Policy for the Development, Approval and Management of Key Documents

Department / Service:	Clinical Governance
Originator:	Elaine Chapman, Clinical Effectiveness Manager
Accountable Director:	Chief Medical Officer
Approved by:	Clinical Effectiveness Group
Date of approval:	16th April 2024
Review date: This is the most current document and should be used until a revised version is in place	16th April 2027
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	All
Target staff categories	All

Policy Overview:

This policy provides a robust framework for the management of key documents, including policies, procedures, protocols, guidelines, clinical treatment pathways, standard operating procedures and clinical patient information leaflets.

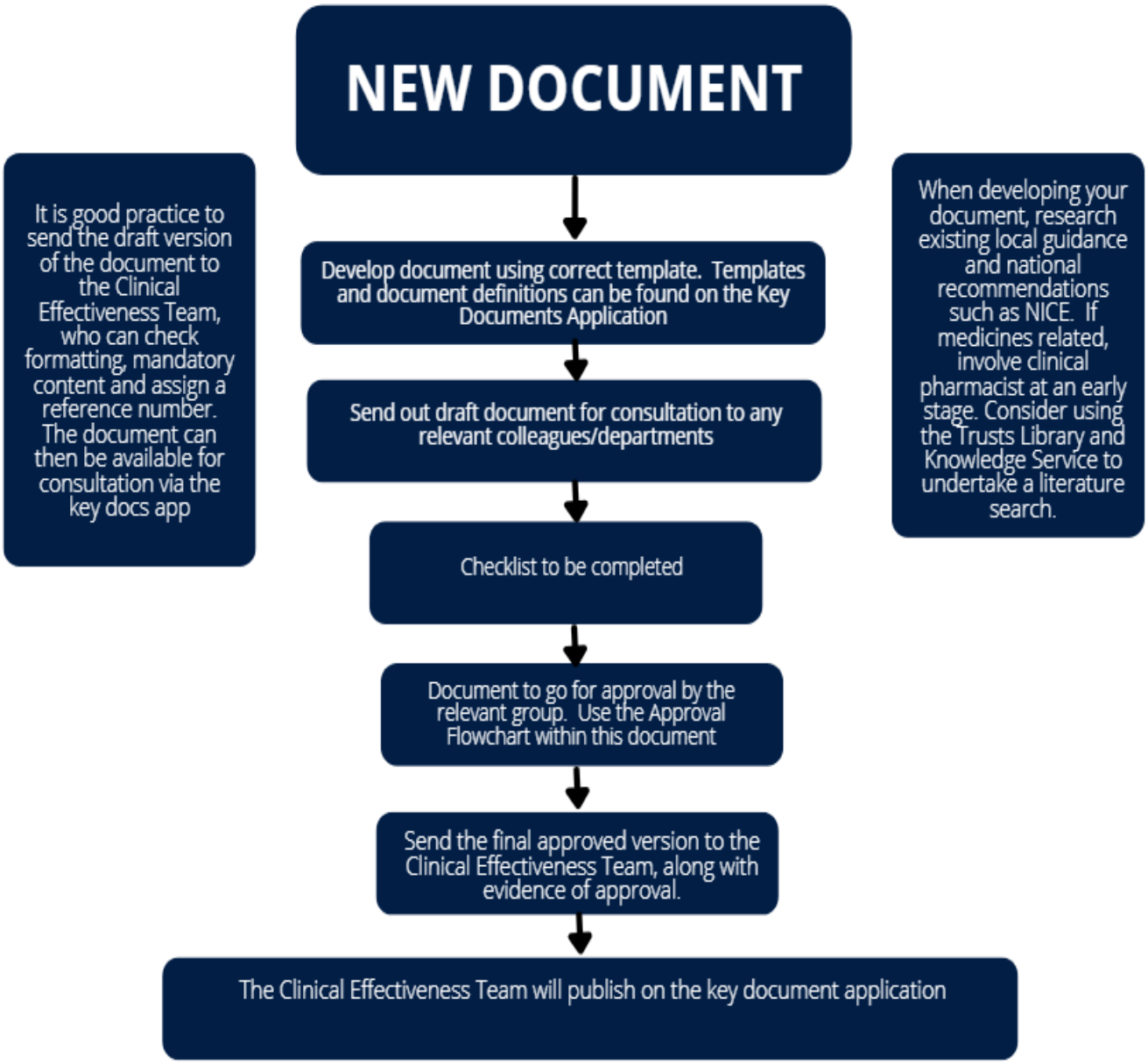
It covers the format, production, consultation process and approval of key documents as well as their accessibility, distribution, acceptance by designated staff, communication, revision and the archiving of obsolete documents.

