

Policies, Procedures, Guidelines and Protocols

| Document Details | | |
|--|--|---|
| Title | Policy on the Development and Management of Procedural Documents (Strategies, Policies, Protocols and Guidelines) | |
| Trust Ref No | 1361-47743 | |
| Local Ref (optional) | | |
| Main points the document covers | This policy detail how documents must be developed, consulted upon, approved and published within the Trust | |
| Who is the document aimed at? | All staff who write procedural documents | |
| Author | Peter Foord, Corporate Risk Manager | |
| Approval process | | |
| Who has been consulted in the development of this policy ? | Executive team, chairs of committees and groups | |
| Approved by (Committee/Director) | Audit Committee | |
| Approval Date | 05/11/2018 | |
| Initial Equality Impact Screening | Yes | |
| Full Equality Impact Assessment | No | |
| Lead Director | Julie Thornby, Director of Corporate Affairs | |
| Category | Governance | |
| Sub Category | | |
| Review date | 01/11/2021 | |
| Distribution | | |
| Who the policy will be distributed to | Electronically to senior staff and available to all staff via the Trust website | |
| Method | Directors, approving committees | |
| Keywords | Policy, policies, procedures, documents, procedural documents, SOPs, Operating procedures, standard operating procedures, author | |
| Document Links | | |
| Required by CQC | No | |
| Other | | |
| Amendments History | | |
| No | Date | Amendment |
| 1 | September 2015 | Updated post and committee names Inclusion of SOP template |
| 2 | November 18 | Review, minor changes to names |
| 3 | | |
| 4 | | |
| 5 | | |

Policy on the Development and Management of Procedural Documents (Strategies, Policies, Procedures Protocols and Guidelines)

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1 Introduction

Strategies, Policies, Procedures, Protocols and Guidelines are an essential part in delivering the Trust objectives, and in the maintenance of high standards of care. This policy details how the Trust will ensure that these documents are fit for purpose.

2 Purpose

The purpose of this policy is to clarify:

-) What types of policies, procedures and strategies need to be formally adopted by the Trust.
-) The minimum common format to be used for all Trust policies/procedures, and general guidance on policy content.
-) The approval processes which must be followed for a document to become formally adopted (i.e. approved by which person or Committee).
-) The central control system to authorize, distribute and keep an up to date database of policies.
-) How approved policies/procedures will be made available in the Trust.

2 Definitions

Types of documents covered by this policy:

Strategy – long-term view (e.g. two years plus) of the direction the Trust is going in relation to a particular service area, outlining what it plans to achieve in that time, and allowing annual updates to tighten up broader intentions.

Policy – a plan of action, or way of doing things, to be adopted or pursued by the organization. A policy reflects an objective and guides managers and employees toward that objective in situations requiring discretion and judgement. The use of policies increases the chances that different managers and employees will make similar choices when independently facing similar situations.

Procedure, including Standard Operating Procedure – the method or approach by which a policy will be implemented. Procedures set out the way things should be done e.g. Codes of Practice/Standard Operating Procedures. They define activities and how actions are to be performed in order to reflect practice.

Protocol – similar to procedure, but tends to be used more frequently in clinical areas e.g. criteria. Clinical protocols are agreements to a particular sequence of activities that assist clinicians to respond consistently in complex areas of practice. They may be established on a uni-disciplinary or multi-disciplinary basis.

Guidelines – set of directions or principles that give general advice but allow for local discretion e.g. standards.

Other Definitions

Stakeholder

A party with an interest in the organisation, and that is likely to have an interest in the contents of the document. They may be internal or external to the organisation.

Approval

The document has been agreed as fit for use by the person or group defined within this policy.

Consultation

Requesting individuals or groups for views on the content of documents, reviewing these views, and adjusting the document's content where appropriate.

