The Dudley Group
NHS Foundation Trust

Trust Headquarters
Russell's Hall Hospital
Dudley
West Midlands
DY1 2HQ

Ref: FOI-062023-000157

Date: 28/6/23

Address / Email:

Dear

Request Under Freedom of Information Act 2000

Thank you for requesting information under the Freedom of Information Act

2000. **Request**

I'm therefore emailing to ask if you would be able to send us a copy of your organisation's policy for developing, approving, reviewing and/or approving clinical guidelines. We will store these confidentially and analyse them to understand the different processes used across the NHS. We will not share them with anyone outside our research team, or identify organisations who supply policies.

Response

Please see attached document.
Names have been redacted but job titles have been left in

If you are dissatisfied with our response, you have the right to appeal in line with guidance from the Information Commissioner. In the first instance you may contact the Information Governance Manager of the Trust.

Information Governance Manager
Trust Headquarters
Russell's Hall Hospital
Dudley
West Midlands
DY1 2HQ
Email: dgft.dpo@nhs.net

Should you disagree with the contents of our response to your appeal, you have the right to appeal to the Information Commissioners Office at.

Information Commissioners Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Tel: 0303 123 1113
www.ico.org.uk

If you require further clarification, please do not hesitate to contact us.

Yours sincerely

Freedom of Information Team
The Dudley Group NHS Foundation Trust

The Dudley Group NHS Foundation Trust

PROCEDURAL DOCUMENT DEVELOPMENT & MANAGEMENT POLICY		
	Document Title:	**PROCEDURAL DOCUMENT DEVELOPMENT & MANAGEMENT POLICY** (including guidelines for developing Procedural Documents)
	Name of Originator/Author /Designation & Specialty:	[redacted] – Compliance Officer
	Director Lead:	Chief Nurse
	Target Audience :	All staff involved in developing, implementing, monitoring and reviewing a procedural document
	Version:	12.0
	Date of Final Ratification:	30 March 2021
	Name of Ratifying Director	[redacted] (Chief Nurse)
	Review Date	31/03/2024
	Registration Requirements Outcome Number(s) (CQC)	All CQC Fundamental Standards of Quality and Safety
	Relevant Documents /Legislation/Standards	N/A
	Contributors:	**Designation:** [redacted] – Deputy Director of Governance
	The electronic version of this document is the definitive version	

CHANGE HISTORY

Version	Ratification Date	Reason
1	Feb 2010	Policy Development
2	Sept 2010	Review of policy of the same name approved in Feb 2010
3	March 2012	Updated to review the development and management of all procedural documents to meet NHSLA standards.
4	May 2012	Minor amendments of title and review and recommendation process
5	Sept 2012	Minor amendments to clarify documentation development.
6	January 2013	Minor amendments to reference list
7	April 2013	Amendments to the Procedural Checklist
8	October 2013	Amendments to the template
9	May 2014	Removal of equality screening elements and changes to Board Committee meetings for ratification. Previous ratification dates apply.
10	Dec. 2014	Full review.

11	Sept. 2017	Full review and new framework for procedural document management
11.1	Dec. 2017	Minor amendment section 5.11
11.2	June 2018	Minor amendment to **Appendix 3**- colour coding added in yellow for any external documents that may come into Trust
12.0	March 2021	Full review including change in consultation and ratification process

A translation service is available for this policy. The Interpretation/Translation Policy, Guidance for Staff is located on the intranet under Trust-wide Policies.

Contents

THE DUDLEY GROUP NHS FOUNDATION TRUST

PROCEDURAL DOCUMENT DEVELOPMENT AND MANAGEMENT POLICY

1. INTRODUCTION

High quality organisational documentation is an essential tool of governance, required to support the achievement of strategic objectives, operational requirements and bring consistency to day to day practice. A common format and approved structure for such documents helps reinforce corporate identity, helps to ensure that policies and procedures in use are current and reflect an organisational approach.

2. STATEMENT OF INTENT/PURPOSE

The aim of this policy is to clarify the steps that must be taken to develop and secure approval for all new or reviewed strategies, policies, procedures or guidelines to be used within The Dudley Group NHS Foundation Trust (DGNHSFT).