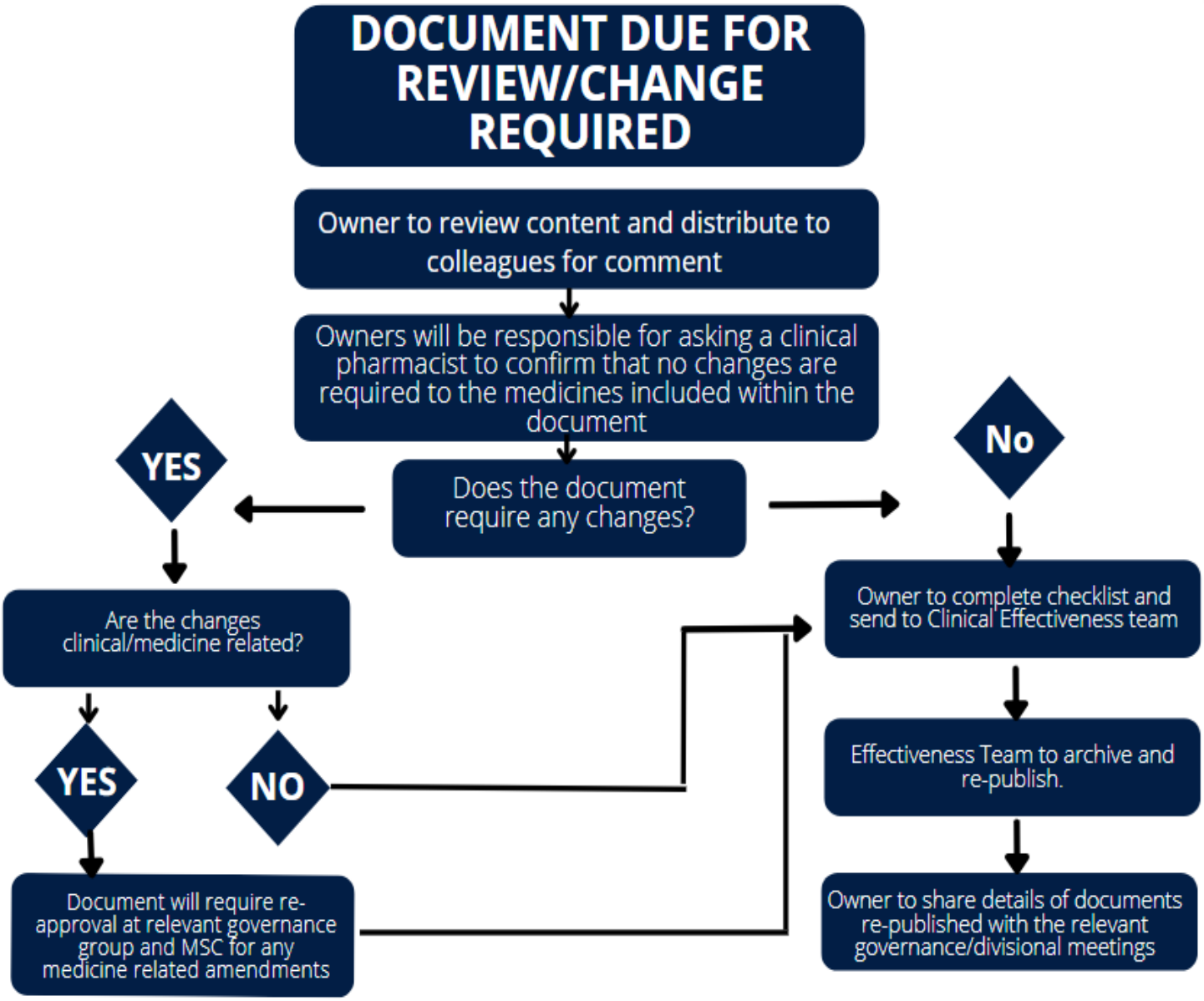
Key Amendments to Document

Date	Amendment	Approved by
November 2017	Treatment pathway policy made obsolete, to allow policy to be reverted back to original format. Minor amendments made to approval process and committee names	TLG
25th January 2019	Addition of sentence stating author's responsibility to forward document to MSC, paragraph 5.7.3 Change of Name from Medicines Optimisation group to Medicines Safety Committee	Elaine Chapman
June 2019	Remove references to the Key Documents Approval Group, stood down by the Trust Management Executive. Amend Approval Flowchart at Appendix 1 to reflect revised governance structures. 5.6 Amended to expand on consultation process for HR policies & requirement to consult Local Counter Fraud Specialist where documents have potential impact in relation to fraud. 5.9 Added a sentence to outline that the Clinical Governance Department will notify authors when their key documents have been published to the intranet. 5.10 Revise maximum review date for all key documents from 2 years to 3 years. Revise maximum extension period from 3 to 6 months, as approved by CGG May 2019.	Elaine Chapman/Heather Webb

	5.13 Addition to clarify that the Clinical Governance Department manage the version control of documents. Appx 5 – addition to checklist in relation to considering fraud implications & the need to consult Local Counter Fraud Specialist. Appx 5 – addition to checklist to remind authors of the need to check that all references within documents are up-to-date.	
August 2019	Updated Equality Impact Assessment Template, as approved by Equality & Diversity Committee June 2019.	Equality & Diversity Committee.
March 2020	Updated Approval Flowchart	
April 2021	Various amendments made to the policy: • Appendices removed that made the policy confusing. These are referred to as being included in available templates instead…EIA form and Financial risk assessment • SOPs removed from list of excluded documents in this policy • New SOP definition added to list. • Change to Procedure definition to Clinical Procedure • Extra information added to the Clinical Guideline definition • Section 5.1 Archiving arrangements added • Section 5.2 and 5.10 Library services added to undertake literature searches • Section 5.3 Sentence added re SOPs being exempt from some mandatory sections i.e. monitoring and new template available • Section 5.11 'Expiry' date changed to 'Review' date • Appendix 1 – updated approval flowchart to include specialty specific key documents, and when to obtain MSC approval in the process. Updated HR and H&S process • Appendix 3 – Amended checklist that asks owners to consider appropriateness of publishing document to the internet • Responsibilities for approving committees updated to include : - Each Committee should be clear about the key documents that it is responsible for reviewing and approving, and have a planned schedule for their review.	Elaine Chapman/ Clinical Governance Group
July 2022	Document extended for 3 months whilst it goes through the approval process.	Elaine Chapman
September 2022	P4 Process chart updated Section 4.4 Change from Head of Clinical Governance and Risk to Chief Medical Officer Section 4.5 Change from Clinical Governance department to Clinical Effectiveness Change made as above throughout the document Approval flow chart updated New Clinical Patient Information Leaflet process chart included New checklists included in appendices Section 5.6 Consultation-inclusion of the ability to add draft document to new key docs application	
May 2023	Comments received following trustwide consultation: 'How to' guide on p4 - new comments added re involving clinical pharmacist Section 4.5 and 4.7 updated clinical 'governance' to 'effectiveness' Removed wording from PGD paragraph in section 2 - 'in principle'	Elaine Chapman
November 2023	Changes to original flowchart-split into 2 to reflect existing document process Section 5.10 has been re written to reflect new process for existing documents that require no change at their scheduled 3 year review Amendment to section 5.10.2 – key document owners responsible for arranging for literature searches to check references are still up to date	

