St Helens and Knowsley Teaching Hospitals NHS Trust

Procedural Document Development Policy

Version No: 4

Document Summary:

This policy defines the standard approach to drafting procedural documents on behalf of the Trust. It provides a framework within which procedural documents are managed and explains the roles, responsibilities and process for the development, review, approval, dissemination, version control and monitoring of all Trust procedural documents.

Document status	Approved	
Document type	Policy	Trust-wide
Document number	STHK0001	
Approving body	Executive Committee	
Date approved	03/12/2020	
Date implemented	04/12/2020	
Review date	31/12/2023	
Accountable Director	Director of Nursing, Midwifery & Governance	
Policy Author	Deputy Director of Governance	
Target audience	All staff who produce procedural documents	

The intranet version of this document is the only version that is maintained. Any printed copies should therefore be viewed as "uncontrolled", as they may not contain the latest updates and amendments.

Document Control

Section 1 – Document Information	
Title	Procedural Document Development Policy
Directorate	Quality and Risk
Brief Description of amendments	
Full review and minor formatting changes throughout. Document control sheet updated. Added requirement to consult with all the Trust's services, including primary care and community where applicable. Clarified process where consultation is required if there have been significant changes/updates. Updated job titles where applicable.	
Does the document follow the Trust agreed format?	Yes
Are all mandatory headings complete?	Yes
Does the document outline clearly the monitoring compliance and performance management?	Yes
Equality Analysis completed?	Yes

Section 2 – Consultation Information* *Please remember to consult with all services provided by the Trust, including Community & Primary Care where applicable			
Consultation Completed	☐ Trust wide ☐ Local ☐ Specific staff group		
Consultation start date	N/A	**Consultation end date**	N/A

Section 3 – Version Control		
Version	**Date Approved**	**Brief Summary of Changes**
4	03/12/2020	3 yearly review of document Amendments listed in section 1 above
3	09/11/2017	3 yearly review of document • Template changes • Review of supporting documents • Review of checklist • Title amendment
2	12/06/2014	Policy rewritten & title amended
1	14/04/2011	Policy drafted

Section 4 – Approval			
Document Approved	☐ Approved		
Assurance provided by Author & Chair	☐ Email with Chairs approval		
Date approved	03/12/2020	**Review date**	November 2023

Section 5 – Withdrawal	
Reason for withdrawal	☐ No longer required ☐ Superseded

Assurance provided by Author & Chair	☐ Minutes of Meeting ☐ Email with Chairs approval
Date Withdrawn:	Click here to enter a date.

St Helens and Knowsley Teaching Hospitals NHS Trust

Quick Reference Guide

This guide is to be followed for all policies, guidelines, procedures, standard operating procedures (SOPs) and protocols. If you have any queries please contact – documentcontrol@sthk.nhs.uk

Is the document new or being reviewed?

New document
Check if the document already exists on the Trust intranet or if there is a similar document that could be revised to meet the need.

When creating a new document, ensure that approval is gained from the appropriate manager

Create document using Trust template

Document enters the consultation process

- **Author to send word version of document to documentcontrol@sthk.nhs.uk stating the document is for consultation**
- **The author must send document to relevant staff groups for comment**
- **Relevant manager must review the equality analysis section of the document**

The Document Control Team will place the document on intranet for 2 week consultation period, unless longer is requested. Any comments/suggestions and/or amendments will be sent directly to the author

Complete the approval process

- **Author to send final version of document to the relevant Approving Body for final approval.**
- **Author to attend the meeting to present their document and have the checklist signed off by the Chair of the Approving Body.**

Once the document has been approved, the author must send the final version in a word document with evidence of approval to documentcontrol@sthk.nhs.uk. Stating the following:

- **That the document is new and if it supersedes any old documents**
- **What department/category the document comes under on the intranet**

Review document
Update information and check that it is in the correct Trust format/template

Is further consultation required, for example, significant changes/updates

Yes → Document enters the consultation process

No → Check below guide in order to establish process to follow

Type	Definition	Process
Minor changes to content	Changes that do not impact on practice/ staff responsibilities	Staff Information – approving body, chair approval. Patient Information – clinical lead approval.
Changes to clinical guidelines	Changes to local clinical guidelines	Approval by specialist area clinical experts
Major changes	Changes that impact practice or staff responsibilities. Full changes to content	Full consultation and approval process
No longer required	Document is no longer required due to processes or document superseded	Staff information – approving body, chair approval. Patient information – clinical lead approval.

