University of East Anglia

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The best care for every patient

Norfolk and Norwich University Hospitals
NHS Foundation Trust

SOP 001
Production, Review, Approval and Control of Standard Operating Procedures (SOPs)Related to NHS/Healthcare Research Activities

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of health care research
Division responsible for document:	Research & Development
Key words:	SOP, Production, Review, Approval, Control
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Assessed and approved by:	Julie Dawson: Research Services Manager NNUH Sarah Ruthven: Research Manager UEA
Date of approval:	05.07.2023
To be reviewed before: This document remains current after this date but will be under review	05.07.2026
Reference and / or Trust Docs ID No:	15947
Version No:	2
Description of changes:	Re-write of procedure to clarify creation and review processes

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

NNUH	Norfolk and Norwich University Hospital
R&D	Research and Development
RGA	Research Governance Administrator
RGOG	Research Governance Operations Group
RGC	Research Governance Coordinator
SOP	Standard Operating Procedure
UEA	University of East Anglia

3. Objectives

The aim of this SOP is to describe the process for preparing, changing, updating, reviewing, approving, distributing and filing of Standard Operating Procedures (SOPs) for all health and social care research activities within the UEA and/or NNUH

4. Scope

The Standard Operating Procedures (SOPs) shall be written taking into consideration the Trust's document, Procedural Document Development Policy Trust ID 19976 and in line with any related UEA regulations or policies.

5. Purpose

To maintain Quality Assurance, SOPs are managed, administered and reviewed according to a defined process. The function of SOPs is to establish standard procedures:

- To ensure procedures are carried out correctly and consistently.
- To reflect best practice to ensure quality and integrity of the data.
- To communicate these procedures to those who will undertake them and underpin training.
- To leave a permanent record of the methodology during the performance of the conduct of studies or activities.

6. Rules

Please note:

- SOPs should be reviewed every 3 years from the date of issue, unless there are any changes to processes or legislation that have an impact on the SOP or earlier at the request of either NNUH or UEA. Any such request must be recorded as a change request on the NNUH Q-Pulse document management system.
- SOPs are joint documents and therefore need to be authorised both by the Norfolk and Norwich University Hospital NHS Foundation Trust (NNUH) and the University of East Anglia (UEA).
- SOP progress and creation should be a standing item on the Research Governance Operations Group (RGOG) meeting
- The NNUH R&D Office maintains a list of all SOPs and their status via the Q-Pulse Document Management System.
- The NNUH R&D Office will manage the numbering and version number of the document. The version number will be displayed on the front page of the SOP. Updates to the SOP will result in an increase in version number, this will increase by one whole number when being changed i.e v1, v2.
- Active SOPs are available in Q-Pulse and are published on the NNUH website (via the Trust Docs web system).
- The Trust Docs identification number will be the same for each version of each SOP. For new SOPs an identification number will be allocated by the system on creation.
- Compliance with SOPs should be evidenced in staff training records, and for the NNUH documented using the SOP Training Matrix.

SOP Numbering

Each SOP will be issued with a reference number. The reference number will identify the type of document and the organisations to which it applies. The reference numbers will be grouped accordingly:

00	Document Management
200	Safety
300	Clinical Operations
400	Approvals/Initiations
500	Staff Training
600	Statistics
700	QA/QC
800	Data management
900	Storage and Retention of Research documents

Responsibilities of all staff
• Ensure the correct version is used and understood • Promptly raise any concerns regarding SOP accuracy or inability to follow the SOP via Office.RD@nnuh.nhs.uk

7. Procedure

7a SOP Creation

SOP Creation
• A new SOP should be created where there is an identified change / gap in practice or a change in operations at NNUH/UEA or new laws or regulations necessitate the creation of a procedure. • Once the need for a new SOP is agreed an appropriate Author should be identified. • All SOPs, which are in preparation, will have a 'DRAFT' watermark which should be removed once the version is finalised. • The final version will be signed as the authorised version and approved via DocuSign.

	**Creating the SOP** • Contact the Research Governance Administrator (RGA) for a SOP number / creation of the record card in Q-Pulse • Ensure that the Author has sufficient knowledge in the area • The responsibility of the Author is to collate relevant information (e.g. via research or discussions with relevant stakeholders (who can also be named as Authors) and create draft content for the SOP
	**Drafting the document** • Start drafting the document using the current version of the SOP template – See SOP 001 App 1 • Make sure that the most up-to-date source, regulations, NNUH /UEA policies are referenced in the documents, where applicable • Specialist expertise, where required, may be requested • Make the SOP clear and easy to follow
	**Reviewing the draft** • Once the draft has been finalised, the RGA should receive a copy so that the draft can be circulated for review • The relevant and appropriate personnel within the respective Research Offices will review and comment as required. NNUH R&D personnel will be contacted via the Q-Pulse system and review information should be added directly to Q-Pulse. The RGA will contact all other personnel, including relevant UEA staff via email, retaining copies of tracked comments

Completing the reviews

- Once the reviews are complete, the RGA will advise the Author so that the SOP can be finalised
- Where authors and or reviewers cannot agree the procedural text/actions, the advice of RGOG and finally the Joint Research Governance Committee shall be sought as appropriate

Finalising the SOP

- The RGA will check and finalise the SOP (adding reference numbers and an effective date) and will send the final version to the assigned SOP Approvers for electronic signature via DocuSign
- Once approved, the RGA will upload the SOP to Q-Pulse, Trust Docs and arrange with NNUH Communications for it to be added to the NNUH website
- The RGA will notify key personnel that the SOP is available: the R&D team will be notified via Q-Pulse, for other staff/partner organisations the SOP (or a weblink) will be emailed to the contact for distribution

