

DEVELOPMENT, APPROVAL, IMPLEMENTATION AND REVIEW OF CLINICAL PROCEDURES, GUIDELINES, SOPs AND PATHWAYS PROCEDURE

Document Category:	GOVERNANCE		
Document Type:	PROCEDURE		
Keywords:	Policy for policies; on; SOP; Standard Operating Procedures, non-clinical,		
Version:	Issue Date:	Review Date:	
2.0	September 2023	August 2026	
Supersedes:	v1.0, Issued January 2018 to Review Date end June 2023 (ext ²)		
Approved by (committee/group):	Patient Safety Committee	Date Approved:	14-08-2023
Scope/ Target Audience: (delete as applicable / describe)	Trust-wide (for the majority) – this procedure is applicable: <ul style="list-style-type: none"> 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:	<ul style="list-style-type: none"> NHS LA (April 2009) An Organisational-wide Document for the Development and Management of Procedural Documents. NHS LA. London. NHS LA (March 2013) <i>Risk management standards for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care</i>. NHS LA. London. NICE (Oct 2014, last updated Oct 2022) <i>Developing NICE guidelines: The manual</i>. NICE. London SIGN (2019) SIGN 50. <i>A guideline developer's handbook</i>. SIGN. Edinburgh www.nice.org.uk www.cqc.org.uk 		
Lead Division:	Corporate		
Lead Speciality: (Or Division if 'divisionally' owned)	Nursing/ Governance Support Unit		
Lead Author: (position/ role and name)	Clinical Policy Officer, Sue Dale		
Co-Author(s): (position/ role and name)	Not Applicable		
Sponsor (position/ role):	Director of Nursing – Quality, Safety & Governance		
<i>Name the documents here or record not applicable</i>			
<i>(these are documents which are usually developed or reviewed/ amended at the same time – ie a family of documents)</i>			
Associated Policy	<ul style="list-style-type: none"> Development, Approval, Implementation and Review of Policies, Procedures, Guidelines, Standard Operating Procedures and Pathways – Policy (Trust Policy for/ on Policies) 		
Associated Guideline(s)	None		
Associated Pathway(s)	None		
Associated Standard Operating Procedure(s)	None		
Other associated documents e.g. documentation/ forms	<ul style="list-style-type: none"> Trust Committees/ Groups to Submit Clinical Documents for Consultation and/ or Approval – Guidance and Information for Authors (last reviewed/ amended June 2023) Guidance notes and information for authors of clinical documents (Last reviewed/ amended June 2023) 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) 		

	<ul style="list-style-type: none"> • Templates – Procedure, Guideline, SOP and Pathway – reviewed/ amended with this procedure
Consultation Undertaken:	v2.0 <ul style="list-style-type: none"> • Divisional Management Teams (July 2023) • Divisional Clinical Governance Leads (July 2023) • Quality Governance Leads (July 2023)
Template control: v2.0 July 2023	

Amendments from previous version(s)

Version	Issue Date	Section(s) involved (author to record section number/ page)	Amendment (author to summarise)
2.0	Aug 2023	Throughout	<ul style="list-style-type: none"> • Full review undertaken to align more closely to overarching policy
		Page 3	<ul style="list-style-type: none"> • Addition of overarching principles
		Page 4	<ul style="list-style-type: none"> • Process flowchart moved to near front
		Section 4	<ul style="list-style-type: none"> • Addition of requirement for documents being newly developed to be tracked to completion by owning specialty or division
		Section 5	<ul style="list-style-type: none"> • Information added for implementation of documents, obsolete documents, rolling-on review dates and external documents
		Templates (Procedure, Guideline, SOP, Pathway)	<ul style="list-style-type: none"> • Amendment table added • Header/ footer information revised in line with policy template • Some additional guidance added