4 **Duties**

4.1 Duties within the Organisation

Directors

All policies, procedures and strategies will be placed in one of six categories. Directors will take overall responsibility for each of the 6 categories of policies as follows:

| | |
|------------------------|------------------------------------|
| Clinical | Director of Nursing and Operations |
| Financial | Director of Finance. |
| Human Resources | Director of Corporate Affairs |
| Corporate Governance | Director of Corporate Affairs |
| Information | Director of Strategy |
| Estates and Facilities | Director of Finance |

With support from other staff they nominate within their Directorate, Directors will ensure policies in their category are drafted, adopted, reviewed and archived appropriately and in line with this policy. Nominated staff will liaise with the Corporate Risk Manager, who oversees the Trust-wide policies and procedural documents, as appropriate.

Authors/Reviewers

Staff in these roles may have been nominated by their Director to undertake the work, or may have identified the need for such work themselves.

In either case, their responsibility is to;

-) liaise with their Director to ensure the Director's awareness of and approval for the work, in line with this policy,
-) In the development of the policy they will identify persons and groups that must be consulted with,
-) steer the policy through each stage of the process, and ensure an equality impact assessment is completed and agreed where needed,
-) The author will present the policy to the approving person or group detailed in this policy,
-) once the policy is approved as per this policy, contact the Corporate Risk Manager so they can register, and disseminate the policy as appropriate.

Corporate Risk Manager

The post holder will;

-) advise staff on all aspects of this policy,
-) monitor decisions from key committees to ensure new policies, once agreed, are all being referred to him/her by their authors as per this policy,
-) maintain the policy database.
-) issue alerts to managers of all new or revised policies asking them to disseminate policies to their staff as appropriate
-) oversee document control
-) oversee, maintain and monitor compliance with this policy

The post holder will provide advice and support users where procedural documents are required to meet legislation or standards

5 Style and Format of Procedural Documents

5.1 Front Page

All procedural documents will use the front page template approved by the Trust with all sections completed unless indicated as optional. This will be available in Word format on the policies section of the Trust Website, and is attached as appendix 1

5.2 Style

All policies, procedures and strategies must be written in clear, unambiguous language and explain abbreviations/acronyms.

All policies will use Arial 11 or 12 font. Underlining should only be used for hyperlinks. Numerical numbering should be used e.g. 1, 1.1, 1.1.1

5.3 Format

Headings used will be dependant on the type of document being introduced. As a minimum the following headings should be used:

| Heading | Notes |
|--|---|
| Introduction | A brief description of why the document has been developed. |
| Purpose | What the document is intended to achieve. |
| Definitions | Key aspects that will need further definition than their common meaning. |
| Duties | Who is to take action and what they must do. |
| Body of policy (headings will be according to the content of the policy) | |
| Consultation | Who has been consulted and how consultation has been carried out. |
| Monitoring compliance | How implementation and ongoing compliance is to be monitored, including standards and key indicators. |
| References | Further documents that could be referenced, e.g. external guidance. |
| Associated documents | E.g. other Trust policies. |

A template for the development of Standards Operating Procedures is attached as Appendix 2

6 The Development of Organisation-wide Procedural Documents

6.1 Prioritisation of Work

The development of procedural documents should be balanced against the operational needs of the Trust. The level of detail contained in the document should be linked to need. The need for and content of the document should be discussed with the lead director for the category when appropriate. The Corporate Risk Manager will be able to advise further if necessary.

6.2 Identification of Stakeholders

Stakeholders can be internal or external to the organisation. As part of the development process appropriate stakeholders should be identified and consulted with. Authors are encouraged to consult with a wide range of relevant stakeholders and to think beyond simply those who have been consulted historically. The following are stakeholders that could be involved:

| Stakeholder | Notes |
|---|--|
| Professional Leads | e.g. Professional discipline leads. |
| Advisors/ Specialists | e.g. Medical Adviser, Risk Manager. |
| Directors | Where the document will have an impact on directorates other than that which is developing the document. |
| Unions | For HR policies. |
| Patient Groups | e.g. for key clinical treatment policies. |
| Other providers | Where the policy may have an impact on them. |
| Other Trust Committees | Other than the approving committees. |
| Managers/ Directors | Where the policy will need to have their agreement or where the policy has a significant effect on their services. |
| Others as identified by the Author/director responsible | |

6.3 Equality Impact Assessment

All public bodies have a statutory duty under The Equality Act 2010 (Statutory Duties) Regulations 2011 to consider the impact of policies on “protected characteristics”.

