

Executive Summary

Report to the Board of Directors

Being Held on 28 September 2021

Subject	Controlled Documents Policy
Supporting TEG Member	Sandi Carman, Assistant Chief Executive
Author	Judith Green, Corporate Governance Manager
Status	For ratification

PURPOSE OF THE REPORT

To seek ratification of the Controlled Documents Policy as approved by the Trust Executive Group on 8 September 2021.

KEY POINTS

- The Trust's Reservation of Powers to the Board and Delegation of Powers outlines a number of areas where the approval of the Foundation Trust's policies and procedures is reserved to the Board.
- An important element of the Trust's governance framework is the provision of a robust mechanism for the development, approval, management and dissemination of policy and procedural documents to ensure achievement of the organisation's objectives and the promotion of its values.
- As such, and to define clear governance arrangements for policy development in areas where this is delegated, the Board is asked to approve this policy which outlines the overarching framework for the development and management of controlled documents, which include; Trust policies and procedures, terms of reference and clinical guidelines.
- The Controlled Documents Policy presented to the Board is a substantial rewrite of an existing policy and defines a new framework for the development and review of controlled documents which will be supported by the introduction of MicroGuide; the new controlled documents management system currently being rolled out across the Trust.
- The implementation of this policy will be supported by practical procedural guidance for staff aligned to the introduction of MicroGuide.
- The updated policy has been approved by TEG following consultation with key Trust stakeholders.

IMPLICATIONS²

AIM OF THE STHFT CORPORATE STRATEGY		TICK AS APPROPRIATE
1	Deliver the Best Clinical Outcomes	✓
2	Provide Patient Centred Services	✓
3	Employ Caring and Cared for Staff	✓
4	Spend Public Money Wisely	✓
5	Deliver Excellent Research, Education & Innovation	✓

RECOMMENDATIONS

The Board of Directors is asked to **RATIFY** the Controlled Documents Policy.

APPROVAL PROCESS

Meeting	Date	Approved Y/N
Trust Executive Group	08/09/2021	Y
Board of Directors	28/09/2021	

Controlled Documents Policy

1. Introduction

An important element of the Trust's governance framework is the provision of a robust mechanism for the development, approval, management and dissemination of policy and procedural documents to ensure achievement of the organisation's objectives and the promotion of its values.

Documents are 'controlled' when their development, any revisions to their content or their removal from circulation are subject to a defined approval process, and their revision status, approval body and date of approval is evident within the document.

Controlled Documents include strategies, policies, terms of reference, procedures, protocols and guidelines providing direction to staff. These types of documents have been categorised by the Trust under the main classification headings of:

- policies,
- clinical guidelines and protocols,
- procedural / guidance documents; and
- terms of reference.

Patient Information Leaflets (PILs) are also classed as 'controlled'. The standards and procedure that should be followed in the production, development and management of patient information in the Trust are outlined separately in the [Code of Practice for Producing, Publishing and Managing Patient Information Materials](#).

Where sub sets of Controlled Documents need to be governed within a defined legal framework, for example Patient Group Directions (PGD), the process for managing these are set out within associated Trust policies signposted from this policy.

2. Purpose

The purpose of this policy and its associated documents is to ensure that Sheffield Teaching Hospitals NHS Foundation Trust (the Trust) has in place policies, guidelines and procedural documents which are controlled and implemented appropriately.

It outlines a structured and systematic approach for the development, approval, management and dissemination of Controlled Documents which ensures that such documents are:

- (i) consistently delivered to a high standard and in accordance with statutory and mandatory requirements
- (ii) version controlled and previous versions removed from circulation with a copy archived for reference / legal reasons
- (iii) written clearly and succinctly, using plain language appropriate to the intended audience
- (iv) easily accessible to all staff and published in accordance with the Trust's Freedom of Information Act Publication Scheme
- (v) implemented effectively by ensuring adequate awareness and providing appropriate training and support
- (vi) assessed for training needs, resource implications and equality / human rights impact
- (vii) systematically reviewed and revised regularly, responding to changes in legislation, standards and good practice; and compliant with Information Governance requirements.