CONTENTS

	Description	Page
	OVERARCHING PRINCIPLES	3
	PROCESS FLOWCHART	4
1	INTRODUCTION/ BACKGROUND	5-6
2	AIMS/ OBJECTIVES/ PURPOSE (including Related Trust Documents)	6
3	DEFINITIONS AND/ OR ABBREVIATIONS	6-7
4	ROLES AND RESPONSIBILITIES	7-8
5	PROCEDURE DETAILS (including flowcharts)	9-16
	5.1 Introduction	9
	5.2 Developing new documents	9
	5.3 Layout/ format	10
	5.4 Consultation and approval	11
	5.5 Associated (Supporting) Documents	13
	5.6 Documents which are required urgently	13
	5.7 Equality Impact Assessments	13
	5.8 After approval	14
	5.9 Implementation of documents	14
	5.10 Planned reviews and early reviews/ amendments	14
	5.11 Obsolete documents	15
	5.12 Rolling on review dates	15
	5.13 Extensions to review dates	15
	5.14 External clinical documents	15
	5.15 Status reporting	16
6	MONITORING COMPLIANCE AND EFFECTIVENESS	16
7	EQUALITY IMPACT ASSESSMENT	16

OVERARCHING PRINCIPLES

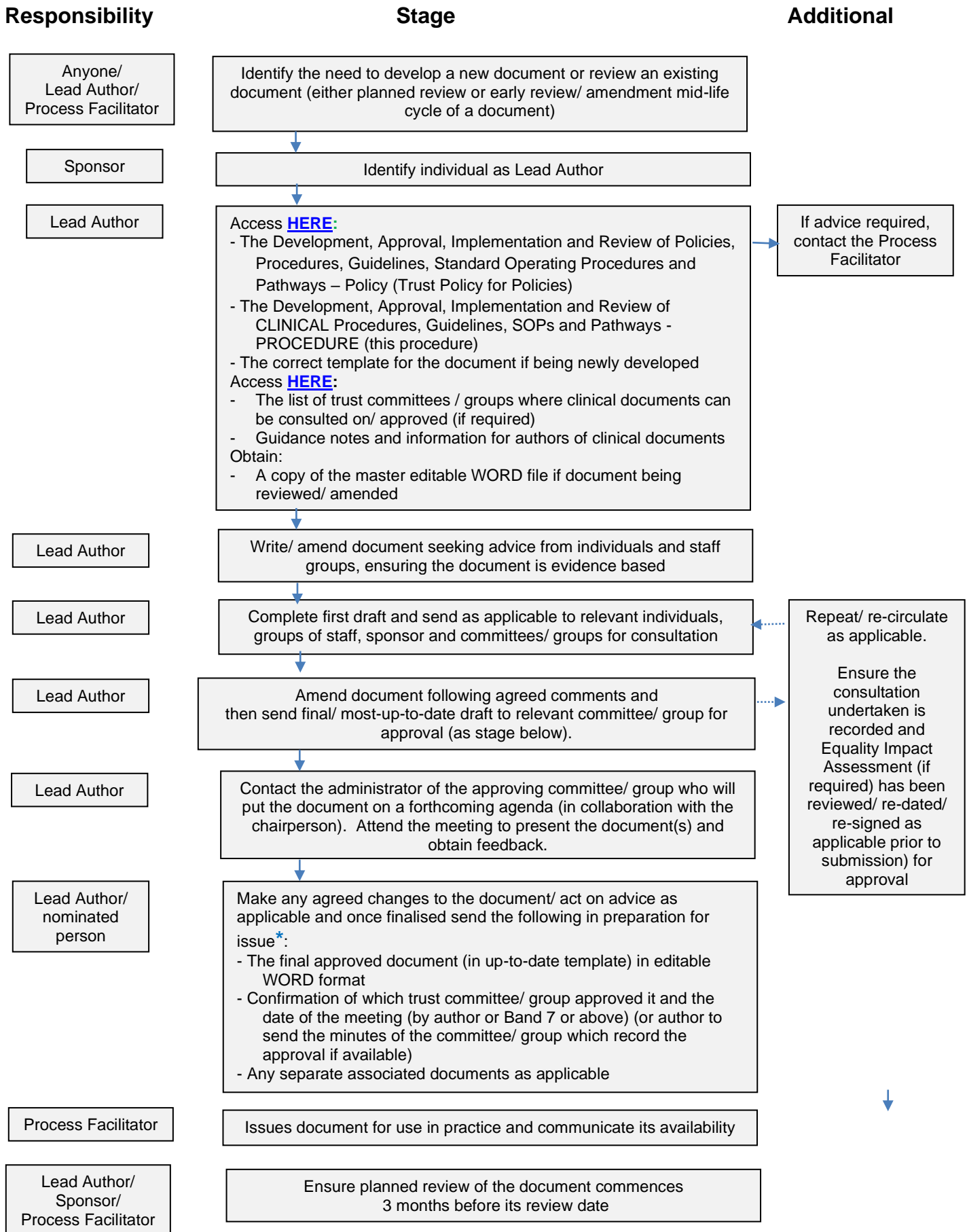
DO

- 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.
- 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 – ie 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/ governance page) before submission for approval
- Ensure appropriate consultation has been undertaken and is recorded on the front/ governance 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 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 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.

DO NOT

- Allow your existing document to exceed its review date without providing a reviewed/ amended version
- Submit a revised version by updating the extant version on an outdated template, rather than transferring to the current up-to-date trust approved template
- Assume that there has been no relevant evidence, legal or policy changes (national or local) on your subject matter since the previous version was implemented
- Download/ obtain a PDF of the current version and transfer to WORD as this throws out the formatting, making it difficult to amend/ work with.