Authors should use the Equality Impact Toolkit to assess the impact of the policy. In the first instance this will mean screening the policy and, where the screening indicates, completing a full assessment. The toolkit can be found on the Trust website in the policies section, keyword “equality”. A procedural document will not be considered approved until the Author has confirmed that the screening process has been carried out and where identified a full impact assessment has been completed. Where a full assessment is completed this should be submitted along with the approved policy for registration.

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are

placed at a disadvantage over others. The Equality Impact Assessment Toolkit is designed to help consider the needs and assess the impact of the policy.

7 Consultation and Approval Process

7.1 Consultation Process

At the outset of the document development process the stakeholders should be identified. The consultation with them could take several forms including;

-) requesting content suggestions prior to development,
-) circulating drafts to individual asking for comments,
-) discussing drafts at meetings,
-) by questionnaire.

Sufficient time should be given to allow stakeholders to give proper consideration to the document.

The table on the next page details the consultation process for specific policy types.

7.2 Document Approval Process

The table on the next page gives the approval process.

| |
|--|
| Consultation and Approval processes matrix |
|--|

| Document Category | Sub Category | Consultation | Approving Committee/person | Notes/extra actions needed |
|-------------------|--|--|---|--|
| Clinical | Infection Control | Appropriate service managers. | Infection Prevention and Control Committee. | Approved documents will be notified* to the Quality and Safety Delivery group |
| | Medical Devices | Medical Engineering Services Service and Clinical Leads | Quality and Safety Delivery Group | |
| | Medicines | Appropriate service managers Service Drugs and Therapeutics Committees. Sub-groups of medicines management Group (Including PGDs) | Medicines Management Group | Approved documents will be notified to the Quality and Safety Delivery Group |
| | Clinical policies and protocols which are relevant to all services | Professional leads and advisers, Patient groups where appropriate. Service Managers | Clinical Audit policy will be approved by the Quality and Safety Delivery Group Policies relating to significant clinical governance issues (e.g.) CPR will be approved by the Quality and Safety Delivery Group. This is at the discretion of the Director of Nursing and Operations All other policies will be approved by the Clinical | Approved documents will be notified to the Quality and Safety Delivery Group where they are not the approving committee Where clinical policies are approved by the Quality and Safety Delivery Group these will be notified to the Quality and Safety Committee at the discretion of the group |

| | | | | |
|-------------------------|---|--|---|--|
| | | | Policies Group | |
| | Service or division Specific Documents e.g. Clinical Protocols and Standard Operating Procedures | Professional leads and advisers, Patient groups where appropriate. | Clinical Services Manager or Divisional Manager | Approved documents will be notified to the Divisional Quality and Safety Groups |
| | Safeguarding | Safeguarding Board and sub committees. Specialist safeguarding staff. Service managers as appropriate | Trust Safeguarding Group | Notified to Quality and Safety Delivery Group. |
| Finance | Standing orders (including SFIs, delegation, reservation) | Audit Committee | Board | |
| | Finance procedures | Relevant members of Finance team. | Director of Finance, | |
| | Estates Policies | Relevant services and professionals | Capital and Estates Group | |
| | Security and Counter Fraud | Relevant professionals and service heads | Strategy – Audit Committee Policies and procedures- Director of Finance | |
| Corporate Governance | Corporate Governance | Audit Committee | Board or Audit Committee | |
| | Health and Safety | Health and Safety Representatives, Appropriate service managers. | The Statement of Intent must be approved by the Board Quality and Safety Delivery Group | |
| | Risk Management (including Complaints) | Services as appropriate Audit Committee for the | Audit Committee for the Risk Management | The Risk Management Policy should be notified |

| | | | | |
|-----------------|--|---|---|--------------|
| | and Claims) | Risk Management Strategy/Policy | Strategy/Policy Quality and Safety Deliver Group for all others | to the Board |
| Information | Information Governance (including records management) | Service Managers as appropriate Clinical Policies group (for clinical record keeping) | Information Governance Operational Group | |
| Human Resources | Workforce/HR | Joint Negotiating Partnership Professional leads and advisers. Other committees and groups as appropriate. | Workforce Group | |

*notified - Specified group should be informed of revision or introduction of a policy, as they may need to take this into account in their decision making processes. They are not the approving committee.

