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SOP 865 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
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Date of approval:	07/03/2023
To be reviewed before: This document remains current after this date but will be under review	07/03/2026 (3 years, unless legislation or process changes)
Reference and / or Trust Docs ID No:	15433
Version No:	2
Description of changes:	New template Updated information re document access

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
CI	Chief Investigator
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
Essential Document	Documents which individually and collectively provide the primary quality system for validating the safe and appropriate initiation and conduct of clinical trials, compliance with the study protocol and the quality of data obtained. The filing of essential documents in an orderly manner greatly assists the smooth running of a project and any research evaluation and/or audit by a sponsor or regulatory authority (such as the MHRA). Please see SOP 305 ‘Creating and Maintaining a Trial Master File’ to specify the types of essential 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
IRAS	Integrated Research Application System
Issue	A process whereby an approved document is made available to users
NCTU	Norwich Clinical Trials Unit
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
PI	Principal Investigator
Policy	A statement that communicates the intent, objectives, requirements, responsibilities, and standards for an organisation
Review	A checking process, performed by an expert (the reviewer) in the procedure that ensures the document is fit for purpose

Study Team	For the purpose of this SOP this term refers to the Chief / Principal Investigator, and any other members of the study team
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

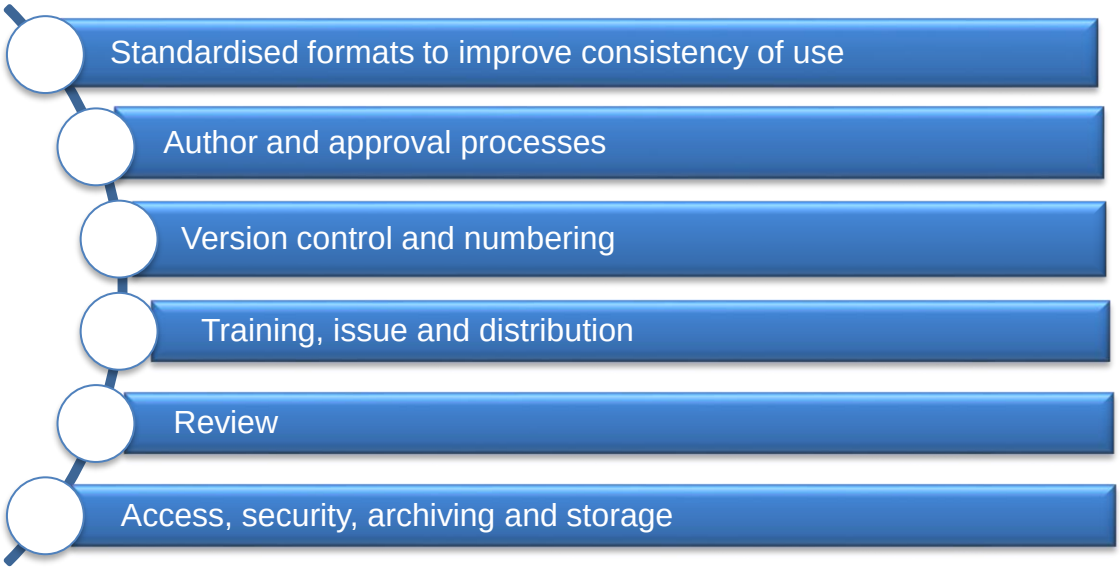
The focus of this SOP will be on the management and control of study specific research documents, produced mainly by the Chief Investigator (CI) and Sponsor, including administrative, clinical and data management documents which meet the criteria for essential documents as described in the ICH Guidelines for Good Clinical Practice. Examples of study specific documents included in this field are:

- Protocols
- Participant information sheets (PIS)
- Informed consent forms (ICF)
- Consent forms
- GP letters
- Study advertisements
- Data collection media - case report forms
- Subject diaries

5. Purpose

Different types of documents will need different levels of control. Some documents may not be formally controlled however, procedures should be in place to ensure these are updated regularly and only current versions are accessible. For other documents such as study protocols 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.