- Embed any documents as they cannot be accessed once your procedure, guideline, SOP or pathway is published to the intranet. All information needs to be displayed in full within your document (either in the main narrative or be an appendix) or it can be a separate document (associated or related) and referred to from within your document as necessary.

PROCESS FLOWCHART



***For centrally maintained clinical documents, send to the Clinical Policy Officer (Process Facilitator)**

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):

- [Development, Approval, Implementation and Review of Policies, Procedures, Guidelines, Standard Operating Procedures and Pathways – Policy](#) (Trust Policy for/ on Policies)

The Trust categorises its policies (and thus other document types) as either clinical or non-clinical. The latter is further divided as follows: Business Continuity; Estates and Facilities (including Fire and Security); Finance; Governance; Health and Safety; Human Resources; and Information Governance. 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 head-quarters.

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

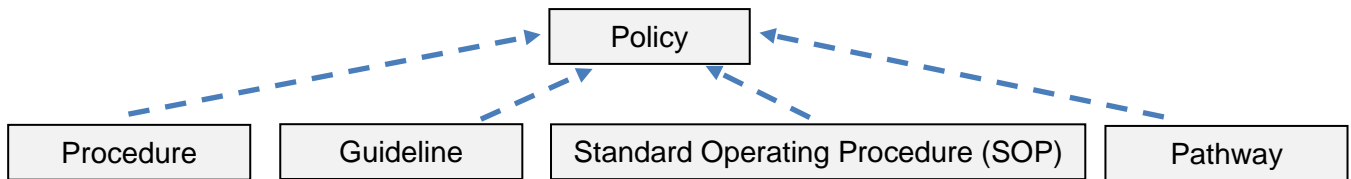
For the requirements surrounding clinical policies, see the above linked policy.

This procedure describes the governance surrounding the above clinical document types which are centrally published/ maintained by the Clinical Policy Officer within the Policies, Procedures and Guidelines intranet site. 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.

Where there are a number of associated documents (families of documents) for a particular subject matter, the best practice approach is that all the documents should ideally be supported by a brief overarching policy to bring these together as detailed in the diagram below. This means that a Procedure, Guideline, SOP or Pathway should be supported by a **short** overarching policy. It is accepted however that this approach may not always be appropriate and therefore it is acceptable to develop these documents in isolation.