This document details the organisational-wide processes and responsibilities for developing, ratifying, publishing and disseminating procedural documents.

The purpose of this policy is to:

- Ensure agreed practice is followed throughout the organisation, with regard to the development of approved procedural documentation
- Ensure all procedural documents are accessible to all relevant staff
- Promote consultation to ensure the content of procedural documents supports the highest standards of care, are well-researched, evidence-based and reflect the views of stakeholders
- Avoid duplication and ensure there is a genuine need for any new procedural documents
- Encourage ownership and accountability for procedural document development and implementation
- Achieve a standardised corporate style and format for procedural documents throughout the organisation, which supports document management, ensuring documents are up to date and reviewed appropriately
- Clarify the ratification routes of all procedural documents
- Confirm how databases and archives of all procedural documents are maintained

3. DEFINITIONS

For the purpose of this policy, the term “procedural document”-refers to (and this policy applies to) the following document types (**refer Appendix 1**):

Strategy: An overarching document that reflects the long-term plan designed to achieve particular goals or objectives of the organisation.

Policy: A high level statement of intent or set of principles with widespread application that provides a basis for consistent decision-making and resource allocation.

Procedure: Sometimes called a Standard Operating Procedure (SOP) or Protocol. A SOP is a series of related steps that are designed to accomplish a specific task in a specified chronological order. They describe how tasks or activities should be carried

out in order to achieve the highest standards possible, and to ensure efficiency, consistency and safety. SOPs are rigid statements/steps allowing little or no flexibility.

Guideline: Guidelines are systematically developed statements, which assist clinicians and patients in making decisions about appropriate and effective treatment for specific conditions.

Local clinical guidelines need to be developed when no national guidelines exist, or national guidelines exist but need adapting for local use taking into account local resources.

Within the DGNHSFT, guidance also relates to any diagnostic tools or management guides that assist in decision making.

Guidelines should relate to an overarching policy but may be stand alone.

Stakeholders: People with an interest in a procedural document and who can usefully contribute, comment and agree to the content of the document. They include specific committees, groups or forums, individual clinicians, whole departments, service users and their families. Consultation is a core requirement for all procedural documents.

Approved: Formal consultation by a group or committee that the document meets the required standards and may be put forward for ratification.

Ratification: Formal agreement by either a group or lead Director (dependent on type of document) to be used within the organisation and to be published on the Trust procedural document page**.**

4. ABBREVIATIONS

DIPC – Director of Infection Prevention and Control

5. DUTIES

5.1 Chief Executive

The Chief Executive as the accountable officer has overall responsibility for ensuring that appropriate arrangements are in place for the development of all procedural documents.

5.2 Directors

Directors have a collective responsibility as a Trust Board to ensure that the procedural document management processes are providing adequate and appropriate information and assurances.

They are responsible for ensuring they have pertinent Strategies, Policies, Guidelines and Standard Operating Procedures for their areas of responsibility and have assurance these are being complied with.

Additionally, they are accountable and have overall responsibility for ensuring that their Directorates/Divisions are developing and implementing robust procedural documents that are in date and comply with best practice and legislation. They are responsible for ensuring that they have structures in place to support this.

5.3 Director Lead (Director/Sponsor)

The Director Lead is the executive director of the Trust Board who is responsible for the management of a specific procedural document (policy) which sits within their sphere of responsibility/ accountability. A Director Lead will consider and approve the development of a procedural document and assign an author or group to develop it.

The Director/Sponsor is responsible for the timely formal ratification of the updated/ newly created policies or delegation for this responsibility; confirming any delegation to the Key Document Administrator to update the central records.

5.4 Directors, Chiefs of Surgery/ Medicine, Directors of Operations and Divisional Chief Nurses

Directors, Chiefs of Surgery/ Medicine, Directors of Operations and Divisional Chief Nurses are responsible for ensuring that their Divisions/Directorates have robust frameworks including meeting structures that enable identification, development, quality assurance, sign off and dissemination of all procedural documents and ratification of Standard Operating Procedures and Guidelines.

