Trust Policy

The Development and Management of Formal Documents

Issue Date	Review Date	Version
November 2016	November 2021	Version 5.3

Purpose

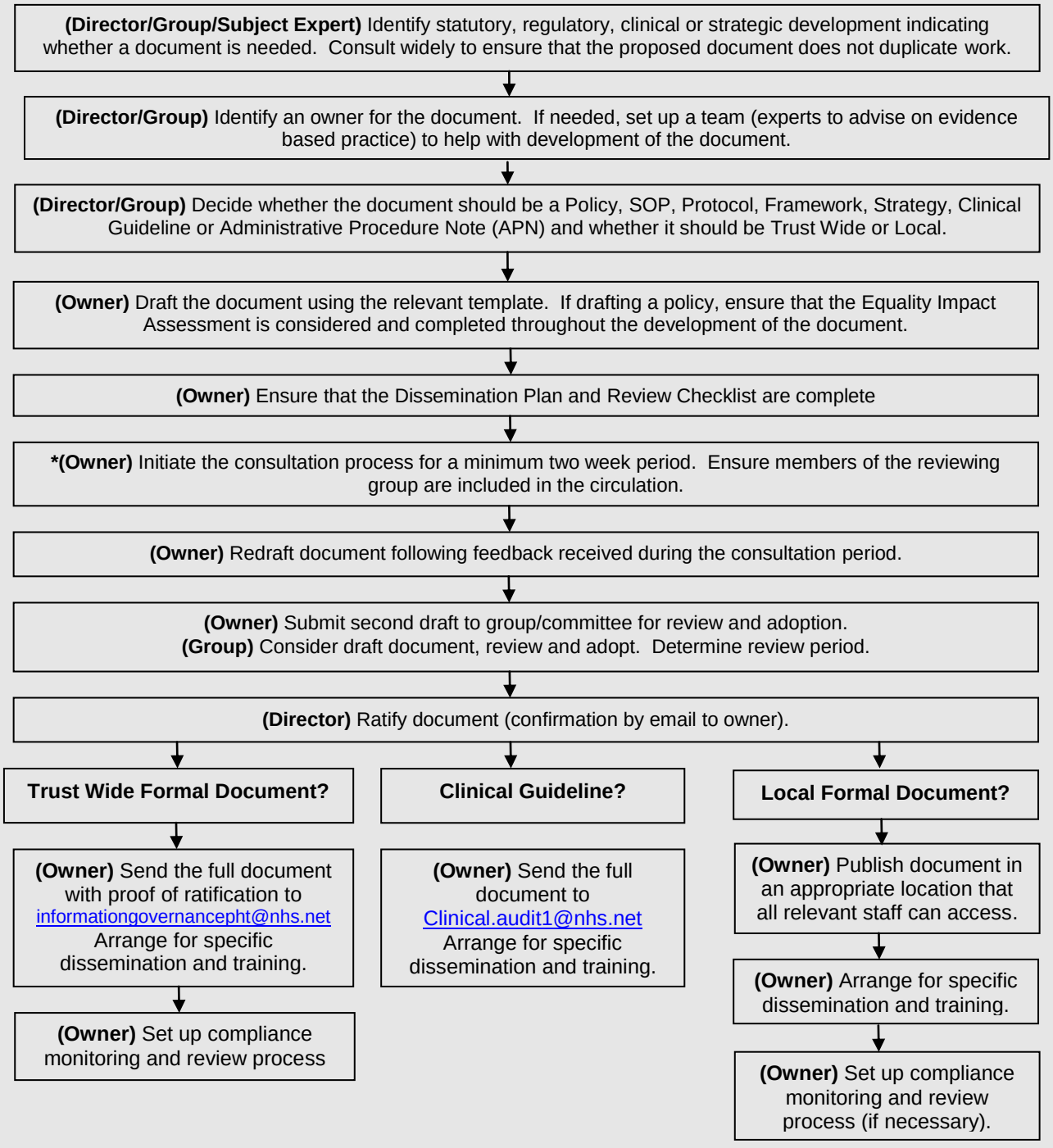
This policy describes the development process for Trust Wide and local formal documents.

Who should read this document?

All staff involved in the process of developing, or maintaining formal documents.

Key Messages

The following flowchart summarises the key steps required to develop a formal document.



Core accountabilities	
Production	Information Governance Support Manager
Owner	Head of Information Governance and Library Services
Review	Caldicott and Information Governance Assurance Committee
Ratification	Director of Corporate Business on behalf of the Trust Board
Dissemination (Raising Awareness)	Head of Information Governance and Library Services
Compliance	Caldicott and Information Governance Assurance Committee

Links to other policies and procedures
The principles set out in this policy must be applied to all formal documents.