Once the document has been approved, the author must send the final version in a word document with evidence of approval to documentcontrol@sthk.nhs.uk. Stating the following:

- **That the document has been reviewed, what the changes are, version update and if it supersedes any old documents**
- **What department/category the document comes under on the intranet**

The Document Control team will then:

- **Save the information centrally**
- **Upload the information to the intranet**
- **Update the Trust database**
- **Advise staff of new/updated document via monthly Team Brief**

Contents

1. Scope

This policy is to be used by all staff responsible for the development of a procedural document. It provides a framework within which procedural documents in the Trust are managed and explains the roles, responsibilities and process for the development, review, approval, dissemination, version control and monitoring of all Trust procedural documents.

2. Introduction

Good policy management underpins all clinical and non-clinical processes within the Trust to ensure they are consistent, effective and safe. This policy sets out the Trust requirements when developing, modifying or updating written procedural documents to ensure consistency in quality and compliance. All Trust procedural documents must follow the standards and format set out in this document.

3. Statement of Intent

The Trust aims to ensure, through this policy:

- All procedural documents follow a standardised approach that reflects the needs and objectives of the Trust and conforms to any external requirements or standards
- All documents are realistic in their content and requirements so that they are practical to follow and implement
- Compliance with procedural documents is monitored and action taken as required

4. Definitions

- Strategy: A long term plan of action (usually covering 3 – 5 years) with a defined intended outcome
- Policy: A set of governing principles providing a basis for consistent decision-making and resource allocation
- Guidance/guideline: A description of recommended action(s) or 'best practice' to inform a way of working. Guidance is not necessarily mandatory
- Procedure/standard operating procedure (SOP)/protocol: A set of mandatory or necessary actions, steps or requirements that must be followed by staff to achieve a particular aim/outcome
- Local: The term 'local' is used to refer to procedural documents that only apply to certain departments, rather than across the Trust
- Trust wide: refers to documents that relate to all areas across the Trust

5. Duties, Accountabilities and Responsibilities

5.1. Trust Board

The Trust Board is accountable for the management of all procedural documents and has delegated authority for approval of Trust documents through the corporate governance structure.

5.2. Chief Executive

The Chief Executive has overall responsibility for the strategic and operational management of the Trust including ensuring that Trust procedural documents comply with all legal, statutory and good practice guidance requirements.

5.3. Executive Directors

Every procedural document must have a lead Executive Director, who is identified within the document control process. The Executive Director is:

- Responsible for overseeing the work of the lead author(s)
- Accountable for the procedural document

5.4. Document Author(s)

The Author is responsible for writing, reviewing and auditing the procedural document in accordance with this policy and its supporting documents (see Quick Reference Guide). The author(s):

- Must ensure they follow the latest Trust Policy and format when updating and revising procedural documents
- Is responsible for submitting the procedural document for approval via the appropriate channel
- Responsible for ensuring the procedural document is reviewed within the required timescale and that it is valid and in date at all times
- Is responsible for ensuring the appropriate consultation has taken place, including Trust-wide consultation and relevant staff/stakeholder consultation, including subject matter experts where appropriate
- Should attend the relevant approving body to discuss their document and update on any changes for approval
- Is responsible for sending a word version of the policy, with evidence of approval to **documentcontrol@sthk.nhs.uk** for upload
- Must ensure that any amendments to the document are maintained and briefly outlined in the version control section of the procedural document
- Must ensure that any forms in the document are made available separately on the intranet for staff to access – all forms must be sent to **documentcontrol@sthk.nhs.uk** for uploading to the intranet as supporting documents
- Is responsible for completing the Equality Analysis
- Must update Document Control when requested providing status updates for their document when the document is due for review.
- Must ensure that monitoring compliance and performance management of the documents are met and audited as stated

5.5. Head of Patient Inclusion and Experience

Responsible for advising and supporting staff in the completion of the equality analysis (where required)

5.6. Deputy Director of Governance

Has overall responsibility for the processes in place for the administration and dissemination of procedural documents.