5.5 Clinical Directors/ Senior Managers/ Divisional Leads/ Line Managers

Clinical Directors/ Senior Managers/ Divisional Leads/ Line Managers are responsible for leading/contributing to the development of Strategies, Policies, Standard Operating Procedures and Guidelines, including; following the consultation process set out within this policy and ensuring the dissemination and implementation of all procedural documents.

They are responsible for the monitoring of compliance of their staff to the procedural document, and reporting of exceptions and adverse experiences/incidents of the document to those responsible as appropriate.

5.6 Trust Compliance Team

The Trust Compliance Team is responsible for:

- Supporting and advising staff on procedural document development
- Updating the Procedural Document Tracker for all procedural documents and uploading procedural document to the central document page on the HUB;
- For performing compliance checks on all procedural documents. Archiving any historical versions of each document within the relevant section of the Document Version Tracker;
- Providing monthly Directorate/ Divisional procedural document reports identifying all procedural documents that have been ratified in the previous month and the position of procedural documents and projection of this position for the next six months.

5.7 Document Originator/Author

The document author(s) are responsible for drafting procedural documents in the format detailed in the Procedural Document Development Guideline and ensuring that draft documents are circulated for consultation with all relevant staff, groups and key stakeholders. Once consultation has been completed they are responsible for submitting the document for ratification (policies to the Key Document Administrator and guidelines and SOPS to Divisional Governance/Speciality group).

The procedural document author(s) is responsible for reviewing the document, when legislation / standards change, ensuring it's amended as required within the review

timeframe and the distribution of the final ratified document to all staff it applies to (stakeholders).

The author is responsible for the development and delivery of a communications plan to disseminate, ensure staff are aware, trained or competent to work in line with the procedural document.

5.8 All Trust Employees (including agency and bank staff).

Every member of staff may contribute to the development of strategy, policy, procedure and guidance as per the consultation process set out within this document. Staff are responsible for following all applicable policies, procedures and guidelines and reporting any adverse event to their line manager. Staff should know how to access all Trust procedural documents.

5.9 Specialist Groups

Specialist Groups are responsible for evidence based contribution and review of documents as part of the consultation and drafting process. The specialist remit of the groups will be defined by their terms of reference. Specialty Groups (with a reporting line to a Committee) are responsible to undertake challenge, check and ratification of specialty specific guideline or standard operating procedure.

5.10 Board of Directors

In some cases the Board of Directors may be asked to formally ratify a Policy if there is an urgency/requirement for this.

5.11 Quality and Safety Committee

The Quality and Safety Committee will receive a bimonthly assurance report providing an overview of all ratified procedural documents and any actual or potential risks of compliance to the timely review and development of procedural documents.

5.12 Board Committees

The Board Committees will receive Trust strategies which sit within their terms of reference they will review, challenge and ratify. They may receive policies as part of the consultation process

5.13 Divisional Governance Groups

Divisional Governance Groups are responsible for ensuring that all operational standard operating procedures and guidelines meet the requirements of the Procedural Document Development Guideline that they comply with best practice and legislation, are fit for purpose and that adequate consultation has taken place to validate content (Specialty Groups/Specialists who will have confirmed their fitness for purpose and evidence base) prior to sign off / ratification.

The Divisional Governance Groups will receive a monthly procedural document position report and drive compliance or hold to account teams or individuals to undertake reviews within set time scales

6. DEVELOPMENT OF PROCEDURAL DOCUMENTS

6.1 Stage 1 – Identification of need

Initial consideration must always be to review documents that are currently in place within the Trust to determine whether the requirements are met in an existing document or whether there is a document that can be amended.

6.2 Stage 2 – Obtain Director sponsor approval

All policies are owned by the Board and as such, each has a director lead who acts as the sponsor when considering the development of a new policy. The director lead for a policy will also identify the person / group to author the policy.

When considering developing a new guideline or SOP, the sponsor would be the Clinical Lead / Manager for the specialty concerned.

6.3 Stage 3 – Developing the document

Procedural documents will be developed following the Trust format (detailed in the Procedural Document Development Guideline). There are no alternative formats to this. Documents should be created using evidenced based documentation and knowledge; library resources are available as required.

The colour banding strip on each document template will denote the type of procedural document for ease of recognition (see **Appendix 3**).