In special circumstances the approval committee/person can agree to nominate approval to a different person or committee.

8 Review and Revision Arrangements including Version Control

8.1 Process for Reviewing a Procedural Document

Each document will include a review date on the front page template. Authors are responsible for ensuring the policy is reviewed within the stated timescale. The Corporate Risk Manager will issue a monthly report to the SDG groups of documents overdue for review, and coming up for review.

The consultation and approval process detailed in section 7 will be followed for the review. Review period should be either 2 or 3 years unless there is an identified need to review on a more regular basis given by an external organisation e.g. Care Quality Commission, Health and Safety Executive, or by incidents, complaints, claims or other national guidance

Policies will need to be reviewed earlier than the review date when it is identified that the contents may no longer be valid.

Minor revisions

Minor revisions may be made outside the consultation and approval process. These revisions should be notified to the stated approval committee or person.

A minor revision is defined as a revision that does not affect the work practices that the document covers.

A document whose review date has been exceeded will stand until it is reviewed and the reviewed document has completed the approval process.

8.2 Version Control

Each document will be given a document number, and the number will be allocated by the document library. The individual version will be given a version number, allocated by the database when the version is registered.

Example

The Adult Safeguarding policy is number 1331
The current version is document no 37428, registered on the 24th August 2017
The version no is 1331/37428

Future versions of the policy will be number 1331/(document no)

A document will not be considered registered, and will not be published without this reference number.

Local references can be used according to local practice. This will be outside of the version control process described above.

9 Dissemination and Implementation

9.1 Dissemination

Directors will supply a list of key personnel, including the document categories relevant to them, who should receive a copy of the policies electronically. These will be issued via the Datix safety alert system. Managers must respond stating what action they have taken. They will ensure that relevant staff are informed of policies, where to access, what action they should take and the policy is brought to the attention of relevant forums e.g. team meetings.

All policies will be published on the staff intranet, and on the public website (if the staff zone is not accessible to the public) where they;

-) have a substantial impact on the general public,
-) the public could reasonably be expected to want to access,
-) meet legislative requirements that the public should be able to access,
-) affect patients individual care.

9.2 Implementation of Procedural Documents

How implementation is to be carried out should be detailed in the document.

As part of the implementation process consideration should be given to communication and training implications. Training issues should be discussed with the Organisational Development team.

Where the policy document is new the need for education, updating, training and support must be identified and the implications of delivery assessed and presented as part of the implementation plan. The lead Director for that document must be alerted so that it can be raised and managed accordingly.

10 Document Control including Archiving Arrangements

10.1 Register/Library of Procedural Documents

Following the approval of documents they should be submitted to the Corporate Risk Manager for registration. They will enter the policy onto the Document Library and update the library record as appropriate. The policy reference number will be detailed on the front sheet, and then published on the Intranet and distributed to nominated individuals.

The Corporate Risk Manager is responsible for the ongoing maintenance of the Document Library.

10.2 Archiving Arrangements

The Document Library will hold all archived procedural documents. Documents can only be deleted by a system administrator. The system is backed up nightly.

Policies will be archived indefinitely.

10.3 Process for Retrieving Archived Documents

If an archived document is required the Corporate Risk Manager must be contacted stating the reason they require the document. It is helpful if the document reference number is given. They will supply a copy of the document.

