Sherwood Forest Hospitals
NHS Foundation Trust

PROCEDURE FOR APPROVAL, IMPLEMENTATION AND REVIEW OF CLINICAL DOCUMENTS (POLICIES, PROCEDURES, GUIDELINES, SOPs, PATHWAYS)

Document Category:	**GOVERNANCE**
Document Type:	**PROCEDURE**

Keywords:	Policy for policies; on; SOP; Standard Operating Procedures

Version:	Issue Date:	Review Date:
V3.0	Oct 2025	Oct 2028

Supersedes:	V2.0		
Approved by (committee/group):	GSU	**Date Approved:**	Oct-2025

Scope/ Target Audience: (delete as applicable / describe)	**Trust-wide** (for the majority) – this procedure is applicable: • across all trust sites and is for all staff and trust committees/ groups involved in the process and management of these documents

Evidence Base/ References:	• NHS LA (April 2009) An Organisational-wide Document for the Development and Management of Procedural Documents. NHS LA. London. • NHS LA (March 2013) *Risk management standards for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care*. NHS LA. London. • NICE (Oct 2014, last updated Oct 2022) *Developing NICE guidelines: The manual.* NICE. London • SIGN (2019) SIGN 50. *A guideline developer's handboook.* SIGN. Edinburgh • www.nice.org.uk • www.cqc.org.uk

Lead Division:	Corporate
Lead Specialty:	Governance Support Unit
Lead Author:	Joanne Loughton, Corporate Compliance Lead,
Co-Author(s):	Emma Farnsworth, Quality Assurance Support Officer
Sponsor:	Candice Smith, Director of Nursing – Quality, Safety & Governance

Name the documents here or record not applicable *(these are documents which are usually developed or reviewed/ amended at the same time – ie a family of documents)*	
Associated Policy	Policies management framework
Associated Guideline(s)	None
Associated Pathway(s)	None
Associated Standard Operating Procedure(s)	None
Other associated documents e.g. documentation/ forms	• NICE guidance interface proforma (locally maintained within GSU – last reviewed/ amended February 2020) • External guidance interface proforma (locally maintained within GSU – last reviewed/ amended August 2020)

Consultation Undertaken:	GSU colleagues

Template control:	v2.0 July 2023

CONTENTS

OVERARCHING PRINCIPLES

- Please use the latest trust approved templates (Procedure, Guideline, Standard Operating Procedure and Pathway) for all newly developed documents or documents being reviewed which are accessible from **HERE**
- Obtain a copy of the master editable file of a current document prior to commencing a planned review/ early amends from the clinical documents inbox
- Ensure that all associated documents have been developed/ reviewed and are either in date or accompany the overarching document for approval (unless progression via a different approval route is needed – i.e. documentation/ forms and information leaflets).
- Adhere closely to requirements for content and formatting as described in this procedure/ the overarching policy and templates
- Fully update as much as possible the document control sheet (front/page) before submission for approval
- Ensure appropriate consultation has been undertaken and is recorded on the front/ sheet prior to submission for approval
- Ensure all consultations have been completed and agreed amends made to the document prior to submission for approval
- Ensure appropriate approval committee/ group
- Ensure Equality impact assessment(s) have been reviewed/ amended/ re-signed/ re-dated on each planned review
- Take a document through a formal review process even if no content amends are required. A document must go through an up-to-date governance review process which can be evidenced (e.g. document on an agenda and discussion/ outcome minuted) for agreement of the requirements and for the document to be given a new 3-year review date.

1 INTRODUCTION/ BACKGROUND

This procedure should be read in conjunction with its overarching policy which provides the essential information for all categories of trust 'policies' (clinical and non-clinical):

- Policies management frameworkTrust Policy for/ on Policies)

The Trust categorises its policies (and thus other document types) as either clinical or non-clinical. The non-clinical categories tend to be mandatory and are thus mainly policies. The management and advice regarding the non-clinical categories is via trust headquarters.

For the purposes of *this procedure* '**documents/ clinical documents** refers to the following ***CLINICAL*** document types:

- Procedures (also previously known as Protocols)
- Guidelines
- Standard Operating Procedures
- Pathways

For the requirements surrounding clinical policies, see the above linked policy.