Contents page:


NEW DOCUMENT
Develop document using correct template. Templates and document definitions can be found on the Key Documents Application
Send out draft document for consultation to any relevant colleagues/departments
Checklist to be completed
Document to go for approval by the relevant group. Use the Approval Flowchart within this document
Send the final approved version to the Clinical Effectiveness Team, along with evidence of approval.
The Clinical Effectiveness Team will publish on the key document application
It is good practice to send the draft version of the document to the Clinical Effectiveness Team, who can check formatting, mandatory content and assign a reference number. The document can then be available for consultation via the key docs app
When developing your document, research existing local guidance and national recommendations such as NICE. If medicines related, involve clinical pharmacist at an early stage. Consider using the Trusts Library and Knowledge Service to undertake a literature search.


DOCUMENT DUE FOR REVIEW/CHANGE REQUIRED
Owner to review content and distribute to colleagues for comment
Owners will be responsible for asking a clinical pharmacist to confirm that no changes are required to the medicines included within the document
Does the document require any changes?
YES
No
Are the changes clinical/medicine related?
Owner to complete checklist and send to Clinical Effectiveness team
YES
NO
Effectiveness Team to archive and re-publish.
Document will require re-approval at relevant governance group and MSC for any medicine related amendments
Owner to share details of documents re-published with the relevant governance/divisional meetings

Policy for the development, approval and management of key documents

1. Introduction

To ensure that the Trust provides a robust and clear governance framework within which service delivery can occur, the organisation needs to develop and implement key documents that are appropriate, practical and followed. The control of key documents is essential in achieving compliance with legislative and governance requirements.

The main purpose of key documents is to standardise practice and service delivery to reflect the best available evidence thereby reducing unjustified variations, hence improving quality. Having effective, up to date and easily followed key documents minimises risk to patients, employees and the Trust.

In addition to the need to identify and eliminate inequality, the control of key documents is essential in achieving compliance with corporate and clinical governance standards. Organisations have a statutory duty to have in place appropriate policies to comply with relevant legislation to enable staff to fulfil the requirements of their role safely and competently. In addition, there needs to be an effective process for managing and reviewing key documents on a regular basis to ensure they are safe, legal and efficient. Good risk management practice requires the Trust to have in place an effective process for the development, approval and management of trust-wide key documents.

2. Scope of this document

This policy applies to all staff involved in the development, approval and management of key documents.

Documents that are excluded from this policy are:

Standing Financial Instructions (SFIs)

Patient Group Direction (PGD)
Approved by Medicines Safety Committee and managed by the Lead Pharmacist for Medicines Safety

Non clinical Patient Information Leaflets
Only clinical patient information leaflets are covered by this policy

3. Definitions

Strategy	A document that describes **a planned series of actions intended to achieve a specific** goal. It usually refers to a longer term, e.g. a three to five year period.
Policy	A policy is a general set of ideas or principle of action in a particular field**,** which should be based on evidence, legislation, best practice and statute and incorporate any standards laid down by recognised professional bodies or other national or NHS institutions where such are available. In general terms, a policy explains ***what*** we will do and ***why*** we will do it. A policy once implemented is mandatory for all staff and failure to comply may result in disciplinary action.
Clinical Procedure	A clinical procedure is a document that sets outs the steps in detail of a specific clinical procedure.
Protocol	A protocol is a document laying down in ***precise detail*** the tests/steps that ***must*** be performed in prescribed circumstances. Protocols should therefore be developed with caution; being more inflexible in nature, exact compliance with the details may be tested should examination in a legal context become necessary.
Guidelines/ Guidance Notes:	Clinical guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum. As the name implies, guidelines are suggested principles**,** which are set down ***to help*** determine a course of action**.** They assist the practitioner to decide on a course of action . It should be noted that clinical guidelines do not replace professional judgment and discretion
Clinical Treatment Pathway	A Clinical Treatment Pathway is a simple flow chart with each step of the patient journey mapped out. These are created to reflect national recommendations and bring together local policies, procedures, patient information and contact information. These are provided electronically on-line for Worcestershire health economy to access.
Standard Operating Procedure (SOP)	SOPs are detailed written instructions used to document and achieve uniformity on the performance of a specific function or process. These should only contain minimal clinical information i.e. how to book transfers for patients, where to store equipment etc. If more clinical information is included, consider whether this should be either a clinical guideline or a clinical procedure.
Clinical Patient Information Leaflets	Patient information leaflets are leaflets containing specific information about medical conditions, procedures and treatments. These should include risks and benefits of the procedures and treatments, supporting the consent process.
National Guidelines	Nationally produced clinical guidelines. As the name implies, guidelines are suggested principles**,** which are set down ***to help*** determine a course of action**.** They assist the practitioner to decide on a course of action but need neither to be automatically nor rigorously applied. It should be noted that clinical guidelines do not replace professional judgment and discretion.
Care Pathway	A care pathway is anticipated care placed in an appropriate time frame, written and agreed by a multidisciplinary team. It has locally agreed standards based on evidence where available to help a patient with a specific condition or diagnosis move progressively through the clinical experience. It forms part or all of the clinical record, documenting the care given. It facilitates and demonstrates continuous quality improvement. It includes patient milestones and clinical interventions noted on the day or stage that they are expected to occur.