6.4 Stage 4 - Consultation Process:

Who to Consult

All procedural documents will need consultation with relevant stakeholders to ensure the accuracy and quality of the procedural document and facilitate effective implementation when ratified. Consultation may be via face-to-face informal discussions, formal meetings, email or paper distribution.

Consultation must include all teams, specialists, departments and groups who are affected by the document as well as individuals who can validate the content as applicable:

- **Lead director, specialty lead, managers of the service/specialty/ department**
  The managerial lead of the document, to enable assessment of the impact of the document, financial, to resources, Trust/service requirements and delivery.
- **Individuals**
  Employees, where the content of the document impacts on their practice, care pathways or specialty to consider the documents implications and confirm if this is practical and possible.
- **Group/ Committee Consultation**
  Group/ Committee consultation where there is a subject related relevant Group or Committee who are required to consider the document's content for accuracy and potential impact e.g. Fire Standard Operating Procedure to the Health, Safety and Fire Assurance Group, finance policies to Finance and Performance Committee
- **Clinical or Specialists in the field of which the document relates**
  Where there is a relevant clinician, specialist or specialist group e.g. DIPC, Infection Control Matron and Infection Control Group. The draft document must be presented and agreed as robust, accurate and relating to best practice.
- **Pharmacy**

If the document involves the prescription or use of medications, a pharmacy representative must be consulted to ensure accuracy of medication information and to determine whether Drugs and Therapeutics Committee review is required.

- **Electronic Patient Record**
  If the document involves changes to clinical documentation, a representative of the Digital Trust must be contacted to ensure that IT development needs are identified, and to determine whether the Digital Trust Clinical Approvals Group review is required.
- **Joint Negotiating Committee**
  As part of the Trust's commitment to employee involvement, draft and revised documents which have an impact on employees and their working lives (not just Human Resources (HR) documents) will be subject to consultation with the Joint Negotiating Committee (JNC) for 30 calendar days.

  The Human Resource Department will, on request, advise the manager responsible for developing a document whether consultation with employee representatives should be conducted.

- **Other Stakeholder Consultation**
  Consideration should be given to consultation with other facilities/PFI partners, HR and other interested parties that may have expertise dependent on the type of document being developed.

A document will not be accepted to be uploaded to the HUB by the Trust Compliance Team if full consultation has not been completed and recorded; or if any other part of the checklist, within the Procedural Document Development Guidelines is not satisfied.

All consultations will be recorded on the consultation form which must be completed in full identifying who has been consulted (there is an individual form for Strategies, Policies, Standard Operating Procedures and Guideline). This includes the full name of the individual (including designation) or name of the Committee/Group and the date they agreed the content of the document. When undertaking consultation by email, agreement with the document is only confirmed if it is received electronically or in writing, a non response cannot be included in the consultation.

If the document has been to a Group for consultation, individual members of the group in attendance when the document was discussed must be documented. The form must be submitted with the procedural document when requesting ratification, refer to Procedural Document Development Guideline for further details.

6.5 Stage 5 - Finalisation

Once the document has been through consultation and any required amendments have been made, the author must complete a final review of the document following the procedural document checklist prior to submitting or ratification.

6.6 Stage 6 - Ratification

Following successful consultation and finalisation check by the author, the procedural document checklist and the procedural document consultation form must be submitted to the ratifying group (standard operating procedures and guidelines) or Key Document Administrator (policies). Please note these differ dependent on the type of procedural document.

Standard Operating Procedure and Guidelines

The ratifying group reviews all documents ensuring that the document is fit for purpose and the content and format complies with this policy and the Procedural Document

Development Guideline. The group confirms/challenges there has been adequate consultation with appropriate stakeholders to ensure that the document reflects best practice, legislation, professional requirements, is evidence based and appropriate for the Trust.

Please note the expectation of the group members is not to be an expert on the subject of the document but is essential they have assurance of appropriate consultation with individuals/groups that do have this expertise and the document complies with Trust policy/guideline.

Once a document has been ratified the final version of the Procedural document and the Consultation Form will be submitted by the group chair or group administrative support to the Key Document Administrator (Trust Compliance Team) who will log the document, make a PDF version and upload on to the Hub.