3. Scope and exceptions

This policy applies to:

Setting	Trust-wide
Individuals	All staff
Speciality	All

4. Policy details

This section describes the overarching framework for the development and management of Controlled Documents.

Detailed instructions for the practical application of this structured and systematic approach are provided in the associated procedural [Checklist for the Development and Management of a Controlled Document](#) with templates available for different types of Controlled Documents including [policies](#), [clinical guidelines](#), procedural documents and terms of reference documents.

In general, Controlled Documents have a Trust-wide application. Documents that do not have a Trust-wide application shall be managed locally by the relevant department, directorate, care group or staff group.

Arrangements for the development, approval, management and dissemination of such locally managed documents should follow the good practice principles outlined

in this policy. Locally managed documents do not require ratification by TEG or the Board of Directors. Guidance for the development and management of locally managed documents is provided in a separate [procedural document](#).

These procedures and templates may be amended from time to time by authority of the Assistant Chief Executive, provided that such amendments are compliant with this framework.

4.1 Principles

The development and management of Controlled Documents must adhere to the following principles:

4.1.1 Decision to develop a Controlled Document / Concept approval

Controlled Document Sponsor

All Controlled Documents must have a Sponsor as defined within Section 5 of this framework. For policies this must be a member of the Trust Executive Group (TEG).

Responsibilities of the [Controlled Document Sponsor](#) are outlined in section 5 of this framework and include the responsibility of approving the development of the Controlled Document.

4.1.2 Developing a draft Controlled Document

Controlled Document Lead

This is the identified lead professional, nominated by the Controlled Document Sponsor, responsible for the development and review of the Controlled Document. Details of the responsibilities of the [Controlled Document Lead](#) are set out in Section 5 of this framework.

In some cases the drafting of a Controlled Document may be assigned to a nominated Author. In these cases the Controlled Document Lead retains responsibility for ensuring that the development, review and management of the Controlled Document is in accordance with this policy.

Stakeholder consultation

The Controlled Document Lead should identify all relevant stakeholders who should be involved in the development or consultation phases of the document.

Persons and groups consulted with during the development or review of a Controlled Document must be listed in the *Groups / Persons Consulted* section of the template document.

As appropriate, patients and the public may be involved in the development or consultation phases. If a decision is made to involve patients or the public please contact the Deputy Head of Patient and Healthcare Governance for further advice and support.

Style and format

Controlled Documents should be written in a style which is concise and clear using unambiguous terms and language. All abbreviations should be written in full in the first instance of use, followed by the abbreviation in brackets.

To ensure compliance with NHS England guidance on implementation of the [Accessible Information Standard](#) all policies, clinical guidelines/protocols and terms of reference must be developed using the most recently approved relevant template. The formatting of the template must not be amended. When reviewing and updating a Controlled Document, a check should be made as to whether a more recent template is available.

Templates are available for standing operating procedures/guidance documents but their use is not prescribed.

All Controlled Documents must have a footer on all pages which includes the document title, version number and page number of total page count.

Data Protection Legislation 2018

If a Controlled Document contains information relating to the handling of or entries into health or corporate records (usually patient confidential data), then consideration must be given to the UK Data Protection Act 2018 (DPA18) and the EU General Data Protection Regulation (GDPR) and its application within the document.

Further guidance on DPA18 and the GDPR is available from the Trust's Data Protection Officer. See also information on the [Information Governance intranet site](#).

Equality Impact Assessment

All Controlled policies and clinical guidelines must be equality impact assessed.

As a public body, the Trust has a legal responsibility under the Human Rights Act not to breach human rights. Controlled Document Leads must consider if a Controlled Document has the potential to impact on human rights. Further guidance on human rights is available on the [Equality, Diversity and Inclusion \(EDI\) Intranet pages](#).