For the remainder of this policy, strategies, policies, procedures, guidelines, clinical patient information leaflets and SOPs will be referred to as 'key documents'

4. Responsibility and Duties

4.1. Trust Board

The Trust Board is responsible for setting the strategic context in which organisational key documents are developed. Key documents may be taken to the Board at the request of the Accountable Director.

The Trust Board approves strategies but has delegated powers of approval for other key documents as described in **Appendix 1.**

4.2. Chief Executive:

Overall responsibility for ensuring the Trust has appropriate key documents in place to ensure the organisation works to best practice and complies with all relevant legislation.

4.3. Accountable Directors

An 'Accountable Director' is responsible for identifying and overseeing the development and effective implementation of key documents relevant to their areas of responsibility. An 'Accountable Director' will be an executive level, Divisional Director, Clinical Director or Clinical Governance Lead.

4.4. Chief Medical Officer

Has responsibility for ensuring that effective arrangements are in place for the development, approval and management of key documents.

4.5. Clinical Effectiveness Department

The Clinical Effectiveness department has an operational responsibility for the system for the management of key documents.

4.6. (Key Document) Author

Ensure the requirements set out in this policy are followed, including consultation, approval and review.

4.7. Chair of Approving Committee

The Chair of an approving committee is responsible for arrangements to communicate approval of a key document back to Clinical Effectiveness Department as soon after the meeting as possible. **Each Committee should be clear about the key documents that it is responsible for reviewing and approving, and have a planned schedule for their review.**

4.8. Divisional Management Teams

- Ensure the requirements set out in this policy are followed
- Ensure that implications are considered for their area of responsibility and they provide constructive feedback with the specified time.
- Ensure documents within their Division are reviewed and that there is a schedule for routine review of documents before they reach their review dates.

4.9. Line Managers

- Work within approved key documents.
- Ensure staff are aware of and have access to relevant key documents.
- Ensure staff been informed of new or amended policies and the impact it will have upon their work.

- Ensure systems exist to identify staff training needs on the implementation of policies and take necessary action to address these where necessary.
- Monitor compliance with key documents within the service as defined in the document

4.10 All Staff

Ensure that their practice is in line with key documents applicable to their work. Information regarding a failure to comply with a policy must be reported to the line manager and, where it is appropriate, report this using the incident reporting system.

5. Policy

5.1 Organisation of key documents

The Clinical Effectiveness department will maintain an electronic index of trust key documents that will serve as a document management system. The system will be the central register for all key documents in the trust.

In addition, the department will maintain a robust archive system for all key documents.

Trust key documents will be published on the trust's intranet with a search tool provided.

5.2 New Document Development

When a requirement for a new key document is identified, the author must, in the first instance, review existing trust documents to ensure that the issues are not already covered and so avoid duplication. The author should also consider whether an amendment or addition to an existing key document is more appropriate than a new stand-alone document.

National guidance should be transferred into trust format and approved following the process outlined in Appendix 1. The Clinical Effectiveness department can provide advice on how this can be achieved efficiently and effectively

Care pathways should always be supported by a clinical guideline.

The key document must comply with all relevant and current legal and statutory requirements, NHS policy and guidance and professional guidance available.

The key document must include references to any supporting materials and evidence, for example, Department of Health, or National Institute for Health and Clinical Excellence (NICE) guidance or internal trust documents. Authors should consider using the Trust's Library & Knowledge Service to undertake a literature search during the key document development process.

All key documents must be presented in a standard structure and format. Please contact the Clinical Effectiveness department or use the trust intranet for the most up to date template. This will include font size, headers and footer etc. Exceptions to these formats may be allowed, for example, when a key document has been developed with other agencies and intended to work across several organisations. Please seek advice from Clinical Effectiveness.

An explanation of any specialised terms used should be included. Any abbreviations used should be written in full in the first instance.

The author of the key document will be responsible for ensuring that the relevant committees and groups, service users, carers and trust solicitors, (where necessary) are consulted about the draft key document.

Implementation issues and training needs must be identified for each key document as an integral part of the approval process.

All draft versions of the document must be clearly marked as such until they have received final approval.

The inclusion of hyperlinks in key documents should be approached with caution, as links can become broken and therefore inaccessible.

Documents must not be embedded within key documents as files as this can raise accessibility issues.

