University of East Anglia

Our Vision
The best care for every patient

NHS
Norfolk and Norwich University Hospitals
NHS Foundation Trust

SOP 800 Non-Study Specific Research Documentation Management

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Document Management
Name of document author:	Ania Spurdens
Job title of document author:	Research Project Manager
Name of document author's Line Manager:	Julie Dawson
Job title of author's Line Manager:	Research Services Manager
Supported by:	Julie Dawson NNUH Sarah Ruthven UEA
Assessed and approved by:	Julie Dawson: Research Services Manager NNUH Sarah Ruthven: Research Manager UEA
Date of approval:	06/02/2023
To be reviewed before: This document remains current after this date but will be under review	06/02/2026 (3 years, unless legislation or process changes)
Reference and / or Trust Docs ID No:	15432
Version No:	2
Description of changes:	New template Updated information re document access – particularly reference to Q-Pulse Addition of NCTU information

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

1. Contents

2. Definitions of Terms Used / Glossary

Approval	A process whereby a document is certified as ready to be used
Controlled Document	Written or electronic information or templates that are used to convey or record information and that are approved, reviewed, and made available to staff. A document must be controlled if an unapproved change may result in a process being performed incorrectly. For the purposes of this SOP, the term document refers to a controlled document, unless specifically stated
Document Controller	Responsible for maintaining and distributing accurate documents
Form	A document that defines the range of data to be collected and allows entry of that data, usually study specific
ICH GCP	International Conference on Harmonization Good Clinical Practice
Issue	A process whereby an approved document is made available to users
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
Policy	A statement that communicates the intent, objectives, requirements, responsibilities, and standards for an organisation
QA	Quality Assurance
QC	Quality Control
Review	A checking process, performed by an expert (the reviewer) in the procedure that ensures the document is fit for purpose
RIN	Research and Innovation
R&D	Research and Development
SOP	Standard Operating Procedure
UEA	University of East Anglia
User	Any individual who uses and applies the information in a controlled document to perform a particular procedure
Working Process Document	A document which guides the user through a particular method for performing a task or process

3. Objectives

The aim of the SOP is to describe how documents are managed to ensure they are fit for purpose and are accessible when needed.

4. Scope

This SOP describes the range of controlled documents that are approved for use in the conduct of all health care research sponsored by the NNUH and UEA, which falls within the scope of the UK Policy Framework for Health and Social Care Research.

5. Purpose

Different types of documents will need different levels of control. Some documents may not be formally controlled (e.g. staff CVs) however, procedures should be in place to ensure these are updated regularly and only current versions are accessible. For other documents (e.g. SOPs) it is essential that only the current approved version is used, therefore a high level of control is required.

The key elements of controlling documents are described below, and include:

Systems used to control documents will vary according to the nature and purpose of the document and its location. For example, NNUH R&D documents are managed in Q-Pulse; trust-wide documents are made available via Trust Docs.

The focus of this SOP is on the management and control of non-study specific research documents, the majority of which will be written by the NNUH R&D department, the UEA RIN office and other central departments. Such documents include, but are not limited to,

policies, forms, Quality Control (QC) and Quality Assurance (QA) data, contracts, agreements, risk assessments, Standard Operating Procedures (SOPs), and Working Process Documents (WPDs).

The production and management of Standard Operating Procedures is also governed by **SOP 001 Production, Review, Approval and Control of SOPs Related to Research Activities**

For the management and control of **study specific research documents**, written mainly by the Chief Investigator such as, protocols, participant information sheets (PIS), informed consent forms (ICF), GP letters, advertisements, and data collection media including case report forms, refer to **SOP 865 Study Specific Research Documentation Management**.

6. Rules

Staff should ensure that:

- Document control is carried out to ensure quality of data.
- Document production and revision can be tracked to demonstrate approved, current procedures were used by trained staff.
- Documents are prepared to meet regulatory and local requirements.
- There should be no deviation from a controlled document.
- If a document is out of date or inaccurate, this must be reported to the author/approver or via the document management system

7. Responsibilities

Document controller (R&D Office)
Must ensure that:

- All controlled documents are approved and follow the guidelines for version control, naming of documents and are in the correct format
- Staff are appropriately trained in the use of the documents. Training will usually be performed by the author or other suitably qualified staff, if required
- Documents are reviewed at regular intervals, if applicable
- Documents remain fit for purpose
- Documents are accessible to all users when required

Document Author
Must ensure they are appropriately experienced and trained to create, and when required, to review and if necessary, update a controlled document