Similarly, the Trust has a legal responsibility under the 2010 Equality Act to comply with the Public Sector Equality Duty which requires the Trust to have *due regard* to:

- eliminate discrimination, harassment and victimisation
- advance equality of opportunity between people who share a relevant protected characteristic (Age, Race, Religion and belief, Disability, Sex, Gender Reassignment, Sexual Orientation, Pregnancy & Maternity, Marriage & Civil Partnership) and people who do not
- foster good relations between people who share a relevant protected characteristic and people who do not.

Having *due regard* means equality issues must be consciously considered in the process of decision-making by the Trust. This requirement is met through Equality Impact Analysis (EIA) which aims to identify and address real or potential inequalities and discrimination resulting from the development and implementation of Controlled Documents and/or identify how equality can be promoted.

An EIA must be undertaken as part of the development of Controlled Documents in accordance with [Trust Rapid Equality Impact Analysis \(REIA\) Process Guidance](#).

An EIA is a mandated section within both the Controlled Document [policy template](#) and [clinical guideline template](#) and must be completed. The Controlled Document Lead is responsible for the validity of any statement made. Controlled Documents that do not have this section completed may not be ratified.

Further guidance on the REIA process is available on the [Equality, Diversity and Inclusion \(EDI\) Intranet pages](#) and further advice sought from the EDI Department.

Other impacts

As part of the development of a Controlled Document, consideration must be given to its impacts in terms of financial implications and training implications.

It is the responsibility of the Controlled Document Lead to undertake a *Training Needs Outline* which considers the training required to implement the Controlled Document.

This must be summarised in the *Training implications* section of the Controlled Document template. It should highlight if the training has been approved by the Trust Executive Group (TEG) as mandatory training, the regularity of the training, implications for new employees and whether it affects all staff or specific staff groups only.

The need for additional resources (including training costs) to implement the Controlled Document must be assessed and the *Financial implications* section of the template (within *Other impacts*) must be completed to confirm that:

- (i) implementation is achievable within existing resources **or**
- (ii) additional resources have been secured, (giving brief details).

4.1.3 Approval and ratification

Controlled Document Approval Body

The content of the Controlled Document should be reviewed and approved by an expert group confirmed by the Controlled Document Sponsor. The responsibilities of the [Controlled Document Approval Body](#), as outlined in section 5 of this policy, include ensuring that the development of the document complies with this framework.

All Controlled Documents with a Trust-wide application, including all Trust policies, must follow the following principals:

- They must be sponsored by the appropriate Trust Executive Group (TEG) Director as noted in 4.1.1 above.
- The Approval Body as confirmed by the TEG Director Sponsor should review and approve the Controlled Document.
- Trust policies that have been approved by the designated Approval Body must be ratified by the (TEG), with the exception of those policies specified in the Scheme of Reservation and Delegation as

requiring Board approval or Controlled Documents that TEG choose to escalate on an *ad hoc* basis to the Board for approval and ratification.

All other Controlled Documents must be approved, and where applicable, ratified by an appropriate body.

A summary of approval and ratification bodies is outlined in the table below:

Controlled Document classification	Approval body	Ratification body
<u>Policies</u> including <u>framework documents, strategies</u> and <u>codes of conduct / practice</u>	Expert group confirmed by the relevant TEG Director in their capacity as Controlled Document Sponsor	Trust Executive Group (TEG)
<u>Reserved policies</u>	TEG	Board of Directors
Guidelines and protocols Including <u>clinical guidelines, clinical protocols</u> and <u>patient record forms</u>	Relevant professional forum or subject specialist(s) confirmed by the Controlled Document Sponsor	Directorate Management Team or Directorate Governance Group (or equivalent)
<u>Procedural documents</u> Including <u>standing operating procedures (SOPs)</u> and <u>procedural / guidance documents</u>	Relevant directorate / professional forum such as Directorate Management Team or Directorate Governance Group [or equivalent] confirmed by the Controlled Document Sponsor	<ul style="list-style-type: none"> Where these support the implementation of a Trust Policy and included as an appendix, TEG ratification is required Local procedural documents – N/A
<u>Terms of Reference (ToR)</u>	The committee/group itself	The committee/group listed within the ToR as the ' <i>accountable to</i> ' group

Some documents are developed outside the Trust, for example national, regional or place based guidelines/policies. In order to be adopted as Controlled Documents for implementation within the Trust they should be approved and ratified in accordance with this framework.