This procedure describes the governance surrounding the above clinical document types which are centrally published/ maintained by the Governance Support Unit. However, the same principles apply if specialties/ departments manage some of their own such documents – for instance, Radiology manage specific SOPs pertinent to their own staff (e.g. how to x-ray a finger/ toe etc) and Medicines Management/ Pharmacy manage specific SOPs pertinent to their staff (e.g. for their pharmacy production and quality control units).

This procedure describes the process for the development, approval, implementation and review of the above four document types. It also describes the process for the early review/ amendment of a document; the extension of review dates; rolling-on review dates; the use of external documents (rather than developing an internal trust one); and removal of obsolete documents.

2 AIMS/ OBJECTIVES/ PURPOSE (including Trust Related Documents)

Alongside the overarching policy, this procedure will promote a consistent approach to the management of clinical documents which, if followed, will promote consistent standards across the Trust.

3 DEFINITIONS AND/ OR ABBREVIATIONS

Clinical Guideline	• NICE defines clinical guidelines as recommendations on the appropriate treatment and care of people with specific diseases and conditions. They are based on the best available evidence and while clinical guidelines help health professionals in their work, they do not replace their knowledge. Guidelines can also be based on broad consensus opinions of experts and be subject to

	professional judgement and justifiable variations in individual circumstances.
Clinical Procedure	• Have the intension of determining, measuring or diagnosing a patient condition/ parameter or describes the official way of doing something which must be followed • Include any practice of a healthcare practitioner that involves the combination of a special skill or abilities and may require medicines, devices, or both.
Clinical SOP	• Usually provides detailed instructions on how to perform a specific operational task in a certain way. They usually include what needs to be done, who needs to do it, when they need to do it and where it needs to be done.
Clinical Pathway	• Is a management tool based on evidence-based practice for a specific group of patients with a predictable clinical course, in which the different tasks (interventions) by the professionals involved in the patient care are defined, optimised, and sequenced. • Generally, a pathway may refer to a clinical guideline on the same subject, but a single pathway may refer to guidelines on several subjects in a well detailed framework, especially within a multidisciplinary context.
Associated Documents	These are separate/ different document types covering the same subject matter – i.e. a family of documents. For example: • A policy will have the overarching principles/ must dos • A guideline will provide more details of how a condition/ disease should be managed • A procedure will describe a particular way of doing something • A piece of documentation/ form will be used for recording patient care • A patient information leaflet would be given to a patient. *Ideally, the suite of documents would be reviewed/ amended at the same time.*
Related Trust Documents	These are documents the lead author may suggest the reader accesses for additional information/ help surrounding an element of the document e.g. consent. If the document being read asks for consent to be gained, the author may refer the reader to the consent policy for more information.
Appendices	These are attached to the end of a document and may provide more detailed information on how to implement a particular element of the document being read.

4 ROLES AND RESPONSIBILITIES

For further details around the roles and responsibilities for policies please refer to the Policy Management Framework.

Patient Safety Committee (PSC)

- Oversees the process for the management of clinical documents including approval of this procedure.
- Delegating responsibility to sub-committees/ groups and the divisional clinical governance structures for the consultation and/ or approval of clinical documents.
- Approving clinical documents:

- Which require higher level approval particularly where there are significant material changes to an existing document.
- Where the document is for trust-wide use (and there isn't an appropriate lower-level sub-committee/ group for the subject matter).
- Which involve multiple divisions/ specialties; or
- Where further advice has been requested from a sub-committee/ group or the clinical divisions.

Trust Committees/ Groups and Specialty/ Divisional Clinical Governance Groups are responsible for:

- Ensuring an appropriate consultation process has been undertaken prior to approving any clinical documents.
- Consulting on and/ or approving subject related clinical documents.
- Ensuring their Terms of Reference are up to date which include the delegated duty and responsibility for consulting on/ approving subject related clinical documents.
- Escalating any clinical documents for higher level approval/ advice in-line with the trust's committee/ group structure and governance structure as deemed necessary.