6. Rules

Staff should ensure that:
• Good documentation and document control is essential for ensuring the safety of participants and quality of data. It must be possible to track any document to demonstrate approved, current procedures were used by trained staff. All documents must also meet regulatory and local requirements. • Staff should not deviate from a controlled document, if staff become aware that a document is out of date or inaccurate, they must report this to the author, approver or document controller.

7. Responsibilities

Chief/Principal Investigator: Must ensure that all controlled and essential documents required for the clinical research study contain the most current and relevant information, are accessible and fit for purpose, are appropriately managed and controlled, and that staff are appropriately trained in the use of the documents.

Sponsor: Must ensure that all controlled documents related to clinical research are approved and follow the guidelines for version control, naming of documents and are in the correct format; support the CI/PI with implementation and training where required and ensure that documents are being followed.

Study Team: Must ensure they are trained and competent to perform the process outlined in a document, and that this training is documented (see SOP 505). Staff should not deviate from a working practice document. If staff become aware that a document is out of date or inaccurate, they must report this to the CI/PI and Sponsor.

8. Controls

8.1 Version Control and Numbering

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 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.

8.3 Essential Information

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

- 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. Procedures

Author and approval process
Documents should always be written by qualified personnel with expertise in the area of the document, where possible templates should be used. Draft documents should be circulated for peer and QA review before the document can be approved. The approver should have the relevant experience and knowledge of the process to enable them to permit the document's use.

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. Document training methods and how these events are recorded are outlined in separate training working practice documents and will range from simple notification through to competency testing See SOP 505 Creating and Maintaining Training Records

Review process
During the lifetime of a study, it may be necessary to review / update documentation in line with new information or study events. This should be carried out in a timely manner to ensure relevant information is available for study teams.

Amendments
Updated study documentation should be sent to the Sponsor for review and authorisation prior to submission using the Amendment Tool. The Amendment Tool will determine whether the changes are classed as substantial or non-substantial, and the sponsor should confirm they agree with the outcome before authorising the amendment (locking the Amendment Tool).

Tracked changes and clean versions of each amended document should be provided for review and submitted to the relevant regulatory bodies.

Once the Amendment Tool has been locked (authorised) by the Sponsor Representative, it can be returned to the study management team for online submission via the Integrated Research Application System (IRAS) Amendments portal.

Superseded copies of documents should be retained in the study files and the front page struck through signed and dated and "superseded" written across the front page to clearly indicate this particular version is no longer in use. The new effective document should be filed at the front, and any logs of current documents should be updated.

Current editable Word and PDF (if deployed) versions will be maintained in the shared workspace with limited access, previous versions of the document will be clearly identifiable from the current versions and saved in a folder labelled 'Superseded Documents'.

10. Access, Security, Archiving and Storage

Document Access
Current versions of documents should be clearly identifiable to document users. For electronic documents the current version should be in a read only format (pdf copies are commonly used).

Archiving and Retention
The retention time and archiving method will be included in the study protocol and departmental archiving procedures and in accordance with SOP 900 Archiving, Retrieval and Destruction of Research Documents.

Security and Storage
Hard copies of current trial documents should be kept in secure lockable storage, such as filing cabinets or controlled access offices.

Security measures for electronically held documents should include:

- Protection from editing (e.g. pdf copies, read only Word copies)
- Back up of electronic copies
- Password protection at network, folder or document level
- Facilities for storage of paper copies (e.g. archiving environment to protect from moisture/fire)
- Security of databases

11. Procedure for Norwich Clinical Trials Unit (NCTU)

Guidance and procedures for writing and releasing NCTU study specific documents are included in the NCTU document 'NCTU_Q_WPD_1 QMS Overview'.

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 305	Creating and Maintaining a Trial Master File
SOP 505	Creating and Maintaining Training Records
SOP 900	Archiving, Retrieval and Destruction of Research Documents.

13. Approval

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Date	07 March 2023 | 7:33 GMT
Approved & Authorised UEA	Sarah Ruthven
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Date	13 March 2023 | 11:55 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 • Removal of flowchart • Inclusion of NCTU
Training Implication	**Yes**
Actions required	• Review SOP • Matrix to be updated