In these circumstances the *Document control* section of the template should still be completed in full but the status will be changed to *adopted* and an *operational sponsor* will be identified in place of the Controlled Document Lead.

In circumstances where a Controlled Document includes an appendix which is 'controlled' or 'locally managed' it is the responsibility of the Controlled Document Lead to ensure that the appendix has been through the appropriate approval process.

4.1.4 Dissemination

New and reissued Controlled Documents are disseminated to staff via the Trust's intranet site.

The Chief Executive's Office is responsible for maintaining access to Controlled Documents on the [intranet site](#) and managing alerts to new and reissued Controlled Documents,

It is the responsibility of the Controlled Document Lead to identify the target audience in the *Intended Recipients* section of the Controlled Document template.

Register / Library of Controlled Documents

The Chief Executive's Office will maintain an up-to-date and controlled electronic library of all Controlled Documents with a Trust-wide application and associated documentation, which will be made accessible via the [intranet site](#).

4.1.5 Review

Formal review

Controlled Documents must be reviewed as a minimum every three years to ascertain whether they:

- are still required
- remain accurate
- continue to comply with the appropriate template

- align with latest guidance, legislation, policy or practice
- comply with any associated Controlled Documents

Controlled Documents should be reviewed immediately; irrespective of the review date, in response to:

- a recommendation following a Serious Incident or other governance findings
- changes in partnership working
- changes in legislation or national guidance

Minor revisions

It is sometimes necessary to make minor revisions to policies outside the approved review dates (for example, to update changed organisational arrangements, job titles, etc., or to correct spelling mistakes). All requests to revise policies outside the approved review dates should be forwarded to the Business Manager, Board of Directors for consideration by the Assistant Chief Executive.

If the suggested revision is not considered material, the Assistant Chief Executive is authorised to approve the revision without recourse to the standard Approval and ratification processes.

Minor amends to other types of Controlled Documents should be undertaken according to the same procedure as for new Controlled Document development.

Urgent material amends

Under exceptional circumstances such as safety alerts about drugs or equipment, the Chair of the approval body can authorise an amendment to the Controlled Document through a Chair's action to allow the updated version to be circulated immediately.

The Chair should notify the approval body of this by email at the time. This should be retrospectively reported at the next meeting of the approval body and recorded in the minutes. If this is a Controlled Document that requires TEG ratification the usual governance process should be followed to secure ratification.

Controlled Documents past their review date

Existing Controlled Documents will remain in force until updated on the intranet or withdrawn, **even if the review date has been passed.**

Obsolete documents

If the Controlled Document Lead undertaking the review concludes that a Controlled Document is obsolete (for example, in response to changes in legislation, service provision, etc) they may request that the Controlled Document be removed from view from the electronic library of Controlled Documents.

This decision must be approved by the Controlled Document Approval Body. The Controlled Document Lead is responsible for informing [Controlled Document Support](#) who will arrange for its archiving.

Archiving

Superseded and obsolete Trust-wide Controlled Documents are retained and managed electronically on the Controlled Documents Library by [Controlled Document Support](#) and are available internally on request.

Process for managing external requests for archived Controlled Documents

Any external requests for archived Controlled Documents under the terms of the Freedom of Information Act will be processed in accordance with the Trust's [Freedom of Information Policy](#).

4.1.6 Monitoring compliance and effectiveness of Controlled Documents

The Trust is committed to ensuring compliance with all Controlled Documents and will actively monitor the effectiveness of such documents.