11 Monitoring Compliance with the Document

11.1 Process for Monitoring Compliance

Processes for monitoring compliance are detailed in the table on the next page. A policy monitoring form (appendix 2) is completed by the risk team. Authors will find useful to check the content of their policies against this form.

| Element to be monitored | Lead | Tool | Frequency | Reporting arrangements | Acting on recommendations and Lead(s) | Change in practice and lessons to be shared |
|---------------------------|--------------|-------------------------------|--------------------------|--|---|---|
| Style and format | Risk Manager | Policy checklist (appendix 2) | After policy is approved | Non compliance will be reported back to the author | Recommendations will be of 2 types - requiring immediate amendments or requirement amendment at next review | Persistent (no change observed following submission of more than 2 policies) problems will be reported to the Quality and Safety Operational Group for dissemination of overall lessons to all areas through service leads |
| Explanation of terms used | Risk Manager | Policy checklist | After policy is approved | Non compliance will be reported back to the author | Recommendations will be of 2 types - requiring immediate amendments or requirement amendment at next review | Persistent problems (no change observed following submission of more than 2 policies) will be reported to the Quality and Safety Operational Group for dissemination of overall lessons to all areas through service leads |
| Consultation Process | Risk Manager | Policy checklist | After policy is approved | Non compliance will be reported back to the author | Recommendations will be of 2 types - requiring immediate amendments or requirement amendment at next review | Persistent problems (no change observed following submission of more than 2 policies) will be reported to the Quality and Safety Operational Group for dissemination of overall lessons to all areas through service leads |
| Ratification process | Risk Manager | Policy checklist | After policy is approved | Non compliance will be reported back to the author | Recommendations will be of 2 types - requiring immediate amendments or requirement amendment at next | Persistent problems (no change observed following submission of more than 2 policies) will be reported to the Quality and Safety |

| | | | | | | |
|---|--------------|---|--------------------------|---|---|---|
| | | | | | review | Operational Group for dissemination of overall lessons to all areas through service leads |
| Review arrangements | Risk Manager | Report of overdue policies | Monthly | A report of overdue policies will be produced monthly and disseminated to authors and directors | Authors to review as necessary. | Where policies are persistently I.e. exceed more than 3 months beyond due date) not reviewed the relevant Executive Director will be informed |
| Control, including archiving arrangements | Risk Manager | A summary of adherence to arrangements will be prepared | Annual Summary | Audit committee as part of scrutiny arrangements | Actions required will be prepared by the risk manager | Dissemination through the alerting system when appropriate |
| Associated documents | Risk Manager | Policy checklist | After policy is approved | Non compliance will be reported back to the author | Recommendations will be of 2 types - requiring immediate amendments or requirement amendment at next review | Persistent problems (no change observed following submission of more than 2 policies) will be reported to the Quality and Safety Operational Group for dissemination of overall lessons to all areas through service leads |
| Supporting References | Risk Manager | Policy checklist | After policy is approved | Non compliance will be reported back to the author | Recommendations will be of 2 types - requiring immediate amendments or requirement amendment at next review | Persistent problems (no change observed following submission of more than 2 policies) will be reported to the Quality and Safety Operational Group for dissemination of overall lessons to all areas through service leads |

12 References

NHSLA template for the Development of Procedural Documents
NHSLA Risk Management Standards, Standard 2, Policy on Procedural Documents

13 Associated Documentation

Trust Risk Management Policy
Equality Impact Assessment Toolkit

| Document Details | | |
|--|------|-----------|
| Title | | |
| Trust Ref No | | |
| Local Ref (optional) | | |
| Main points the document covers | | |
| Who is the document aimed at? | | |
| Author | | |
| Approval process | | |
| Who has been consulted in the development of this policy ? | | |
| Approved by (Committee/Director) | | |
| Approval Date | | |
| Initial Equality Impact Screening | | |
| Full Equality Impact Assessment | | |
| Lead Director | | |
| Category | | |
| Sub Category | | |
| Review date | | |
| Distribution | | |
| Who the policy will be distributed to | | |
| Method | | |
| Keywords | | |
| Document Links | | |
| Required by CQC | | |
| Other | | |
| Amendments History | | |
| No | Date | Amendment |
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