The Board of Directors reserve the right to sign off all documents, at Board if required.

Policies

The Compliance team will review submitted policies ensuring that the document is fit for purpose and the content and format complies with this policy and the Procedural Document Development Guideline. They will ensure consultation with appropriate stakeholders has been undertaken and references have been confirmed as accurate.

On completion of the review the Compliance team will submit the policy to the Director sponsor to confirm agreement with content and ratification. Once the document has been ratified the final version of the policy will be logged, made into a PDF version and uploaded on to the Hub by the Compliance team.

6.7 Dissemination and Implementation process

6.7.1 Author

On final ratification of the procedural document the author is responsible for dissemination of the document to all stakeholders and raising awareness to the heads of service, senior managers and line managers. They are responsible for the development and delivery of a communications plan to disseminate, assure staff are aware, trained or competent to work within the procedural document

6.7.2 Heads of Service, Senior Managers and Line Managers

All newly ratified procedural documents highlighted in the procedural document report will be viewed by Directorate Teams to ensure that potential new procedures/ practices that could impact their team are identified.

Heads of service, senior managers and line managers of DGNHSFT must:

- Communicate new procedural documents to all relevant staff.
- Ensure that all relevant staff have access to, and understand, the procedural document and how it affects their role
- Have arrangements in place to identify any training and support required

The electronic version of the document held on the Trust central document intranet (HUB) database is the definitive version. If any paper copies are printed they must be stringently monitored via a controlled folder to ensure only the latest version is in use. This is the responsibility of the Manager of the service.

7. UPDATING AND REVIEWING PROCEDURAL DOCUMENTS

All procedural documents will be dated using the date of the decision by group/ individual that the document was ratified.

It is the responsibility of the author of the procedural document to ensure a review is conducted by the required date. All documents will have a review date of no longer than 3 years after the ratification date (with the exception of Strategies, which may have a review date of up to 5 years).

It may be necessary to review a document prior to the stated review date, for example as a result of the introduction of new legislation, new NHS requirements, clinical evidence or as a result of risk management reviews.

Policies in Existence Prior to the Approval of this Policy
Such policies do not need to be amended until either the existing review date or if an earlier review is required.

8. MINOR AMENDMENTS

Where minor changes only are made to a procedural document that do not impact on practice or patient care e.g. logos, titles, changes in group or committee names etc. or where it is identified practice contradicts safe practice e.g. dose of medication, these will still need to be approved by the ratifying Group/ Director but will not require resubmission of the Consultation form.

Any changes to clinical practice that impact on patient care MUST go through the formal ratification process and will require resubmission of the Consultation Form.

To assist those considering revisions to existing documents, changes **MUST** be highlighted in some way e.g. by use of track changes/yellow highlight.

9. ARCHIVING

When a new or reviewed procedural document is uploaded onto the HUB the old version will be archived with a version number, for ease of reference should they be required in future. The archive will be held in the shared directory administered by the Trust Compliance Team.

If an author considers that a document is out of date/obsolete and needs archiving, they must email the Key Document Administrator (Compliance Team) requesting the removal / archive. The email will be stored with the archive as evidence of the request.

10. EXTERNAL PROCEDURAL DOCUMENTS

External procedural documents identified to improve or support best practice are stored on the central document page on the HUB. These are uploaded to the HUB following identification of a Lead, addition of a front sheet and an agreed review date of 1-3 years. These will still be required to go through the consultation and agreement of adoption (ratification) by Trust.

11. JOINT PROCEDURAL DOCUMENTS DEVELOPED WITH OTHER ORGANISATIONS

Procedural documents that are developed jointly with other organisations will have a Trust front sheet, but it is accepted that the remainder of the document will have a different layout. The document will comply with all other aspects of this policy.

12. TRAINING/SUPPORT

Those responsible for developing and maintaining procedural documents may request advice from the Trust Compliance Team should they require support with the implementation of this policy or its supporting guideline.