These points are set out in more detail in the Key Documents Toolkit, available on the Key Documents intranet page.

A checklist should be used to accompany the key document and this can be found with the templates and is included in Appendix 3 of this policy.

5.3 Monitoring section

(NB SOPs are exempt from mandatory sections 5.3, 5.4 and 5.5)

It is essential that compliance with key documents is monitored, evaluated and corrective action taken when necessary to manage the risk and achieve the required outcomes.

The frequency and detail of the measurement, monitoring and evaluation processes should be clearly defined and be realistic.

In practice the process varies according to the type of key document as set out below:

Strategies
Strategies will have a set of measurable objectives, achievement of which will be used to determine progress.

Policies/Procedures/Protocols
All policies will describe how compliance with the requirements laid out in the document will be monitored. This maybe in the form of key performance indicators (KPI) monitored through incident/non-compliance reporting, audit or other measures. The arrangements for monitoring compliance with procedure and protocol documents will be described within the relevant policy.

Clinical guidelines/clinical treatment pathways
There must be a method of monitoring compliance with these documents. This may include, for example, clinical audit or outcome information, as measured against key performance indicators. The frequency of audit, where required, will be determined through the development of Clinical Audit Programmes.
Please refer to Appendix 2 – A guide for writing the monitoring section of a key document for more detailed advice.

5.4 Equality Requirements

It is the responsibility of the key document author to undertake the equality assessment by completing the checklist included in the template to determine if the proposed key document is relevant to the trusts general duty under age, disability, gender, marital/ civil partnership status, pregnancy & maternity, race, religion or belief, sex or sexual orientation.

If it is established that the proposed key document is likely to be relevant to the Trusts legal duties the author should contact the Director of Human Resources for advice on what steps to take to develop a more detailed assessment of the impact of the key document and, where appropriate, design monitoring and reporting systems.

The NHS centre for Equality and Human Rights has developed a *Toolkit for Carrying Out Equality Impact Assessments.* Key document authors should refer to this document which provides guidance on the equality impact process.

A copy of the completed checklist form must accompany the key document when it is presented to the relevant body for approval and, where applicable, the outcome of the detailed impact assessment. A copy of this will be included within the document.

5.5 Financial risk assessments

It is the responsibility of the key document author to undertake the financial risk assessment by completing the checklist included in the template to determine if the proposed document requires financial support.

If it is established that the proposed key document requires financial support to implement, please complete a business case which is signed by your Finance Manager and Directorate Manager for consideration by the Finance and Performance Committee before progressing the key document to the relevant committee for approval.

A copy of the complete checklist must accompany the key document when it is presented to the relevant body for approval and, where applicable, the supporting business case.

5.6 Consultation

Consultation enables interested parties to offer their views on a proposed key document. The main purpose of consultation is to ensure that key documents are based on all available evidence, that they take account of the views and experience of those affected by them, that innovative and creative options are considered and that new arrangements are workable, not aspirational.

All key documents should be developed in consultation with their target audience including managers, clinicians, staff, patients and other stakeholders.

In the case of human resources and employment policies, consultation takes place with the Divisions and Corporate services and with Staff side colleagues prior to JNCC. Draft policies are consulted and/or negotiated on with Staff Side Chair and Vice chair/policy Lead at JNCC Sub Group.
Where key documents may have a potential impact on fraud it is the responsibility of the author to consult with the Local Counter Fraud Specialist for advice.

All consultation will be led by the author and must be completed before the key document is submitted for approval. Authors should use the Consultation section of the key documents application, to enable review and comment from a wider audience.

5.7 Approval Process

5.7.1 The process for submitting trustwide key documents for approval by the relevant committee, including the supporting documents that must accompany the key documents, is described in the flowchart at Appendix 1.

5.7.2 Local key documents (that do not affect staff trustwide) will follow directorate/divisional management lines for approval.

5.7.3 All key documents containing details of medicines must be approved by the Trust's Medicines Safety Committee after submission to any other committee (as outlined in Appendix 1). It is the author's responsibility to forward the medicines related documents to Medicines Safety Committee.

5.7.4 All key documents should be sent to the Clinical Effectiveness Department for quality assurance checks. This should be done before the key document is submitted for approval.

5.7.5 No key document will become a valid document until it has been formally approved by the appropriate committee.

5.7.6 Once approved the owner, or relevant committee will send the final approved electronic version of the key document, and a copy of the minutes demonstrating that the document was approved.

5.7.7 It is acceptable for key documents to be approved by 'virtual' committee where the timing of committee meetings means that there would be an unacceptable delay in gaining approval at a scheduled meeting. Evidence of 'virtual' approval, e.g. emails, should be provided to the Clinical Effectiveness Department as the authorisation to publish the key document. The fact that a key document has been 'virtually' approved should be recorded in the relevant committee minutes at the next meeting.

5.7.8 The document code and version number will be appended to the key document, which will be placed onto the Intranet by the Clinical Effectiveness Department. The Department is also responsible for archiving key documents.

5.7.9 Each division must be clear which directorate/divisional meeting will have authority to approve documents, and this should be outlined in the terms of reference. All approvals should be clearly minuted.

5.8 Implementation arrangements

Implementation issues and training needs must be identified for each new key document and for significant changes to existing documents, as an integral part of their development. This will ensure that a systematic approach is taken to the introduction of key documents in order to secure effective working practices.

If there are significant training implications associated with the introduction of the key document a detailed plan of how this will be provided must be recorded.