Appendix 2 - Checklist for the Review of Procedural Documents

| | Title of document being reviewed: | Yes/No/ Unsure | Comments |
|-----------|---|---------------------------|-----------------|
| 1. | Title | | |
| | Is the title clear and unambiguous? | | |
| | Is it clear whether the document is a guideline, policy, protocol or standard? | | |
| 2. | Rationale | | |
| | Are reasons for development of the document stated? | | |
| 3. | Development Process | | |
| | Is the method described in brief? | | |
| | Are people involved in the development identified? | | |
| | Do you feel a reasonable attempt has been made to ensure relevant expertise has been used? | | |
| | Is there evidence of consultation with stakeholders and users (where appropriate) | | |
| 4. | Content | | |
| | Is the objective of the document clear? | | |
| | Is the target population clear and unambiguous? | | |
| | Are the intended outcomes described? | | |
| | Are the statements clear and unambiguous? | | |
| 5. | Evidence Base | | |
| | Is the type of evidence to support the document identified explicitly? | | |
| | Are key references cited? | | |
| | Are the references cited in full? | | |
| | Are supporting documents referenced? | | |
| 6. | Approval | | |
| | Does the document identify which committee/group will/has approved it? | | |
| | If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document? | | |

| | Title of document being reviewed: | Yes/No/ Unsure | Comments |
|------------|--|---------------------------|-----------------|
| 7. | Dissemination and Implementation | | |
| | Is there an outline/plan to identify how this will be done? | | |
| | Does the plan include the necessary training/support to ensure compliance? | | |
| 8. | Document Control | | |
| | Has the document been passed to the Risk Adviser and entered onto the Policy Library | | |
| 9. | Process to Monitor Compliance and Effectiveness | | |
| | Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document? | | |
| | Is there a plan to review or audit compliance with the document? | | |
| 10. | Review Date | | |
| | Is the review date identified? | | |
| | Is the frequency of review identified? If so is it acceptable? | | |
| 11. | Overall Responsibility for the Document | | |
| | Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the documentation? | | |

Standard Operating Procedures – Guidance and template

A Standard Operating Procedure (SOP) is a detailed written instruction whose aim is to achieve uniformity of performance in a specific task or function. It differs from policies and guidance in that it not expected that staff will deviate from the procedure. SOPs are particularly applicable where the same outcome is expected at all times, e.g. where safety is critical.

SOPs are expected to follow the Policy on Procedural Documents Policy for document control and publication. According to this policy they will be approved by the Clinical Service Manager, Divisional Manager, Deputy Director or Executive Director

The template below provides the framework for an SOP

Delete the marked sections above and the guidance to complete your document

Standing Operating Procedure for Title

| Document Details | | |
|-------------------------------------|------|-----------|
| Title | | |
| Trust Ref No | | |
| Author | | |
| Related Trust Policy | | |
| Approval process | | |
| Approved by (Committee/Director) | | |
| Approval Date | | |
| Review date | | |
| Amendments History | | |
| No | Date | Amendment |
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

Purpose

A brief description of what the purpose of the SOP is, and what it aims to achieve. This should include standards, Trust policies or regulatory requirements to which the SOP relates

Introduction

A general introduction to the procedure

Scope

What and who the SOP applies to. Where applicable this should also include circumstances where it does not apply.

Definitions

Detail any relevant definitions

Responsibilities

A brief description of the responsibilities of those involved in the activities detailed in the SOP. It should not include the whole structure, e.g. “the CEO has overall responsibility for Health and Safety” and should not rewrite the procedure.

Procedure

The procedure should be detailed in clear unambiguous terms. The use of flow charts will be beneficial in many cases

Monitoring

Any outcome monitoring to be undertaken. This could include how the procedure user will affirm they have followed the policy or how managers will ensure the procedure has been followed .

References

Detail any relevant internal or external references

Forms/templates

Either list, or attach relevant forms or templates that the SOP requires staff to use