the document at the end of the body of that document. The index of appendices will be documented on the opening page of the main document in the contents section.

  NB. For the purposes of document control, appendices that are Work Instructions, Templates or Guides should be regarded as separate documents that have their own amendment records and review/revision numbers.
  Templates for NJRO Standard Operating Procedures and Working Instructions can be found in the appendix of this document

6. Procedure - Document Control

6.1. Unauthorised changes to documentation

No unauthorised changes may be made to any document. This includes (if a paper copy is held); addition, replacement or removal of pages, handwritten changes, annotations or application of adhesive notes and other supplements

6.2. Approval of new documents

Documents uplifted onto the Q-Pulse system will be assigned the next available unique identifier and listed as revision one. Document author, active date and document authoriser will be established at this point. The document will be forwarded to the listed document approver to read and electronically acknowledge as approved. Documents will always be approved for use by authorised personnel prior to issue. If a paper copy is required the document may then be issued in printed form by the document authoriser, listing a paper copy in the Q-Pulse entry for that document.

6.3. Activation and Distribution

Once a document has been fully approved, an automatically generated email will be sent to the Informatics mailbox and the Q-Pulse system administrator will send a Distribution Proforma to the document Author to indicate the intended distribution. Once this has been completed and returned the System Administrator will activate and distribute the document accordingly.

6.4. Acknowledgement of documents

As part of the activation and distribution process in section 6.3, the document is distributed to all staff involved in the scope of that document. The reason for this is:-

- to ensure staff are made aware of the document and are trained accordingly
- to ensure staff who are responsible for creating, reviewing or revising the document are aware of its existence

For the purpose of Q-Pulse, staff in this process will be called copyholders

The Q-Pulse System Administrator is responsible for distributing the document to copyholders, informing them that a document needs to be acknowledged

Q-Pulse will hold a list of copyholders relevant to each document, stating when the document was distributed and for each copyholder when the document was acknowledged

6.5. Copies

A master copy of all documents will be held on Q-Pulse. Should paper copies be required, the location should be documented on Q-Pulse to allow revision/review of all copies in circulation. Paper copies should be avoided unless absolutely necessary

6.6. Uncontrolled Copies

Occasionally it is necessary to provide an uncontrolled copy of a document to a member of staff or a third party, for example, to inform colleagues outside of the department of our procedures. This is acceptable provided all pages of the document are stamped “Uncontrolled Document – For Information Only”

It is not permissible for members of staff to keep such copies of documents for personal reference in the performance of their day to day duties.

6.7. Documents outside of the Quality System

All documents in use within the department should be controlled and managed through the Q-Pulse system. Any departmental documents which are outside of the Q-Pulse system need justification for this and are not controlled documents. To avoid ambiguity they should be stamped “Uncontrolled Document – For Information only”

6.8. Revising Documents

Revising documents may be necessary for a number of reasons such as when revising a policy or improving a process or methodology. Revisions may also result from activities such as audit, quality improvement, change requests or document review. Revisions can be minor or major.

6.9. Minor Revisions

Minor revisions may include minor changes to procedures or an aspect of departmental policy. They also include correction of typographical errors. Typically they will involve amending a few words or paragraphs of a document.
Minor changes can be instigated by any member of staff through Q-Pulse by logging a change request on the system.
Revisions will be forwarded to the relevant document author who may choose to make immediate changes to the document by the revision process or alternatively choose to wait until the next review of that document where all/any change requests can be made at once.
In these circumstances the overall version number of the document will take the next consecutive whole number.
It is the responsibility of the document author revising the document to ensure that all copies of the document are updated and that all replaced documents are withdrawn.

6.10. Major Revisions

A major revision of a document will result in the whole of the document being revised. Major changes must go through the approval pathway as described in 5.2 above. Such documents will be given a new revision number.
It is the responsibility of the document author revising the document to ensure that all copies of documents are updated and that all replaced documents are withdrawn.

6.11. Archiving Documents

All inactive/obsolete documents are held in the Q-Pulse System and can be accessed only by the Quality Assurance Manager/Regulatory Compliance Manager or Q-Pulse System Manager (Information Specialist)

6.12. Reviewing Documents

All documents must be reviewed at the intervals specified by the review date listed on Q-Pulse.
All revisions will be triggered and then recorded on Q-Pulse.
Each time a document is reviewed the date and details of the person reviewing the document will be documented on Q-Pulse.
Expiry date periods (for guidance only)

- New Documents/New Processes (Formal SOPS, WI's) – **1 Year**
- Standard documents reviews/revisions – **2 Years**
- Templates, Guides, Informal documentation – **3 years**

6.13. Revision Record

All revisions will be recorded on Q-Pulse with the next consecutive revision number being assigned on authorisation of the document.
A brief description of the revision will be recorded in the revision history field on Q-Pulse.

7. Associated Documentation

It is the responsibility of the Document Author to ensure working instructions, templates and other associated documents are listed as an appendix to the SOP where their use is described with reference to their Q-Pulse unique identifier to enable the user to easily find on the system.
They should have their own available document type for clarity e.g.

Appendices

1. NJRO Document Preparation, Creation and Approval using Q-Pulse (NJRO-GEN-SOP- 024)

8. References

The Newcastle upon Tyne Hospitals NHS Foundation Trust, Policies and Procedural Documents: Development, Approval and Dissemination

9. Appendices

1. NJRO SOP Template (NJRO-GEN-T-001)
2. NJRO WI Template (NJRO-GEN-T-002)