5.9 Dissemination process

The author has responsibility for overseeing the effective communication of the approved key document to all relevant staff.

The Clinical Effectiveness Department will:

- Place approved documents on the Intranet, which will be the primary location for all key documents.
- Place relevant key documents on the Trust's Internet.
- Maintain a definitive list of all key documents.
- Confirm with document authors when key documents have been published to the intranet.

Staff may print key documents at need but must be aware that these are only valid on the day of printing and must refer to the Intranet for the latest version. Hard copies must not be stored for local use as this undermines the effectiveness of an intranet based system.

Individual members of staff have a responsibility to ensure they are familiar with all key documents relevant to their work and should ensure that they are working with the current version of a key document. Therefore, the Intranet must be the first place that staff look for a key document.

Line managers are responsible for ensuring that their staff are aware of Trust key documents and that they understand and use them. This information must be given to all new staff on induction.

5.10 Key Document Review

5.10.1 Key Documents require regular review to take account of changing circumstances and all key documents must be subjected to a review no later than 3 years, unless there is a specific requirement for this to be undertaken sooner.

5.10.2 The review of the document should start 6 months prior to the review date.

5.10.3 Key document owners should arrange for a review of the references within the document via library services. Please use this email address, with the subject heading Key Document Reference Check, wah-tr.ALX-Library@nhs.net

5.10.4 The Clinical Effectiveness Team will maintain a central register of all key documents and ensure identification of key documents approaching their review date.

5.10.5 If there are no clinical changes to the document, the owner can complete and return the relevant checklist that will be provided by the Clinical Effectiveness Team, and the document can be re-published for a further 3 years.

5.10.6 Owners will be responsible for confirming with Medicines Safety that there are no changes to the medicines included within the document

5.10.7 If there are clinical or medicine changes needed to the document, owners should obtain approval via the relevant approving committee and MSC where appropriate.

5.10.8 If a change is required to the document prior to its usual 3 year review date, owners should follow points 5.10.4, 5.10.5 and 5.10.6

5.10.9 All revisions made to key documents, will be re-published and the obsolete document will be archived for reference purposes by the Clinical Effectiveness Team.

5.10.10 Where any changes to the document could have implications on resources the existing Financial Assessment should be reviewed and amended where necessary.

5.10.11 Where any changes to the document could impact on any of the personal characteristics outlined within the current EIA form, the existing Equality Impact Assessment should be reviewed and amended where necessary.

5.10.12 The Clinical Effectiveness Department must be provided with the revised document so that the correct approval and publication process can be followed.

5.10.13 When revisions are made to key documents, the obsolete document will be archived for reference purposes in case of subsequent litigation or complaints. The Clinical Effectiveness Department is responsible for archiving key documents.

5.11 Escalation

The following escalation process will apply to all key documents;

6 months prior to review date	Email to document author, details included in monthly divisional governance exception reports
3 months prior to review date	1st follow-up email to author, included in monthly divisional governance exception reports
1 month prior to review date	2nd follow-up email to author, details included in monthly divisional governance exception reports
Monthly reminders will continue to be sent, until the document is reviewed and re-published	

A report will be provided of clinical key documents to the Clinical Effectiveness Group at a frequency as required by the Group that will include details of documents overdue a review and those that will require a review imminently.

A report of non-clinical overdue key documents will be provided to the Trust Management meeting at a frequency as required by the group.

5.12 Training and awareness

This policy requires all policies to state the high level training requirements associated with the document.

5.13 Version control and archiving arrangements

Unique reference number

All key documents will be allocated a unique reference number. This number will be consistent throughout the life of the document.

Version Control
Version control enables us to tell one version of a document from another. All key documents will be version controlled, and the current version of the key document will be recorded on the document itself, within the key document management system. The Clinical Effectiveness Department will be responsible for managing version control.

Archiving
Obsolete key documents will be archived so that they can be retrieved at a later date. The Clinical Effectiveness Department will be responsible for managing the archival of key documents following local procedures.

6. Implementation

6.1 Plan for implementation

This is a long-standing policy and consequently already implemented. The Policy is brought to the attention of all new starters at induction.

6.2 Dissemination

The Policy will be placed on the Trust's Intranet and all staff made aware through the use of the Trust-wide e-mail process and in regular Trust communications.
The key staff identified in this policy will be informed of the policy and any changes to it directly by the Clinical Effectiveness Department.

6.3 Training and awareness

For this policy, the following actions will be taken:

- Clinical Effectiveness staff involved with document management will be trained to:
  - Use the software provided to manage and publish key documents.
  - Follow the processes set out in this policy

- Awareness will be raised by the dissemination of this policy to all staff via the Intranet and through monthly Trust updates. Access to key documents is also included in the Trust's induction programme.
- Clinical effectiveness staff will offer assistance on request in the production/review of key documents.

7. Monitoring and compliance

Monitoring and compliance against **this policy** will be the responsibility of the NICE and Key Documents Manager. The process will ensure that key documents are only published if they meet the requirements set out in this policy.

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	Scheduled review of this policy to ensure that it meets its own requirements for document management	Policy review and revision	Every 3 years – or earlier if necessary	Clinical Effectiveness Team	Clinical Effectiveness Group	Every 3 years – or earlier if necessary
5	Management of review process	Report of all Key Documents overdue review or due to review in the next 6 months	Monthly	Clinical Effectiveness Team	Divisional Management Teams and Corporate Heads of Department	Monthly

8. Policy Review

This policy will be reviewed 3 years from the date of approval.