Should it become evident, through the monitoring process, that the document is not being followed or that staff are unaware of its existence, the Controlled Document Sponsor is responsible for implementing appropriate measures to address the situation.

Monitoring arrangements and Key Performance Indicators (or standards) to demonstrate compliance and effectiveness **must** be detailed in the *Monitoring* section of the Control Document template.

5. Roles and responsibilities

Role	Responsibility
Assistant Chief Executive	<p>TEG Sponsor for this policy document.</p> <p>Also has specific responsibility for approving minor amendments and determining the Controlled Document Sponsor arrangements for a particular Controlled Document where there is any uncertainty.</p>
Board of Directors	<p>Responsible for all Controlled Documents, (including this policy) but with the exception of a number of policies defined as Reserved Policies. Has delegated responsibility to the Trust Executive Group.</p>
Controlled Document Approval Body	<p>It is the responsibility of the Controlled Document Approval Body to:</p> <ul style="list-style-type: none"> (i) confirm it is the most appropriate Approval Body in terms of resident expertise to properly challenge and scrutinise the Controlled Document. (ii) review the content of the Controlled Document as the expert group. (iii) ensure that the development of the document complies with this policy. (iv) approve the document / approve the document for ratification* or recommend the author(s) to undertake additional work. <p><i>*In line with the summary of approval and ratification bodies outlined in section 4.1.3, documents requiring TEG ratification include policies, procedural documents with a Trust-wide application and terms of reference where TEG is the 'accountable to' group.</i></p>
Controlled Document Author	<p>In many cases this will be the same individual as the Controlled Document Lead. Where another individual is nominated to draft the content of the Controlled Document the wider responsibilities of the Controlled Document Lead (below) are retained by the Controlled Document Lead.</p>
Controlled Document Lead	<p>The Controlled Document Lead is the identified lead professional, nominated by the Controlled Document Sponsor, responsible for the development and review of the Controlled Document.</p> <p>It is the responsibility of the Controlled Document Lead to</p>

	<p>ensure that the document is developed in accordance with this policy. In doing so they must:</p> <ul style="list-style-type: none"> (i) ensure that a new Controlled Document is not duplicating other work, either locally or nationally (ii) secure any necessary outline support for developing a new Controlled Document, including sponsorship by the appropriate Director, noting that for policies this must be a TEG Director (iii) identify and confirm with the Controlled Document Sponsor the Approval Body (for policies Controlled Document Leads should contact the Business Manager, Board of Directors and/or the sponsoring TEG Director for guidance concerning an appropriate Approval Body) (iv) ensure a new Controlled Document is consistent with corporate and relevant directorate strategies, service priorities and other existing Controlled Documents (v) ensure that the Controlled Document is up-to-date and fit for purpose and should consider the impact of changes in legislation, guidance and organisational structure since the document was developed or last reviewed. (vi) ensure that the Controlled Document is in the correct and most recently issued template format. (vii) confirm that any 'controlled' or 'locally managed' appendices have been through the appropriate approval process. (viii) confirm that implementation is achievable within existing resources or that enabling resources have been secured. (ix) identify the target audience in the <i>Intended Recipients</i> section of the template document Control Pages. <p><i>Where drafting of a Controlled Document is assigned to a nominated Author the Controlled Document Lead retains these responsibilities.</i></p>
<p>Controlled Document Sponsor</p>	<p>The Controlled Document Sponsor is the identified Director, or person to whom such responsibilities have been delegated, who has responsibility for approving the development of the Controlled Document.</p> <ul style="list-style-type: none"> • Policies: Development of any policy must be approved by the member of TEG who heads the area of the Trust to which the policy most relates • For clinical guidelines the Controlled Document Sponsor