Document Reviewer
Must ensure they are appropriately experienced and trained to review a controlled document

Document Approver
Line manager of the Document Author or higher, with the experience and knowledge of the process to enable them to permit the document's use

Users
Must ensure the following:

- They are using the most recent version of a controlled document
- They are trained and competent to perform the process outlined in a document
- Training is documented (see SOP 505)
- They raise a change request, or make the author/Document Controller aware if they notice a change is required

8. Controls

8.1 Versioning

All documents must comply with a standard numbering system to ensure that only current versions are used. The version number and title must be consistent throughout the document. The version numbering system for the NNUH R&D Office is set out below:

- The first **draft** of a document should be labelled 'Draft' version and dated
- The first **final** version of the document should be labelled 'Final' version 1 and dated
- If the document is then updated, the draft versions should be labelled 'Draft' version and dated.

The final version of the updated document will be labelled 'Final' version 2 and so on.

It is not advisable to use the Microsoft Word versioning tool as it substantially increases the size of the document which wastes valuable server space.

8.2 Tracking

All changes to a document should be tracked in a single document.

8.3 Electronic document filename format

When saving documents as electronic files, the filename should accurately reflect the document title, using abbreviations and acronyms only if clear. The filename should provide sufficient information to identify the document, including its version number and/or date.

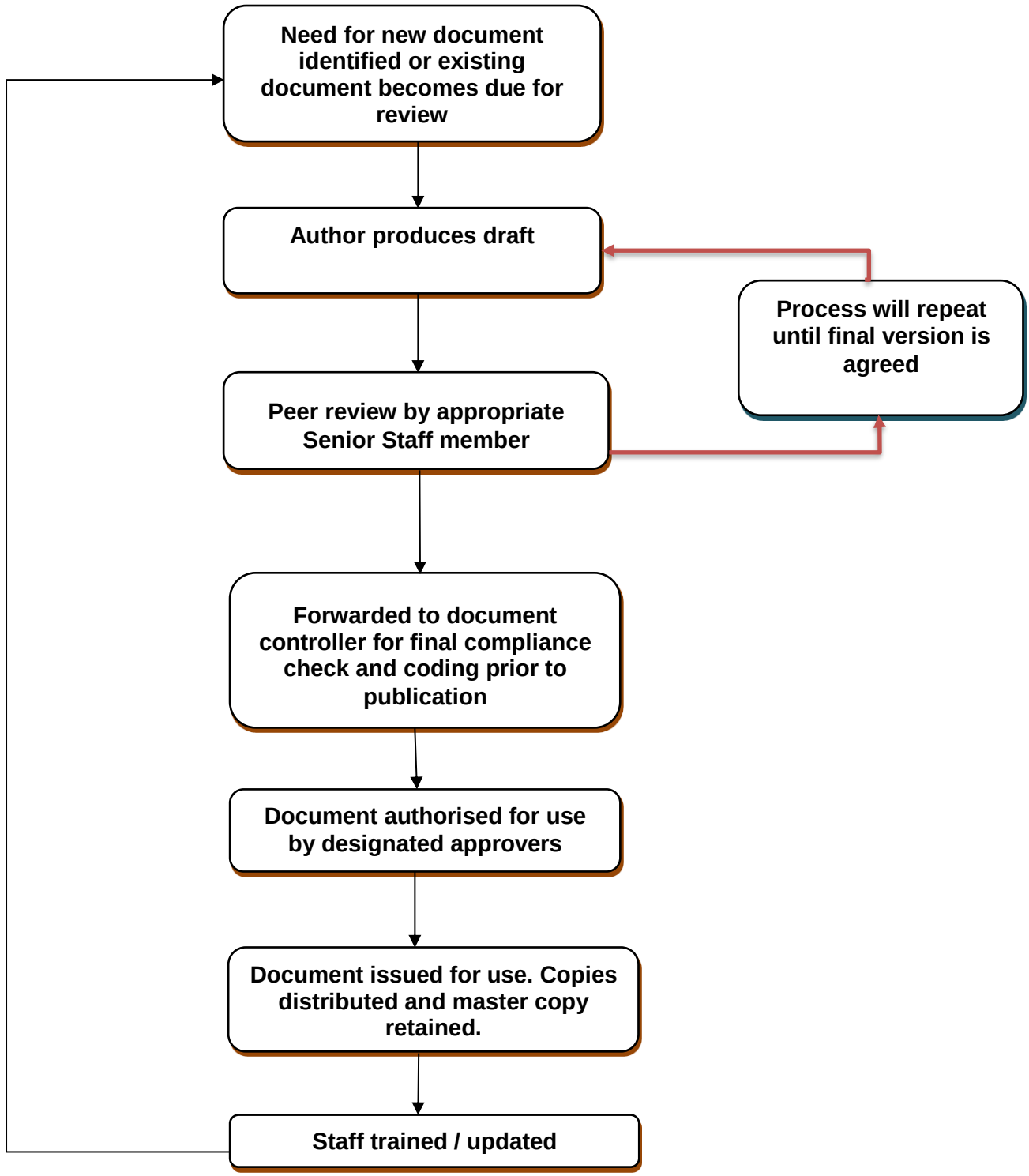
Finalised documents will be uploaded onto Q-Pulse with the relevant format specified e.g. templates will be labelled as TEMP and given a number.