13. PROCESS FOR MONITORING EFFECTIVE IMPLEMENTATION

	Lead	**Tool**	**Frequency**	**Reporting arrangements**	**Acting on recommendations and Lead(s)**	**Change in practice and lessons to be shared**
100% of Trust procedural documents meet the requirements of this policy and supporting guideline	Key Document Administrator	Review documentation format and adherence to policy on submission of final documentation to upload to the HUB	BI Monthly	Bi Monthly report to Quality & Safety Committee	Document Authors	Divisional governance meetings outlined in the procedural document report.
Notification of 100% of documents to be reviewed within 3 months of the review date	Key Document Administrator	Audit of Procedural Document Hub Page	BI Monthly	Bi Monthly report to Quality & Safety Committee	Document Authors	Divisional governance meetings outlined in the procedural document report.

14. EQUALITY

During the development or review of the Policy, consideration must be given to the actual or potential impact on equality. Due care is given to ensure that they do not contravene the article of the Human Rights Act 1998 or could be interpreted as containing any matters of a discriminatory nature, including but not limited to age, disability, sex, race, religion or belief, gender reassignment, marriage or civil partnership, pregnancy or maternity.

The Dudley Group NHS Foundation Trust is committed to ensuring that, as far as is reasonably practicable the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds.

15. REFERENCES

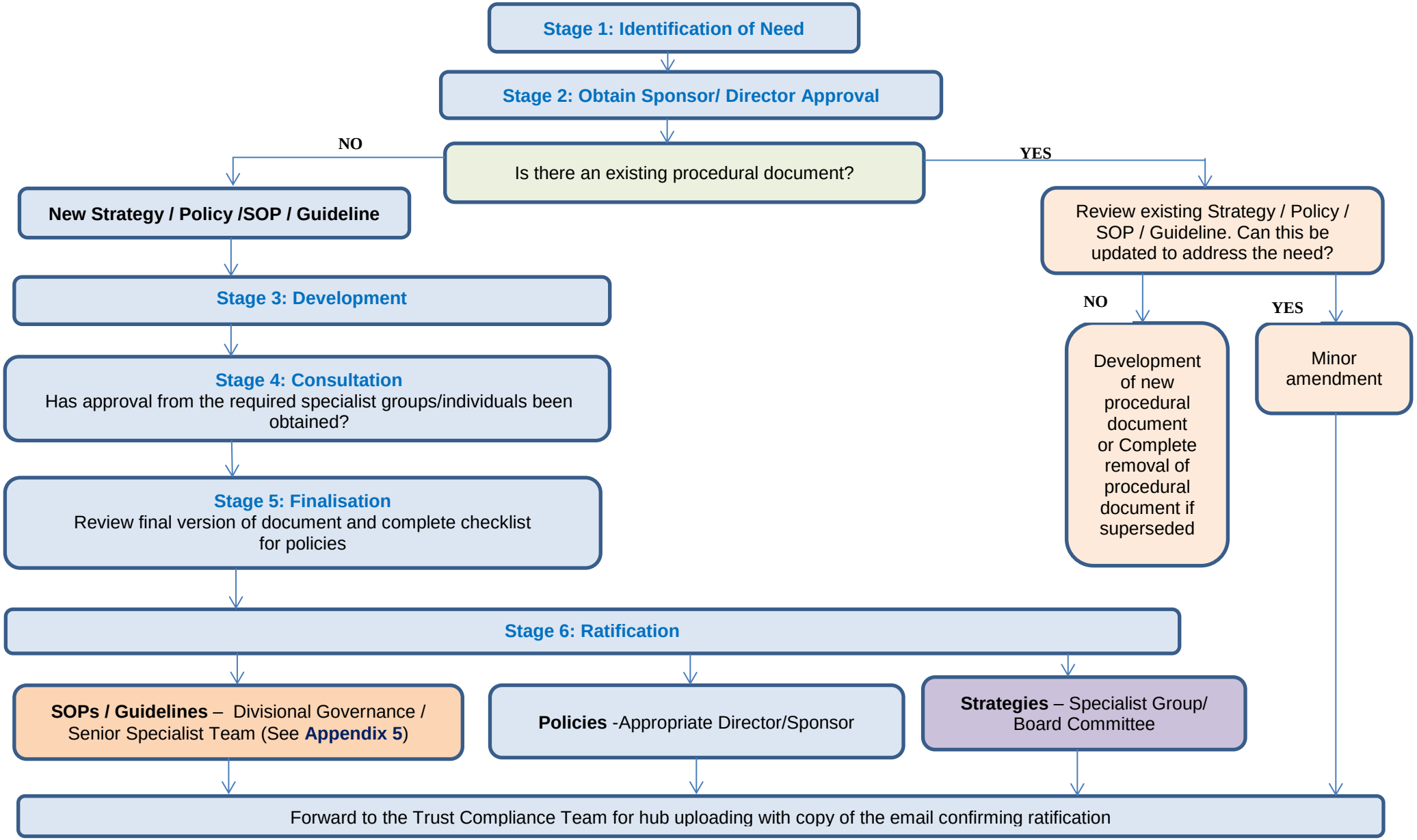
All references must be cited in full, using the Harvard referencing style. If you require any assistance the Trust Library Services will provide guidance and support.