	<p>is the Clinical Director</p> <p>Where there is any uncertainty as to the identity of a Controlled Document Sponsor for a particular Controlled Document, the Assistant Chief Executive shall determine the Controlled Document Sponsor.</p>
<p>Controlled Document Stakeholder</p>	<p>A stakeholder is anyone with an interest in a Controlled Document and includes staff (at all levels), staff side organisations, governors, departments, directorates, committees, patients and the public, external stakeholders and/or people with specialist skills or knowledge such as the Local Counter Fraud Specialist. Stakeholders can contribute to or comment on the content of a document and may recommend additional stakeholders.</p>
<p>Line Managers</p>	<p>It is the responsibility of line managers to:</p> <ul style="list-style-type: none"> (i) ensure that their staff are aware of and have access to Controlled Documents that are relevant to their working environment. (ii) ensure staff have access to any training identified as necessary for effective implementation of the Controlled Document. (iii) ensure that current and/or superseded or withdrawn Controlled Documents stored as hard copy or shared drives or websites within their areas are removed. Only under exceptional circumstances (e.g. when staff do not have access to the intranet) can hard copy Controlled Documents be stored locally and in such circumstances the line manager is responsible for ensuring the hard copy Controlled Documents are current.
<p>Staff</p>	<p>It is the responsibility of staff (including contractors and agency staff) to be aware of and to comply with relevant Controlled Documents. Please note:</p> <ul style="list-style-type: none"> (i) information regarding the failure to comply with Controlled Document, for example because of lack of training or inadequate equipment, must be reported to the Line Manager and the incident reported according to the Incident Management Policy. (ii) failure to comply with relevant Controlled Documents <u>that are mandatory</u> will be dealt with in accordance with the Trust Disciplinary Procedure.

<p>Controlled Document Support (CDS)</p>	<p>Controlled Document Support (CDS) is responsible for:</p> <ul style="list-style-type: none"> (i) providing advice and support on aspects of this policy (ii) administering the development and approval process in line with this policy (iii) completing or updating relevant information within the <i>Document control</i> section of the Controlled Document template prior to publication / issue of the Controlled Document (iv) maintaining access to Controlled Documents on the electronic library of Controlled Documents. (v) maintaining associated databases / content management systems in relation to Controlled Documents (vi) maintaining an archive of superseded or withdrawn Controlled Documents (vii) monitoring and supporting the effective and timely review of Controlled Documents (viii) liaising with the Communications Departments to issue a regular 'What's New' listing of new and revised Controlled Documents for Trust-wide e-mail circulation.
<p>Trust Executive Group (TEG)</p>	<p>Responsible for ratifying all Controlled Documents that have been approved by the designated Approval Body as requiring TEG ratification*.</p> <p>Where TEG reserve responsibility as the Approval Body itself, the Controlled Document must be ratified by the Board of Directors.</p> <p><i>* In line with the summary of approval and ratification bodies outlined in section 4.1.3, documents requiring TEG ratification include policies, procedural documents with a Trust-wide application and terms of reference where TEG is the 'accountable to' group.</i></p>

6. Monitoring

Standard, process or issue to be monitored	Monitoring method	Monitored by	Reported to	Frequency
Controlled Documents in date	KPI Report	CEO Office	TEG	Bi - monthly

7. Definitions

For more guidance on developing a Controlled Document in line with the defined classifications outlined below please refer to the associated procedural [Checklist for the Development and Management of a Controlled Document](#).