Lead Authors are responsible for:

- Developing or reviewing/ amending documents aligned with evidence-based practice.
- Ensuring that the Trust approved templates are used (accessed here on the intranet alongside this procedure and its overarching policy).
- Reviewing/ amending documents at either the review date or earlier if new evidence emerges to support improved or a change to practice.
- Leading the consultation (circulating drafts, collating comments, making agreed amendments), ensuring that the steps required for approval are followed and submitting final approved documents (along with confirmation of the approval) for publication/ upload to the intranet (or issue for practice).
- Ensuring the sponsor supports the document.
- ***Current documents requiring review (planned or early)*** – obtaining a copy of the current editable WORD file (usually retained centrally) prior to commencing the task.
- ***New documents being developed*** – obtaining the up-to-date blank template accessed from link above.

Sponsors are responsible for:

- Endorsing the need/ requirement for having the document.
- Ensuring that an appropriate lead author is nominated.
- Assigning a new lead author, where a lead author has changed job role or left the organisation and the role not filled/ replaced.
- Supporting/ advising authors on appropriate consultation.

Divisions / Specialties / Departments are responsible for:

- Ensuring documents owned by them are reviewed/ amended and issued for use in practice.
- Ensuring that documents are in date, monitoring this through governance/ other meetings.
- Tracking documents being newly developed to completion

Governance Support Unit is responsible for:

- Maintaining (reviewing and amending) this procedure for ***clinical*** **documents.**
- Managing the process and maintaining the overall list of clinical documents that fall within this procedure and are published to the Policies, Procedures and Guidelines intranet site.
- Publishing new/ uploading reviewed clinical documents to the intranet and ensuring accurate document control.
- Providing advice and support to lead authors on aspects of this procedure.
- Providing status reports to Specialties and Divisions.
- Providing escalation reports to divisions as needed detailing documents which are not completed by their review dates.
- Providing assurance reports to the Nursing, Midwifery and Allied Health Professionals Committee (N,M&AHPC) and/ or Patient Safety Committee (PSC) Executive Board & Quality Committee.

5 PROCEDURE DETAILS

5.1 Introduction

Documents should be internally produced/ developed or reviewed (rather than opting to use externally produced documents) and be presented in the Trust approved template.

Documents should be owned by and aligned for reporting purposes to ***one*** of the following:

- Division
- Specialty

Documents should have ***one*** named:

- Lead author
- Sponsor

If other staff are closely involved with the development/ review of a document they should be added as 'co-authors'.

All new and existing documents should be developed/ reviewed for trust-wide use – they should only be developed for specialty/ cross specialty/ divisional use if really deemed necessary and as agreed within the relevant owning specialty/ division. They should all be approved by a trust committee or group.

5.2 Developing new documents

New Clinical documents must be developed on the correct Trust blank template. If required contact the Library and Knowledge Services for help with a literature search for your subject matter. And if needed liaise with fellow peers/ colleagues at other trusts or browse the internet for examples which could help inform your content/ flow of information. Depending on the target audience and who needs to implement it, it may require an initial wide consultation. (Subsequent versions may not need as wide a consultation).

Prior to developing a new clinical document, the following should be identified:

a) Why the document is needed
b) The purpose
c) Document type
d) Who it is for (i.e. target audience)
e) Whether anyone else is likely to be addressing the same/ a similar issue or if a similar document already exists (as the new document may supersede it or an existing document may need reviewing and amending to include the new information rather than developing a new one)
f) Who needs to be involved (key stakeholders/ consultation required/ approval committee-group)
g) Timescale for completion (ideally recorded on the relevant tracker to ensure progression and completion)
h) Lead author; and
i) Sponsor.

5.3 Layout/ format

Documents must be developed or reviewed using the most up-to-date trust approved templates (provided in editable WORD format) accessed here:

- Procedure Template
- Guideline Template
- Pathway Template
- Standard Operating Procedure Template

For documents undergoing a planned review, the lead author will be sent a copy of the master editable WORD file in the most up-to-date trust template. The editable file will have been prepared for the lead author to use and make amends and take through the process to completion.

The above document templates have appropriate front sheets which must be completed in all cases. The procedure and guideline templates contain best practice section headings for that type of document, but they are for guidance only and can be deleted or substituted if it is felt they are not applicable to the subject matter of the document you are developing/reviewing. Consider the use of section headings on a case-by-case basis depending on the subject matter of your document/ target audience.