5.7. Quality and Risk Administrative Team

- Responsible for ensuring efficient and robust processes are in place for the administration and dissemination of procedural documents; this includes archiving old versions of documents
- Will hold a central database for all procedural documents and provide monthly updates to the Policy Governance Group regarding the status of Trust/local procedural documents
- Will provide monthly updates to Clinical Effectiveness Council, Patient Safety Council and Patient Experience Council – this will include any documents that are over their

review date or are due for review in the next 3 months (that are approved by that specific Council)
- Responsible for checking documents to ensure they are formatted correctly and signed off as approved before uploading
- Responsible for uploading approved documents/consultation documents to the Trust intranet pages that meet the requirements in this policy
- Provide a monthly update to the Deputy Director of Governance regarding the procedural documents uploaded for monthly Team Brief
- Keep an accurate list of all procedural documents and their StHK document numbers
- Ensure the central archive for procedural documents is efficient and up to date at all times
- Ensure consultation documents are disseminated to staff via IT Global Email and that staff are advised of the approved documents through Team Brief

5.8. Governance Meeting Administrator(s)
Responsible for contacting Document Control to request updates on procedural documents that are due at their meeting. The request should be in correlation to the frequency of the meeting. This will include any documents that are over their review date or the review date is due to expire in the next 3 months.

5.9. Line Managers
Responsible for ensuring that all staff comply with Trust and local procedural documents.

5.10. All Staff
All staff are responsible for ensuring they are familiar with Trust procedural documents and local procedural documents.

5.11. Approving Bodies and Chairs of the Approving Bodies
Members of approving bodies are responsible for reviewing all procedural documents prior to providing final approval. Members' comments and suggestions will be minuted and made clear to the author for consideration.

Approving body Chairs are able to approve minor changes, with no material impact to the content of the published documents without the need for approval by the full approving body.

6. Process

6.1. Process for Writing a New Procedural Document
This section will advise staff on how to create a new procedural document and the steps to follow:
- Check if the document already exists on the Trust intranet or if there is a similar document that could be revised to meet the need, using the search function
- Use the standard Trust style and format – available on the Trust intranet pages. The author must ensure that the mandatory sections are completed (outlined in the Trust Procedural Document Development Template)
- Author to follow the consultation process (see section **6.3 for consultation process**)
- Once the consultation period has finished (and any relevant amendments made), the author must send to the relevant approving body for approval
- The Author must attend the meeting to present their document

- Once the document has been formally approved the author must send a word version of the document with evidence of approval to documentcontrol@sthk.nhs.uk for upload to the intranet

6.2. Process for Reviewing an Existing Procedural Document

The below table advises on the process for authors to follow depending on the type of amendment required to the document.

Type of Amendment	Definition	Process
Review Date	Full review of document when the review date is due to expire, ensuring the format is still up to date and that content within the document is accurate and up to date since the last review.	Full review requires approval by the approving body see quick reference guide for step-by-step instructions. Version control section to be updated N.B. if there are only formatting changes and no content changes, this document can be approved outside of the approving body by the Chair of the meeting.
		Version update example: From version 1 to version 1.1
Minor Changes	These are changes which do not impact on practice or staff responsibilities. They normally relate to changes of staff titles, committee names, grammar etc.	The Lead Executive Director will agree the amendments and the approving body Chair will approve the new version. The version control number is updated, the document signed and version control updated. Approving body members are notified of changes.
		Version update example: From version 1 to version 1.1
Changes to clinical guidelines	Changes to local clinical guidelines	Approval by specialist area clinical experts
Major Changes	Changes which impact on practice or staff responsibilities e.g. new responsibilities, changes to content, forms etc.	Full review requires approval by the approving body see quick reference guide for step by step instructions. Version control section to be updated and document signed
		Version update example: From version 1 to version 2
No Longer Required	Document is no longer required due to changes in internal/external processes or document superseded	Procedural document author to seek approval from the Lead Executive Director and completion of withdrawal of document section. Approving body notified.
		Version update example: From version 1 to version 1 – withdrawn (for archive purposes)

6.3. Consultation Process

All new procedural documents or where there have been significant changes require a period of consultation, with subject matter experts and either Trust-wide or with relevant parties. Details of the consultation should be included on the document control sheet. The Author should email a word version of the document to Document Control and request that the document is placed on the intranet for consultation. The consultation period is 2 weeks, unless otherwise requested. Authors should also ensure that relevant subject experts have been consulted, where applicable, and that the document is shared with the relevant staff, groups, service users etc., including union representatives for review. The Equality Analysis Tool should be completed prior to the document being sent out for consultation.

6.4. Mandatory Sections

All sections within the template are mandatory and must be completed in full. There are detailed explanations provided within the Procedural Document Development Template available on the intranet.