Best practice approach:



Accepted approach:



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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<p>These are separate/ different document types covering the same subject matter – i.e. a family of documents. For example:</p> <ul style="list-style-type: none"> • 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. <p><i>Ideally, the suite of documents would be reviewed/ amended at the same time.</i></p>
Related Trust Documents	<p>These are documents the lead author may suggest the reader accesses for additional information/ help surrounding an element of the document eg 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.</p>
Appendices	<p>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.</p>

4 ROLES AND RESPONSIBILITIES

For further details around the roles and responsibilities for policies please refer to the [Development, Approval, Implementation and Review of Policies, Procedures, Guidelines, Standard Operating Procedures and Pathways – Policy](#) (Trust Policy for Policies).

Patient Safety Committee (PSC) is responsible for:

- Overseeing 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

Clinical Policy Officer 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.
- Communicating any new or reviewed clinical documents via the Trust bulletin and Specialty/ Divisional Governance Meetings.
- Providing advice and support to lead authors on aspects of this procedure.
- Providing status reports to Specialties and Divisions using the RAG system as described in section 5.15.
- 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) using the RAG system as described in section 5.15.

- See also process flowchart on page 4
- See also the following additional author resource: [Guidance notes and information for authors of clinical documents](#)

5.1 Introduction

Documents should be internally produced/ developed or reviewed (rather than opting to use externally produced documents) and be presented in the relevant up-to-date trust approved template – this helps with the required format, reputation/ trust image and consistency for the user. It also enables operationalisation of external guidance such as national/ professional body guidelines which in turn helps ensure they are fit for purpose for use within the Trust for staff to follow and implement.

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’.

Documents should ideally 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.

Furthermore, all documents being newly developed or going through the planned review process should be approved by a trust committee or group. (For exceptions see 5.6 further below).

5.2 Developing new documents

Clinical documents being newly developed, whatever the type, must be developed in the correct and most up-to-date template. Much of the information in this procedure is pertinent to the development of new documents but you are starting from scratch with a ‘blank’ template – please take time to read the other sections of this procedure to further help. 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 usually be sent a copy of the master editable WORD file (usually held in the central repository) 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. If a copy of the master file has not been received for the purpose, it can be requested.

The above document templates have appropriate front/ governance 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 – some documents may require an ‘Education and Training’ section, some may not; some may require a ‘Monitoring Compliance and Effectiveness’ section, some may not; and some may require both etc.

As with policies, the footer must display the document title, version, issue date and page numbers using the format Page X of Y using 8pt Arial (see footer of this procedure).

Apart from the front/ governance 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.

Narrative should be left aligned or justified but remain consistent throughout.

If thought helpful to the reader, use space to separate different aspects of the clinical document by starting the next section on the following page/ a fresh page.

Where people are identified within the document, job titles should be used. But on the front/ governance sheet of the document it is useful to have both the job title(s) and the name(s) of the lead author/ co-author(s). Where specific individuals are consulted, it is good practice to include their name next to their role or their initials.

If using appendices, each one must start at the top of the following page/ a fresh page. All appendices must be referred to from the main body of a document (usually but not exclusively from the narrative/ details section) and must also be attached to the end of the document (including those for recording staff information and filing in staff records). 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 (see section 5.5 below for additional guidance on this document type).

Lead authors are advised to view the various document types on the intranet to help with the layout/ format of the one they are developing or reviewing.

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 – *this is not an extension of the review date. An up-to-date governance process needs to be evidenced so a document can be given a new 3 year review date. (And where necessary a new lead author identified).*

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/ governance page of each 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.

The method of consultation is optional; however, it is advised that communication channels such as email or minuted meetings are used in the first instance as these have an audit trail. When circulating documents, give a timescale for responses and follow up key individuals as necessary. Phone calls and corridor conversations are not advised as these are ambiguous (although these can be backed up with a confirmatory email).