Apart from the front sheet (and Equality Impact Assessment if needed) wherever possible, the font should be in Arial 12 point. However, the font size can be reduced to help narrative/ flowcharts fit on a single page for ease of viewing – but use reduced font size sparingly.

Appendices must each be on a separate page and at the end of the document. They must be referred to from the main body of a document (usually but not exclusively from the narrative/ details section). The only exception to this is if the appendix is a piece of documentation/ form which needs to be printed/ completed and filed in a ***patient's*** medical notes. These should be separate documents to the main clinical document.

5.4 Consultation and approval

Newly developed documents are more likely to need a wider consultation process than current documents being reviewed/ amended.

At the review date of a current document, it must go through the planned review process in-line with this procedure, even if the content does not need to change. An up-to-date governance review process needs to be evidenced so a document can be given a new 3 year review date.

Prior to circulating a document for consultation, the lead author should review the current document and use their knowledge and expertise of the subject matter to make any initial amends.

When undertaking a planned review or early review/ amendment to a clinical document, authors must use either electronic track changes or a different colour type and/ or highlight so the amends can be easily identified by those consulting/ approving the document. (This also helps when summarising the changes in the amendment table).

There should then be a formal consultation process, and this should be recorded on the front sheet of the document in the space provided. The responsibility for the consultation is down the author of the document in collaboration with the approving committee/group. Support and advice on appropriate consultation should also be sought from line managers/ sponsors if needed. The consultation process is an opportunity to raise awareness of an existing document, particularly if there are any implementation issues. Ensure key stakeholders are included in the consultation. Where necessary include junior staff to help with the readability/ flow and understanding of the content.

Consultation should include individuals and/ or groups of staff (e.g. Matrons) and/ or trust committees/ groups. It is particularly important to include staff that will be using the document or use more senior staff representing staff using/ implementing it. Ensure any specialist colleagues are included in the consultation (e.g. training advisors for training and education, IG colleagues for IG issues etc). ***If information on any medications are mentioned in any clinical document, it must be referred to the relevant specialty/ divisional pharmacist for consultation and their role/ name or initials recorded in the consultation section.***
For some larger/ more complex documents, it may be necessary to set up a 'task and finish/ table-top group' to help with the requirements.

Consultation can be undertaken with more than one trust committee/ group however, approval must be the responsibility of ***one*** committee/ group only – this should be the local (lowest level) expert committee/ group for the subject matter.

Specialty documents can be approved at Specialty Clinical Governance Meetings. And trust committees/ groups can approve subject related documents. However, if the approval committee/ group feel there are significant material changes to an existing document or further

guidance is required then the document may require submission for higher level approval as per the Trust's governance/ committee structures.

The approval for a document must sit with a recognised trust committee/ group and the delegated responsibility/ duty recorded as part of their Terms of Reference.

Any pertinent changes made to the document must be summarised in the amendment table provided in the template. If no changes have been made, this should be recorded.

5.5 Associated (Supporting) Documents

There are other documents which may be associated to the document being developed or reviewed as described within this procedure. Such associated documents fall outside the remit of this procedure and their development/ review need to follow the separate arrangements in place, and include:

Document Type	Department/ Group Responsible	Contact for additional advice
Patient Information Leaflets	Communications Team	Patient Information Officer
Nursing Documentation/ Forms including Core Care Plans	Documentation Group	Corporate Matron
Medical Documentation/ Forms	Clinical Records Advisory Group (MRAG)	CRAG Chair

It is the author's responsibility to ensure that any documents which fall into the above types are approved by the appropriate channel.

5.6 Documents which are required urgently

The approval of documents should not rest with just one individual. It is however recognised that in some circumstances for expediency some documents may be an exception to this; only the relevant Executive for the document category or relevant Director has the ability to approve a document instead of a recognised trust committee / group (for clinical documents this will be either the Chief Nurse or the Chief Medical Officer).

5.7 Equality Impact Assessments

All documents should not discriminate against individuals directly or indirectly on the basis of gender, colour, race, nationality, ethic or national origins, age, sexual orientation, marital status, disability, religion, beliefs, political affiliation, trade union membership, and social employment status.