9. Background

References:

How to carry out an Equality Impact Assessment (EIA)
Mandatory Training Policy
Medicines Policy
National Guidance Implementation Policy

10. Background

10.1 Equality

The assessment conducted for this policy reveals no equality issues. The record of the assessment is appended (**Supporting Document 1**)

10.2. Financial Risk

A financial risk assessment has been performed and appended and reveals there are no financial implications to this policy. (**Supporting Document 2**).

10.3. Consultation

As this policy defines the format and process for developing and maintaining the Trust key documents, the views of a wide range of managers and clinicians in a broad selection of functions and services have been sought.

Key individuals involved in developing the document

Name	Designation
Heather Webb	Clinical Effectiveness Manager
Elaine Chapman	NICE and Key Documents Manager

This key document has been circulated to the following individuals for consultation;

Committee
Divisional Management Teams
Corporate Heads of Department
Chief Medical Officer/Deputy Chief Medical Officer

10.4 Approval Process

This policy will be approved by the Clinical Effectiveness Group

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

NHS Worcestershire Acute Hospitals NHS Trust

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	X	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Elaine Chapman	**NICE and Key Documents Manager**	**elaine.chapman8@nhs.net**
Date assessment completed	**15/09/2022**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Key Document Process			
What is the aim, purpose and/or intended outcomes of this Activity?	The main purpose of key documents is to standardise practice and service delivery to reflect the best available evidence thereby reducing unjustified variations, hence improving quality			
Who will be affected by the development & implementation of this activity?	❑	Service User	❑	Staff
	❑	Patient	❑	Communities
	❑	Carers	❑	Other _____
	❑	Visitors	❑	

Is this:	❑ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Document available to all staff during consultation period via the trust Key Documents Application
Summary of relevant findings	

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		X		Individual key documents all have separate EIA assessments
Disability		X		Individual key documents all have separate EIA assessments
Gender Reassignment		X		Individual key documents all have separate EIA assessments
Marriage & Civil Partnerships		X		Individual key documents all have separate EIA assessments
Pregnancy & Maternity		X		Individual key documents all have separate EIA assessments
Race including Traveling Communities		X		Individual key documents all have separate EIA assessments
Religion & Belief		X		Individual key documents all have separate EIA assessments
Sex		X		Individual key documents all have separate EIA assessments
Sexual Orientation		X		Individual key documents all have separate EIA assessments

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		X		Individual key documents all have separate EIA assessments
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		X		Individual key documents all have separate EIA assessments

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	**3 years as part of documents regular review schedule**			

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	E Chapman
Date signed	15/09/2022
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval

Appendix 1 - Key Documents Approval Flowchart

Each Committee should be clear about the key documents that it is responsible for reviewing and approving, and have a planned schedule for their review.

Key Document Type	Human Resources (excludes Medical Policies)	Human Resources – Medical Policies only	IM&T, includes data quality, security, Health Records	General Nursing Practices	Infection Prevention & Control (IPC)	Health and Safety	Trustwide Clinical Policies, Guidelines, SOPs (excluding IPC)	General Non-Clinical Policies i.e. patient access, emergency planning, patient transfer and discharge (excludes technical estates policies)	Technical Estates Policies	Medicines	Speciality clinical : Specialty specific – to directorate meeting for approval, then divisional meeting for information. Directorate Specific – to directorate meeting for approval, then divisional meeting for information. Divisional specific – to divisional meeting for approval	Finance e.g. SFI, SO	Strategies and Schemes
All key documents to be sent to the Key Documents Team for governance checks prior to approval													
Approval Group/ Committee	JNCC (Policies must only be submitted to JNCC following review by the Policy Working Group)	Medical Management Committee (then People and Culture Committee for information)	Information Governance Group	Clinical Governance Group	Trust Infection Prevention and Control Committee	Health and Safety Committee Policies to go to JNCC for interest/ Comment.	Relevant group e.g. Resus Committee, Child/Adult Safeguarding Group, Blood Transfusion If no relevant group, direct to Clinical Governance Group	Trust Management Executive	Authorising Engineer	Medicines Safety Committee	Relevant department/divisional governance meeting	Trust Management Executive	
						Policies that are not a legal requirement such as slips, trips and falls, to have final approval at JNCC and not TME	Medicines Safety Committee (only if medicines are included)						
Final Ratification	People and Culture Committee (information only)		Trust Management Executive			Trust Management Executive (then People and Culture Committee for information)	Clinical Governance Group		Health and Safety Committee		Medicines Safety Committee (only if medicines are included)	Finance and Performance Committee	Trust Board
Final approved document, copy of relevant minutes and completed checklist to go to the Key Documents Team for publishing and archiving any previous versions													

Any key document that contains information relating to medicines must have approval by the Medicines Safety Committee.

Appendix 2 – How to complete a monitoring section

Monitoring Compliance with Policies/ Procedures/ Guidelines

A guide for writing the 'monitoring' sections of key documents

1. What is Monitoring?

Our policies and procedures contain systems and processes that have been designed so that we provide a safe environment for patients, staff and visitors. They do this by reducing and, where possible, eliminating the risk of loss/harm. We need to know whether we are actually following these systems and processes, and we do this through continual monitoring.

When we are developing systems and processes we need to build in a routine to check;

- whether the systems/processes are being followed precisely as described;
- whether the systems/processes are being effective in reducing risks.