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. (For exceptions see 5.6 further below).

For further information on the consultation and approval of clinical documents see the following author resource:

- [Trust Committees/ Groups to Submit Clinical Documents for Consultation and/ or Approval - Guidance and Information for Authors](#)

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	Governance Arrangements Described In:	Department/ Group Responsible	Contact for additional advice
Patient Information Leaflets	Patient Information Development and Distribution Policy	Communications Team	Patient Information Officer
Nursing Documentation/ Forms including Core Care Plans	Development, Approval and Implementation of Admission / Assessment / Monitoring Documentation, Core Care Plans and Care Pathways SOP (for N,M&AHP documents)	Documentation Group	Corporate Matron
Medical Documentation/ Forms	To Be Confirmed	Medical Records Advisory Group (MRAG)	MRAG Chair

It is the author's responsibility to ensure that any documents which fall into the above types are approved by the appropriate channel. The responsibility for the above document types usually falls outside the approval process of the committee/group assigned to approve the respective procedure, guideline, SOP or pathway with which they are associated – advice can be sought as above.

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 Medical Director).

5.7 Equality Impact Assessments

All documents should not discriminate against individuals directly or indirectly on the basis of gender, colour, race, nationality, ethnic 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

- 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 (or someone nominated by them) should submit the document for issue. It should be accompanied with any separate appendices/ associated documents (as outlined above). You should send the document(s) along with the minutes of the meeting where the document was approved or for expediency if the minutes are not available you should ask a band 7 or above manager to provide the assurance the document has been discussed and approved. This could be your Quality Governance Lead or your Specialty Clinical Governance Lead for example.

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). Review dates are always in the format of 'Month Year' and are deemed to be the last day of the month recorded (e.g. May 2023 means 31st May 2023).

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

Much of the information in this procedure is pertinent to the review/ early review and amendments of clinical documents, but you are starting with a copy of the current document – please take time to read the other sections of this procedure to further help with the requirement. If needed contact the Library and Knowledge Services for help with an up-to-date literature search for your subject matter.

Planned reviews are triggered 3 months prior to the review dates of documents. If not already in progress, the process facilitator will initiate the process at this time by releasing a copy of the current document and will subsequently send at least one further reminder, followed by an overdue reminder if not completed within the timescale.

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. Ideally, such mid-lifecycle amends must be approved by the relevant trust committee/ group and minuted accordingly. However, for clinical documents, where there is no impact on practice, it may be possible to agree minor amends directly with the Clinical Policy Officer – such amends will be identified on documents using a change to version control and completion of the amendment table. 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).

As mentioned in the consultation/ approval section above, 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 will also help when summarising the changes in the amendment table.

Documents must not have electronic track changes or electronic comments in them when submitted for issue as the process facilitator is not responsible for accepting/ removing them. However, the process facilitator may change different coloured type to black and/ or remove any highlight.

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 process facilitator so the document can be archived/ removed for use.

5.12 Rolling on review dates

A document review date can be 'rolled-on' only if the current 'full' version was given a review date of less than 3 years following month of approval. For a document to have its review date rolled-on, it must be confirmed by the author that there are no amends to be made. A document review date can be 'rolled-on' several times to the maximum of 3 years following the month of approval. After that time, if necessary, the document would then need to go through the extension process as described below.

5.13 Extensions to Review Dates

A pragmatic approach must be undertaken if requesting the extension of a document review date. This will only be permitted in exceptional circumstances with a valid reason and on a case-by-case basis. Extensions should be agreed and minuted by the approval committee/ group where any patient safety issues/ risks may be highlighted. If unsure about the requirements, authors are advised to liaise with the Clinical Policy Officer.

5.14 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.

5.15 Status reporting

Status reports for clinical documents are provided (usually monthly) for the specialties/ divisions using the following RAG system:

Red	Past Review Date	Amber	Due within 3 months	Green	In Date
-----	------------------	-------	---------------------	-------	---------

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)