6.5. Style and Format

All procedural documentation must be written in a style which is concise and clear, using unambiguous terms of phrase and language. If such documents are intended for the general public, consideration must be given to the aptness of producing them in an alternative format or in a different language in line with the Policy for the Production of Written Patient Information and Accessible Information Policy.

The Trust Procedural Document Development Template has the style and format set out for authors for ease and efficiency. Hyperlinking will already be included for mandatory headings and there is a separate hyperlink/bookmark guide to help staff to hyperlink any additional information and a separate contents page guide to help staff.

The following style and formatting must be used where appropriate. The requirements below facilitate reading for those with visual impairment.

Style & formatting area	Required format
Heading font	Arial 12, bold and numbered
Body text - font	Arial 11 or 12, single line spacing or 1.15 spacing
Tables - font	Arial 10 or 12
Justification	Align left
Spacing	Line spacing as above with 6pt before and after paragraphs
Trust name and logo	On first page
Footers	Policy name and page numbers, Arial 8
Margins	1-2 cms left/right/top/bottom
Watermark	Include DRAFT until such time as approved
Capitals	Do not use block capitals, except for abbreviations
Underlining	Do not use underlining and use bold for emphasis if required
Italics	Do not use italics

7. Training

There is no mandatory training for this policy. Any member of staff who requires training/ guidance in order to fulfil the criteria for the development and review of procedural documents as laid down within this policy should contact their line manager in the first instance. If further assistance is required staff should contact the Deputy Director of Governance.

8. Monitoring Compliance

The Trust Policy Governance Group will oversee the monitoring of compliance with any procedural document and monthly ad hoc reviews will be scheduled.

8.1. Key Performance Indicators (KPIs) for this Policy

No.	Key Performance Indicators (KPIs) Expected Outcomes
1	Procedural documents on the intranet are in date
2	Procedural documents on the intranet are in the correct style and format (according to approval date)
3	Procedural documents contain all the appropriate sections
4	All procedural documents are subject to analysis of the effects on equality
5	Consultation process is appropriate
6	Approval process is appropriate
7	Archive process is appropriate

8.2. Performance Management of the Policy

Minimum requirement to be monitored	Lead(s)	Tool	Frequency	Reporting arrangements	Lead(s) for acting on recommendations
Audit of at least 3 procedural documents	Deputy Director of Governance /Policy Governance Group	Random review of procedural documents to be agreed by the Policy Governance Group	Monthly review of 3 random documents	Policy Governance Group	Author(s) Policy Governance Group Members
95% of procedural documents on the intranet are within review date	Quality & Risk Office Manager/ Deputy Director of Governance	Monthly report to be submitted to Policy Governance Group showing compliance	Monthly	Policy Governance Group	Author(s) Policy Governance Group Members Lead Executive Director(s)

9. References/Bibliography

No.	Author	Year	Title	Edition	Place of Publication	Publisher
1.	Parliament	2010	Equality Act	/	London	The Stationery Office

10. Related Trust Documents

Other related documents to this Policy are:

No.	Related Document
1.	Corporate Records Management Policy St Helens and Knowsley Teaching Hospitals NHS Trust
2.	Equality & Human Rights Policy St Helens and Knowsley Teaching Hospitals NHS Trust
3.	Policy for the Production of Written Patient Information St Helens and Knowsley Teaching Hospitals NHS Trust

11. Equality Analysis Form

The screening assessment must be carried out on all policies, procedures, organisational changes, service changes, cost improvement programmes and transformation projects at the earliest stage in the planning process to ascertain whether a full equality analysis is required. This assessment must be attached to all procedural documents prior to their submission to the appropriate approving body. A separate copy of the assessment must be forwarded to the Patient Inclusion and Experience Lead for monitoring purposes Cheryl.farmer@sthk.nhs.uk. If this screening assessment indicates that discrimination could potentially be introduced then seek advice from the Patient Inclusion and Experience Lead. A full equality analysis must be considered on any cost improvement schemes, organisational changes or service changes that could have an impact on patients or staff.