7b SOP Revision

SOP Revision

- All SOPs, which are in revision, will have a 'DRAFT' watermark which should be removed once the version is finalised
- The final version will be signed as the authorised version and approved via DocuSign

Allocating the review

- NNUH R&D will monitor the standard review of SOPs via Q-Pulse. Where Change Requests and/or legislative/policy changes necessitate earlier review, the review date will be brought forward by the RGA (with the agreement of the Research Governance Coordinator (RGC)/Research Services Manager and the UEA representative) or via agreement with the RGOG.
- For SOPs that are due for review the RGA will prepare the review process in Q-Pulse and notify the Author providing a link to the next version or attaching the version to an email, if the Author does not have access to the NNUH shared file area.

Reviewing the draft

- Once the SOP has been initially reviewed and amended, the changes will undergo review as described in the '*Reviewing the draft*' section above.
- If no revisions to the SOP are required, the next scheduled review will be allocated via the Q-Pulse Document Management System and the RGA will ensure that the Trust Docs system is updated (see WPD 008 SOP Production) so the document remains live on the NNUH website.

Completing the reviews

- Once the reviews are complete, the RGA will advise the Author so that the SOP can be finalised as per the sections *'completing the reviews'* and '*finalising the SOP*' above

Superseded SOPs

- The previous version of the SOP then becomes superseded, and Q-Pulse and the Trust Docs system make this change automatically. The RGA will update the documents/folders on the shared drive to reflect the changes and notify other relevant parties by e-mail.

Please see WPD008 SOP Production for specific detail about SOP Production and uploading to Trust Docs and the NNUH website.

8. References and Related Documents

References and Related Documents
ICH GCP E6 / SI 2004/1041
Procedural Document Development Policy Trust ID 19976
WPD 008 – SOP Production
The UK Policy Framework for Health and Social Care Research

9. Approval

Author	Jackie Orford
Role	Research Governance Administrator
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	DocuSigned by: Julie Dawson 4CBAB366CF354A2...
Date	17 July 2023 | 2:54 BST
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	DocuSigned by: Sarah Ruthven 50D5F3BEE2F04C1...
Date	17 July 2023 | 4:59 BST

10. Reason for new version and Training Implication

This SOP replaces the previous version number V1.5

Changes made	What changes have been made to the contents of the document
Reason	• Revision in procedure
Training Implication	**Yes**
Actions required	• Additional training may be required • Matrix to be updated

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SOP 001 Appendix 1
Enter SOP Number, Enter SOP Title

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	List key words associated with the SOP
Name of document author:	Enter Name
Job title of document author:	Enter Role
Name of document author's Line Manager:	Enter Name
Job title of author's Line Manager:	Enter Role
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:	*TBC*
To be reviewed before: This document remains current after this date but will be under review	Add date (3 years, unless legislation or process changes)
Reference and / or Trust Docs ID No:	See previous version in trust docs for ref number
Version No:	Enter current version number

Version and Document Control:

If two SOP's have been merged into one, detail the SOP numbers and titles that have been merged here.

Version No:	Date of update	QPulse Change Request reference (CR no.)	Change Description	Author
1			New document	
2	02/08/19		Reissued – no changes	
3	Xx/05/2022	NA	To add revision history	

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SOP Number and TITLE

1. Contents Edit as required for SOP (Add or removed lines for sections required)

2. Definitions of Terms Used / Glossary

R&D	Research and Development
SOP	Standard Operating Procedure

NB

- *Content should be drafted in Font: Arial pitch size 12*
- *Website references can be used but they must not be hyperlinked. If the hyperlink breaks the SOP would then need to be updated.*

3. Objectives

What are the aim/s of this service / practice / role etc.

4. Scope

Describe any additional limitations to the application of the processes described in this document.

5. Purpose

Why was the document written?

6. Rules

Enter important information in here which you want the reader to pay particular attention to

- Add bullet points to help
- This makes things stand out and clearly separated

7. NNUH Procedure

This should document the procedures and could expand on some aspects of required processes to be followed. Remember to consider identifying where appropriate, the duties of individuals as well. Also remember that a policy or procedure should have processes worded as 'must' and shall, not should or will.

- You can bullet point steps to follow by the user or use one line for each action.
- If more lines are required, right click in the table and select insert row
- You can copy and paste the arrow into the new line created
- Delete any rows you don't require by right clicking and select delete rows

- You can copy and paste this table if there is more than one procedure documented within the SOP

Add any further steps / important information here

- Add bullet points to help
- This makes things stand out and clearly separated

8. UEA Procedure (if applicable)

This should document the UEA procedures and could expand on some aspects of required processes to be followed. Remember to consider identifying where appropriate, the duties of individuals as well. Also remember that a policy or procedure should have processes worded as 'must' and shall, not should or will.

9. NCTU Procedure (if applicable)

This should document the NCTU procedures and could expand on some aspects of required processes to be followed. Remember to consider identifying where appropriate, the duties of individuals as well. Also remember that a policy or procedure should have processes worded as 'must' and shall, not should or will.

10. References and Related Documents

Describe any associated documents that are nationally available or available on Trust Document Management Systems

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 xxx	

11. Approval

Author	
Role	
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	
Date	
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	
Date	

12. Training Implication

	See Amendment History
	•
Training Implication	**Yes** or **No**
Actions required	List any actions that may be required i.e. • Additional training may be required • Matrix to be updated