2. What does monitoring do?

Monitoring forms all the major underpinning work from which **assurance** can be taken (or not) by an organisation that its **systems** and **processes** are **working** well.

Monitoring aims to **demonstrate** whether or not the **process for managing risk**, as described in the approved documentation, is **working** across the **entire trust**.

Where the process is not being followed, or is not effective, **action plans** must be drawn up and **changes made** to reduce the risks.

Monitoring is normally **proactive**, so it is designed to **highlight** issues **before an incident occurs**.

3. Describing Monitoring in Key Documents

Our key documents must include a section that sets out **how** we will check whether or not the **process for managing risk**, as we have described it in the approved documentation, is **working** across the **entire trust**.

The document must:

- Be explicit about what is being monitored. **WHAT**
- Describe the method/tool we will use to measure each control within the process /system. **HOW** ('Controls' are the key elements of the process that manage risk. We should not attempt to monitor every single stage in a process, just the most crucial elements.)
- Describe how often each process or system should be monitored. **WHEN**
- Describe where the findings from monitoring and action plans will be reported to. **WHERE**
- Describe who will undertake any actions required as a result of the findings from monitoring. **WHO**

In order to ensure ongoing improvements, we should also;

- Describe how any required process or system changes will be implemented.
- Describe how lessons learned will be shared locally and if necessary externally.

It is important that our monitoring sections are **SMART**;

Specific – is the process and any monitoring tool specific enough?
Measurable – is the process measurable?
Achievable – is the monitoring realistically achievable?
Relevant – will the monitoring method actually tell us what we need to know?
Timely – can it be achieved within the timeframe available?

All monitoring must result in a **written record** that proves the monitoring has taken place.

4. Addressing Non-Compliance

Where our monitoring information has identified areas where we are not following our policies, we should develop action plans to address the issues. We need to include a description of this process in the key document.

5. Monitoring Table

The table below provides a structured way of describing our monitoring arrangements. It includes guidance notes.

This table is not mandatory, but where it is not used the same principles must apply.

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	*What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)*	*Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.*	*Who is responsible for the check? Is it listed in the 'duties' section of the policy? Is it in the job description?*	*Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.*	*Use terms such as '10 times a year' instead of 'monthly'.*

Appendix 3 – Key Document Checklist

Document title	Click here to enter text.			
Document reference	Click here to enter text.			
Front sheet completed in full? (Approval, review, owner)	**Yes**	☐	**No**	☐
Key amendments box completed in full for all document reviews? (if document has been re-published without changes, this also needs to be reflected in the key amendments box)	**Yes**	☐	**No**	☐
Body of key document conforms to relevant standard template	**Yes**	☐	**No**	☐
Does the content of the leaflet use inclusive language? *Inclusive language is language that does not exclusively refer to the binary of male and female. Please refer to the document A Guide to Inclusive Language in Policies for further information*	**Yes**	☐	**No**	☐
Is there a monitoring section included?	**Yes**	☐	**No**	☐
Are any references included still up to date?	**Yes**	☐	**No**	☐
Are supporting documents included and completed? (This should be a financial risk assessment and new EIA form)	**Yes**	☐	**No**	☐
Approved by appropriate person/committee?	**Yes**	☐	**No**	☐
Details (name of committee/group and date of approval)	Click here to enter text.			
Are there any medicines included in the document?	**Yes**	☐	**No**	☐
If yes, has this been to MSC for comments/approval?	**Yes**	☐	**No**	☐
Date of approval	Click here to enter text.			
Ready for publishing?	**Yes**	☐	**No**	☐

Please be aware that it is normal practice for all key documents to be published on both the trust intranet page and public facing website.

You must consider and confirm that the content does not risk the safety of patients or the public, prior to uploading to public-facing websites. This must be discussed as part of the approval process and included in any subsequent minutes. We therefore require your positive confirmation that this is appropriate to publish to the public facing website?

Yes ☐ **No** ☐ If no, please give reasons:

Click here to enter text.

Key words (these are words that end users may use in the search function, consider any shortened or alternative phrases the document may be known as):

Click here to enter text.

Please return completed checklist with final version of approved document to the key documents team

Clinical Patient Information Checklist

Document title Click here to enter text..

Document reference Click here to enter text.

Body of leaflet conforms to standard template **Yes** ☐ **No** ☐

Are any images used trust approved? **Yes** ☐ **No** ☐

Does the content of the leaflet use inclusive language? **Yes** ☐ **No** ☐

Inclusive language is language that does not exclusively refer to the binary of male and female. Please refer to the document A Guide to Inclusive Language in Policies for further information

Has the leaflet content had patient input/comment **Yes** ☐ **No** ☐

Please give details
Click here to enter text.

Approved by appropriate person/committee? **Yes** ☐ **No** ☐

Details (name of committee/group and date of approval) Click here to enter text.

Are there any medicines included in the document? **Yes** ☐ **No** ☐

If yes, has this been to MSC for comments/approval? **Yes** ☐ **No** ☐

Date of approval Click here to enter text.

Ready for publishing? **Yes** ☐ **No** ☐

Please indicate where you would like this document available

Intranet ☐ Public facing website ☐ Xerox ☐

Key words (these are words that end users may use in the search function, consider any shortened or alternative phrases the document may be known as):

Click here to enter text.

Please return completed checklist with final version of approved document to the key documents team