Equality Analysis				
Title of document/ proposal/service/cost improvement plan etc.:	Procedural Document Development Policy			
Date of assessment	30th November 2020	**Name of person completing assessment / Job Title**:	Anne Rosbotham-Williams	
Lead Executive Director	Director of Nursing, Midwifery & Governance		Deputy Director of Governance	
Does the proposal, service or document affect one group more or less favourably than other group(s) on the basis of their:			**Yes /No**	**Justification/evidence and data source**
1	Age		No	
2	Disability (including learning disability, physical, sensory or mental impairment)		No	
3	Gender reassignment		No	
4	Marriage or civil partnership		No	
5	Pregnancy or maternity		No	
6	Race		No	
7	Religion or belief		No	
8	Sex		No	
9	Sexual Orientation		no	
Human Rights – are there any issues which might affect a person's human rights?			**Yes /No**	**Justification/evidence and data source**
1	Right to life		No	
2	Right to freedom from degrading or humiliating treatment		No	
3	Right to privacy or family life		No	
4	Any other of the human rights?		No	
Lead of Service Review & Approval				
Service Manager completing review & approval Job Title:			Anne Rosbotham-Williams	
			Deputy Director of Governance	

12. Appendix 1 – Approving Bodies Guide

Category		Accountable Director	Approving body
Trust Wide			
Corporate	General	Appropriate Director relating to the category e.g. Procedural Document Development Policy, Director of Nursing, Midwifery & Governance	Quality Committee or Executive Committee
	Quality & Risk/ Governance		Quality Committee or Executive Committee or any relevant Council
Clinical	Infection Control	Director of Nursing, Midwifery & Governance	Patient Safety Council
	Medicines Management /Pharmacy	Medical Director	Patient Safety Council/Clinical Effectiveness Council/ Drugs & Therapeutics Group
	General/ Medical/ Surgical	Medical Director or Director of Nursing, Midwifery & Governance	Clinical Effectiveness Council or Patient Safety Council
Operational		Director of Operations & Performance	Operational Governance Meeting
Safeguarding		Director of Nursing, Midwifery & Governance	Patient Safety Council
Human Resources		Director of Human Resources	Workforce Council
Information Governance		Director of IT	Information Governance Council
Health, Safety & Security/ Estates & Facilities		Director of Estates & Facilities	Risk Management Council/Quality Committee
Paediatrics		Medical Director or Director of Nursing, Midwifery & Governance	Patient Safety Council/Patient Experience Council
Maternity		Medical Director or Director of Nursing, Midwifery & Governance	Clinical Effectiveness Council/Patient Safety Council/ Maternity Risk Management Group
Emergency Planning		Director of Nursing, Midwifery & Governance	Risk Management Council
Research, Development & Innovation		Medical Director	Clinical Effectiveness Council
Finance		Director of Finance	Audit Committee/Finance Committee/Charitable Funds Committee
Clinical Support		Medical Director or Director of Nursing, Midwifery & Governance	Clinical Effectiveness Council/Patient Safety Council/ Patient Experience Council

Category		Accountable Director	Approving body
Local			
Surgical	General	Divisional Medical Director SCG/Assistant Director of Operations/ Appropriate Clinical Director	Surgical Care Quality Governance Group
	Speciality Specific	Divisional Medical Director SCG/Appropriate Clinical Director	Speciality Governance Meeting/Surgical Care Quality Governance Group
Medical	General	Divisional Medical Director MCG/Assistant Director of Operations/Appropriate Clinical Director	Medical Care Integrated Governance & Quality Group
	Speciality Specific	Divisional Medical Director MCG/Appropriate Clinical Director	Speciality Governance Meeting/Medical Care Integrated Governance & Quality Group
Patient Access	General	Divisional Medical Director/Assistant Director of Operations/Appropriate Clinical Director	OPD Operational Meeting
	Speciality Specific	Divisional Medical Director/Appropriate Clinical Director	OPD Operational Meeting/Speciality Governance Meeting
Paediatrics		Divisional Medical Director/Medical Director or Director of Nursing, Midwifery & Governance/ Clinical Director	Paediatrics Clinical Governance Group/Trust Paediatric Surgical Group
Maternity		Divisional Medical Director / Medical Director or Director of Nursing, Midwifery & Governance / Clinical Director	Maternity Risk Management Group
Clinical Support Services		Divisional Medical Director CSS / Assistant Director of Operations/Appropriate Clinical Director	Clinical Support Services Governance Group
Pharmacy / Medicines Management		Medical Director/Chief Pharmacist	Drugs & Therapeutics Group/ Medicines Safety Group (Patient Safety Council also for any safety related documents)

This list is not exhaustive; policy authors who are not clear about the appropriate committee/council etc. to submit final document for approval will discuss with policy sponsor who will guide appropriately.