8.4 Essential Information

All documents should have the following information available either on the front page or as a header/footer on each page:

- Department/Unit name
- Names of individuals responsible for document (author/reviewer/approver)
- Page number
- Title, document number or code and version number – these ensure that every document is uniquely identifiable.
- The effective date and a review date may be added to documents if appropriate

9. Procedure NNUH



Author and approval process
Documents should always be written by qualified personnel (author). Templates should be used, when possible, and draft documents should be circulated for peer review before approval.

The approver should be a line manager or higher, with the experience and knowledge of the process to enable them to permit the document's use.

For documents created by the NNUH R&D Office documents will be authorised for use by Research Services Manager.

Externally Produced Documents
Many documents used in clinical research are likely to have been produced by external authors/organizations e.g. guidelines (e.g. ICH GCP) and equipment manuals. It is the responsibility of the user to ensure they are working from the current version.

Training, Issue and Distribution
Before a new or revised controlled document can be used, all users should be made aware of and, if necessary, be trained on the new version.

Review process
All controlled documents are reviewed prior to first issue, when initial drafts are circulated.

Major changes in content should be recorded (in the document via tracked changes so amendments are clearly visible).

Where a review is not possible in the formal time frame, the author should request an extension from the approver. In the case of SOPs and research specific policies, the process is managed via the R&D document management system, Q-Pulse, and quarterly reports are made to the Research Governance Operations Group (RGOG) including review dates and progress.

Document Access
Only current versions of documents should be available to document users. Where possible the current version must not be available to users in an editable format (pdf. copies are commonly used).

At the NNUH, template documents should be downloaded from the following locations:

Trust Website www.nnuh.nhs.uk/research-and-innovation/information-for-researchers/standard-operating-procedures
- Accessible to internal and external users
- For joint research SOPs, SAE and Protocol breach reporting forms
- Documents can be printed and/or downloaded but are only valid on the day of printing or downloading.

Trust Docs Management System http://trustdocs/
- Accessible to staff who have a NNUH access account
- For joint research SOPs, SAE and Protocol breach reporting forms and other non research specific Trust documentation and policies

- Use the search bar to locate the required document

Q-Pulse

- Published documents within Q-Pulse are accessible to Q-Pulse users with an account created by R&D
- For Internal R&D working process documents, forms and research related template documents
- Type in the Documents search bar to find the required template

Archiving and Retention

See SOP 900: Storage and Retention of Research Documents.

All previous versions of documents can be accessed by contacting the NNUH R&D office.

10. Procedure UEA

UEA has a separate process for the management of non-study specific research documents which is overseen by the relevant Schools, Faculties and RIN.

11. Procedure for NCTU

NCTU non study specific documents are included in the NCTU Quality Management System (QMS). The document 'NCTU_Q_WPD_1 QMS Overview' describes the QMS system and the process for writing and releasing QMS documents.

12. References and Related Documents

References
ICH GCP E6 / SI 2004/1041

SOP No.	**SOP Title**
SOP 001	Production, Review, Approval and Control of SOPs Related to Research Activities
SOP 505	Training and Training Records
SOP 865	Study Specific Research Documentation Management

13. Approval

Author	Ania Spurdens
Role	Research Project Manager
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	DocuSigned by: Julie Dawson 4CBAB366CF354A2...
Date	13 February 2023 | 4:27 GMT
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	DocuSigned by: Sarah Ruthven 6EB42B4E497249C...
Date	13 February 2023 | 4:51 GMT

14. Reason for new version and Training Implication

This SOP replaces the previous version number 1.3

Changes made	What changes have been made to the contents of the document
Reason	• New layout • Revision in procedure • Additional information regarding document access
Training Implication	**Yes**
Actions required	• Review SOP • Matrix to be updated