Term	Description
Clinical guideline	<p>Clinical guidelines contain evidence-based recommendations on the appropriate treatment and care of patients with specific diseases and conditions. They guide professionals and allow individuals to use their professional judgment and decision-making skills.</p> <p>Clinical guidelines are flexible and act as a support and guide, they are not prescriptive.</p> <p>They do not include Patient group directions (see separate definition below).</p>
Clinical protocol	<p>A clinical protocol is a detailed plan of clinical practice prescribing exactly what must be done and documented in a specific situation. It provides an agreed approach and / or description of roles and responsibilities. It may apply only to particular divisions or be applicable Trust-wide.</p> <p>Clinical protocols do not allow deviation from the agreed practice.</p>
Controlled document	<p>Controlled Documents are documents which provide a framework for safe, effective and acceptable practice. Documents are 'controlled' when their development, any revisions to their content or their removal from circulation are subject to a defined approval process, and their revision status, approval body and date of approval is evident within the document.</p> <p>Controlled Documents include strategies, policies, procedures, protocols and guidelines which aim to provide direction to staff.</p> <p>In general, Controlled Documents have a Trust-wide application. Documents that do not have a Trust-wide application shall be managed locally by the relevant department, directorate, care group or staff group.</p>
Code of conduct or practice	<p>Codes of conduct/practice describe desired staff behaviour in a specific context. For the purposes of this Policy, a code of</p>

	<p>conduct/practice is considered a policy document (see Policy definition).</p>
Framework document	<p>A number of the Trust's policies are designated as Frameworks. These set out a structured and systematic approach to a specific area of practice, outline roles and responsibilities and standards of delivery and are underpinned by detailed procedural guidance documents.</p> <p>For the purposes of this Policy, a framework is considered a policy document (see Policy definition).</p>
Patient group direction (PGD)	<p>A patient group direction is a written instruction for the supply and / or administration of named medicines in an identified clinical situation.</p> <p>It applies to groups of patients who may not be individually identified before presenting for treatment. Separate governance arrangements are in place for these documents. (see Patient Group Directions Policy).</p>
Patient record form	<p>A patient record form is a standardised template/form used to record information relating to the physical or mental health or condition of an individual which has been made by or on behalf of a health professional in connection with the care of that individual, and is part of the patient record.</p>
Policy	<p>A policy is a statement of intent and principles, explicitly stating individuals' responsibilities and accountabilities. It provides the basis for consistent decision making, actions and resource allocation. A policy may result from national or local directives and provides a framework within which individuals or specific groups must work.</p> <p>For the purposes of this Policy, Codes of conduct / practice are to be regarded as policies.</p> <p>A policy is not open to interpretation or professional judgment and compliance is mandatory.</p>
Procedural document	<p>A procedural document must follow from a particular policy.</p> <p>It is a description of operational tasks to be undertaken to implement, or support, a policy.</p> <p>Procedural documents apply across the Trust to all relevant sites and services.</p>

Reserved policies	Reserved policies are those approved by TEG but ratified by the Board of Directors in line with the Reservation and Delegation of Powers.
Standard operating procedure (SOP)	<p>With the exception of local SOPs*, Standard operating procedures (SOPs) are a written set of instructions that staff must follow to complete a job safely and compliantly, with no adverse effect on the personal health of the patient and staff or the environment, or on statutory requirements, and in a way that maximises operational efficiency.</p> <p><i>*Local SOPs are those which affect a very small number of people, are agreed within a team/small department and are not published centrally.</i></p>
Strategy	<p>A strategy is a medium or long-term plan of action designed to achieve a particular goal.</p> <p>The content of strategy documents will tend to be high level and concise, presenting a vision of what it is intended to achieve and why, what benefits are intended to accrue from the strategy and how it is to be achieved over a defined period – usually three to five years.</p>
Terms of reference	A terms of reference (TOR) document details the specific authority that a board, committee or group has to oversee a delegated area of responsibility. It describes the committee's purpose, contains clear and specific information on how it is organised, what it is trying to achieve, who the members are, and when they meet.