APPENDIX 1

PROCEDURAL DOCUMENT TEMPLATE GUIDANCE

STRATEGY	POLICY	STANDARD OPERATING PROCEDURE (SOP)	GUIDELINE
DEFINITION			
An overarching document that reflects the long-term plan designed to achieve particular goals or objectives of the organisation. It can be supported by documents and procedures.	A high level statement of intent or set of principles with widespread application that provides a basis for consistent decision-making and resource allocation. The statement should inform staff of the justification for setting specific outcomes and the course to achieve such outcomes. Policies are underpinned by relevant evidence based procedures and guidelines and enable staff to make correct decisions, work effectively, and comply with relevant legislation and Trust aims and objectives. Policies must be approved by the relevant Trust Board Committee, and once implemented are mandatory for all staff.	A SOP is a series of related steps that are designed to accomplish a specific task in a specified chronological order. They are a set of detailed written instructions that identify the sequence of activities to be adhered to in the management of a specific clinical conditions or performance activity. They are more explicit and specific in their detail than guidelines and specify who does what, when and where appropriate, adhere to national standards for best practice (but this is not mandatory). They ensure efficiency, consistency and safety. SOPs are rigid statements/steps allowing little or no flexibility or variation. A Care Pathway follows the same process and documentation as a Standard Operating Procedure.	Guidelines are systematically developed statements, which assist clinicians and patients in making decisions about appropriate and effective treatment for specific conditions. Guidelines should relate and support how to achieve statements of an overarching policy but may be stand alone. They allow deviation from a prescribed pathway according to the individual circumstances and where reasons can be clearly demonstrated and documented.
CRITERIA			
	Ensures compliance with legal and statutory responsibilities / frameworks, these are generally global statements that govern a plan of action. May be clinical or non-clinical. They are constraining and deliberately set barriers with little or no expectation of variation and provide structured regulations that must be adhered to Are mandatory. It would prove very difficult to defend a case where a national, Trust or directorate policy has not been followed.	Lists tasks/steps in the order in which they should be carried out. Written in step-by-step detail, listing the tasks in the order in which they should be carried out, Detailed guidance how a particular task should be carried out. A step by step guide which someone not familiar with the work can follow. These are generally prescriptive and do not allow for interpretation under individual circumstances Are generally prescriptive, although there may be occasions when professional judgement will need to be used. May not always be mandatory but failure to follow a procedure may prejudice the successful defence of a case against the Trust.	Guidelines describe evidence based statements how and what to do These can relate to national, professional or specialty best practice e.g. NICE guidance, networks etc. that can assist in decision making Deviation from the guideline is acceptable if this can be justified
RATIFICATION			
Ratified by Board Committee of the Board	Relevant Director or nominated deputy	Divisional Governance Groups for operational areas, or appropriate Senior Management Team for all other areas	Divisional Governance Groups for operational areas or appropriate Senior Management Team for all other areas

Appendix 2 - Procedural Document Management Flowchart



APPENDIX 3

PROCEDURAL DOCUMENT COLOUR CODING

The colour banding strip to the left hand side of the front sheet on each document template will denote the type of procedural document for ease of recognition.

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Type of Document	Colour banding
Strategy	
Policies	
Procedure (including Standard Operating Procedures and Care Pathways)	
Guideline	
External Document	