An Equality Impact Assessment (EIA) must be conducted on all

- Policies, Procedures and Guidelines (*unless an EIA has been completed on an overarching document).*

It is not necessary to complete an Equality Impact Assessment on a:

- Pathway or Standard Operating Procedure

Where an Equality Impact Assessment is required, it should be completed prior to submission of a document for approval.

5.8 After Approval

Following approval, the lead author should submit the final approved word document for issue, with any separate appendices/ associated documents (as outlined above). The date and approving committee should also be given along with minutes of the meeting where the document was approved.

Review dates for documents should not exceed 3 years from month of approval. If required, lead authors can record an earlier/ shorter timescale (e.g. if national guidance is anticipated within the next 3 years/ early review of a service is likely/ for evaluation of a new document).

5.9 Implementation of documents

The implementation of clinical documents usually lies with the author and/ or owning specialty/ division and/ or the clinical areas where they are being followed/ implemented. Where there are specific ***monitoring compliance and effectiveness*** sections in a clinical document, this should be undertaken as described. Responsibility for the implementation of clinical documents lies outside of this procedure.

5.10 Planned reviews and early reviews/ amendments

If a document requires an early review, an editable word copy can be requested from the clinical documents inbox. Please follow the review process as detailed above.

3 months prior to the review date of documents, the Governance Support Unit will initiate the review process by sending out an editable word version of the document. An overdue reminder if not completed within the timescale will follow which will be copied to the sponsor. After 2 overdue emails, 1 month apart, the DLT will also be copied into the email.

Minor/ moderate early amends should be undertaken when needed (e.g. change in evidence base) and can occur at any time during the lifecycle of documents without changing the review date. Amends must be approved by the relevant trust committee/ group and minuted accordingly. A document will only be given a new 3-year review date if a full consultation and approval process has been undertaken (e.g. where a document undergoes a review process early).

5.11 Obsolete documents

Where a document is no longer required, the owning specialty/ division should agree and minute this via the relevant committee/ group and then inform the clinical documents inbox so the document can be archived/removed.

5.12 Extensions to Review Dates

If an extension is required, a request form must be requested from the clinical documents inbox and then approved at the relevant committee/group and minuted. Extensions are normally given for a 3 or 6 month period. After 3 extensions, this decision must be approved by the Division's DLT.

5.13 External clinical documents

The first option should be for clinical documents to be internally developed. However, the following are acceptable:

NICE guidance

Where the Trust's process for NICE guidance has been followed and a decision made by specialties not to develop an internal clinical document, it is acceptable to use the relevant 'interface proforma' which must be completed and is subsequently published to the intranet which links to the specified NICE guidance. In such instances a one-year review date will be applied so the validity/ requirements can be checked/ confirmed. An appropriate consultation and approval process must still be undertaken (as described for internally produced documents) for agreement of this need which will be captured/ recorded in the interface proforma.

Joint/ Regional/ Network guidance

Where specialties wish to have joint/ regional/ network guidance published to the intranet, the relevant 'interface proforma' must be completed and will be retained centrally alongside the clinical document in the central repository. In such instances a one-year review date will be applied so the validity/ requirements can be checked/ confirmed. An appropriate consultation and approval process must still be undertaken (as described for internally produced documents) for agreement of this need which will be captured/ recorded in the interface proforma.

In both the above cases, where a review date is embedded in the document, adapted review dates/ governance requirements will be applied (even if using a document past its embedded review date) which will be evidenced by completion/ amendment of the relevant 'interface proforma'.

Service line agreements

Where different specialties/ services have agreements to use other external guidelines (e.g. other trust guidelines), the requirements fall outside of this procedure and responsibility for the use of any such documents lies with the specialty/ service.

5.14 Status reporting

Status reports for clinical documents are provided (usually monthly) for the specialties/ divisions as part of their governance reports

6 MONITORING COMPLIANCE AND EFFECTIVENESS

See overarching policy.

7 IMPACT ASSESSMENTS (FOR THIS PROCEDURE)

- **Privacy Impact Assessment** – not applicable
- **Environmental Assessment** – not applicable
- **Equality Impact Assessment** – not applicable as undertaken on overarching policy Development, Approval, Implementation and Review of Policies, Procedures, Guidelines, Standard Operating Procedures and Pathways – Policy (Trust Policy for/ on Policies)