8. References / standards and statutory legal requirements

Accessible Information Standard - Making health and social care information accessible

Human Rights Act 1998

Freedom of Information Act 2000

EU General Data Protection Regulation (GDPR) 2018

UK Data Protection Act 2018 (DPA18)

9. Associated Trust and external documents

[Code of Practice for Producing, Publishing and Managing Patient Information Materials](#)

[Disciplinary Procedure](#)

[Equality Impact Analysis Guidance](#)

[Freedom of Information Policy](#)

[Incident Management Policy](#)

[Patient Group Directions Policy](#)

[Reservation and Delegation of Powers](#)

10. Appendices

Appendix A - [Checklist for the Development and Management of a Controlled Document](#)

Appendix B - [Guidance for the development, approval, management and dissemination of locally managed documents](#)

[Policy Template](#)

[Clinical Guideline Template](#)

11. Document control

Ref	TBC
Version	1
Status	For approval
TEG Director Sponsor	Sandi Carman, Assistant Chief Executive
Author	Judith Green, Corporate Governance Manager
Approval body	Trust Executive Group
Date approved	8 September 2021
Ratification body	Board of Directors
Date ratified	[28 September 2021]
Issue date	TBC
Review date	30 September 2024

12. Version history

Version	Date issued	Brief summary of changes	Author
1	tbc	New policy to replace Policy for the Development, Approval, Management and Dissemination of Trust Controlled Documents (Ref 55)	Judith Green, Corporate Governance Manager

13. Consultation and review

Groups / persons consulted	Date
Head of Equality, Diversity and Inclusion	23/08/21
Head of Patient and Healthcare Governance	23/08/21
Trust Controlled Documents Project members	23/08/21

14. Intended recipients

Essential reading for	Governance leads, All Trust Managers, MBB, TEG
Information for	All staff

15. Rapid equality impact assessment

What relevant quantitative and qualitative information (data) do you have? This may include national or local research, surveys, reports or research; workforce / patient data; complaints and patient experience data, etc.						
	Positive Impact This will actively promote or improve equality of opportunity or address unfairness or tackle discrimination	Negative Impact This will have a negative or adverse impact which will cause disadvantage or exclusion	Neutral Impact There is no likely impact on any of the protected groups	Does it advance equality of opportunity? (Y/N)	Does it eliminate unlawful discrimination? (Y/N)	Does it foster good relations between people? (Y/N)
Race (including nationality)	✓	x	x	Y	Y	Y
Religion/belief and non-belief	✓	x	x	Y	Y	Y
Disability	✓	x	x	Y	Y	Y
Sex	✓	x	x	Y	Y	Y
Gender Reassignment	✓	x	x	Y	Y	Y
Sexual Orientation	✓	x	x	Y	Y	Y
Age	✓	x	x	Y	Y	Y
Pregnancy and Maternity	✓	x	x	Y	Y	Y

Marriage and Civil Partnership	✓	x	x	Y	Y	Y
Human Rights (FREDA principles)	✓	x	x	Y	Y	Y
Carers	✓	x	x	Y	Y	Y
Other groups e.g. Gypsy, Roma, Travellers, vulnerable adults or children (e.g. homeless, care leavers, asylum seekers or refugees)	✓	x	x	Y	Y	Y

List any specific equality issues and information gaps that may need to be addressed through engagement and/or further research

15.1 Analysing the equality information

In this section record your assessment and analysis of the evidence. This is a key element of the EIA process as it explains how you reached your conclusions, decided on priorities, identified actions and any necessary mitigation

Analysis of the effects and outcomes
 By ensuring that the process and systems in place for the development, approval, management and review of Controlled Documents aligns to EDI legislation this policy will have a positive impact on all above groups.

15.2 Outcome of equality impact assessment

No major change needed	Adjust Policy / proposal	Adverse impact but continue	Stop and remove policy / proposal
✓	✗	✗	✗

15.3 Action plan

Action to address negative impact	By whom	By when	Resource implication
N/A			

15.4 Monitoring, review and publication

Manager signing off EIA (please enter name below)	Date of next review (please enter date below)
Judith Green, Corporate Governance Manager	September 2024
Approved by (please enter name of Committee and date approved below)	Date sent to EDI Team sth.equalityanddiversity@nhs.net: (please enter date below)
Trust Executive Group	
	Date published (if applicable) (please enter date below)

16. Other impacts

Financial implications	None identified
Training implications	None identified
Other	None identified

17. Document imprint

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