Version History		
1	26 September 2008	Ratified by the Trust Board and published Trust wide.
2	16 June 2009	Reviewed – no changes made.
3	3 November 2009	Naming Conventions changed, Minor job roles amended. Approved by the Records Management Steering Group.
4.1	October 2011	Updated to ensure full compliance with NHSLA requirements.
4.2	July 2012	Minor updates in preparation for the NHSLA assessment.
5.1	November 2016	Reviewed in line with document expiry
5.2	May 2018	Minor update to job titles, clarification on definition of dissemination and compliance
5.3	November	Removed the words StaffNet as moved to network share

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Contents

To obtain templates in Microsoft Word format, please contact the Information Governance team by phone (31547/37288) or by email (informationgovernancepht@nhs.net).

1 Introduction

This policy outlines the process for the development, review, ratification and dissemination of all Trust Wide and local formal documents produced across the Trust.

Organisations need formal written documents which communicate standard organisational ways of working. A common format and approval structure for such documents reinforces corporate identity and ensures that documents in use are current and reflect an organisational approach. Their consistent application will promote clarity, consistency and compliance with legislation, statutory requirements and best practice. Ultimately, the effective dissemination, implementation and monitoring of formal documents will help to improve the quality and consistency of patient care.

2 Purpose

The purpose of this document is to provide a standard corporate approach to the development and management of formal documents ensuring accessibility to staff, patients and other stakeholders.

3 Definitions

Formal documents set out the required approach to delivering the way that the Trust works. These documents can be Trust Wide or local.

- **Trust Wide** - A document that may be applicable to all staff throughout the organisation.

- **Local** – A document that is applicable to a restricted area/group of staff in the organisation.

Formal Document Types

Policy - A statement of the Trust's position, determined by the Board, or its appointed committees, stating the governing principles relating to particular issues or situations.

Standard Operating Procedure (SOP) - A description of the set of actions prescribing the Trust's way of doing something and stipulating that any deviation from it should be justified, approved and recorded.

Protocol - A pseudo-legal statement of obligation, which defines and restricts what must happen in a specific situation.

Framework - A document which provides a broad overview or an outline of interlinked items which support a particular approach to a specific objective.

Strategy – A plan of action designed to achieve an aim.

Administrative Procedure Note (APN) - A step by step description illustrating the way that the Trust carries out an administrative task.

Clinical Guideline – A document designed to guide decisions and criteria regarding diagnosis, management, and treatment in specific areas of healthcare, see section 11.

Other Guidance/Guidelines – A document that describes the preferred method of operation and addresses non mandatory activities.

Approval Process

- **Consultation** - Mechanism for seeking advice and opinion from a wider group of potential stakeholders.

- **Review** – Documents are distributed to the reviewing group/committee to ensure that the content is appropriate, has been produced with the right input and consultation and is accompanied by an implementation plan.

- **Ratification** - Making a formal document official. Confirming its status.

- **Adoption** - Publishing and implementing a ratified document

- **Dissemination (Raising Awareness)** – The document owner should be responsible for ensuring all key staff are aware of the existence of the document (see Section 8).

- **Compliance** – The document owner should ensure a named person is responsible for carrying out compliance monitoring. Compliance can be onward reported to a group/committee (see Section 10).

All formal documentation should use the definitions above, where relevant.

4 Roles and responsibilities

Trust Board
The Trust Board is responsible for gaining assurance that the Trust's approved documentation is appropriate, up to date and applied. Responsibility for seeking this assurance is delegated to the Caldicott and Information Governance Assurance Committee.

Director Grade Staff

Director Grade Staff are responsible for the review, ratification and compliance of formal documents. For each adopted formal document, there must be an identified Director who takes overall responsibility.

Directors are responsible for delegating responsibility for reviewing each adopted document to a specific committee, or group and ensuring that compliance is demonstrated.

Caldicott and Information Governance Assurance Committee

The Caldicott and Information Governance Assurance Committee is responsible for overseeing the compliance with this policy. Any areas of concern will be raised with Senior Management in the first instance and if necessary escalated to the Trust Board.

Groups/Committees

Appointed groups/committees (can include formal Trust Board sub committees, corporate committees, Care Group, Service Line, specialty or subject specific groups) are responsible for reviewing specific formal documents and will:

- Approve a proposal for a new document to be produced by a subject matter expert.
- Identify the statutory, regulatory, clinical and professional requirements and expectations that justify and necessitate the document and ensure these are recorded within the introductory section of the document.
- Justify new and significantly revised documentation to show how it will enhance the delivery of the Trust's objectives and priorities.
- Ensure that implementation is affordable and achievable; and that it does not overlap, or contradict other developments within the Trust, or nationally.
- Ensure that adequate document control arrangements, including deadlines and consultation arrangements are agreed at the start of the development process.
- Ensure formal documents are up to date, relevant, in the corporate format.
- Make recommendations to the Director regarding ratification and adoption of the document.
- Monitor the progress of review and revision of adopted documents.
- Assurance of implementation via formal feedback on the results of the monitoring arrangements within each document.

Owner

The owner has responsibility to:

- Identify the programme for development or reviewing the formal document, including the timetable of delivery, consultation process and dissemination arrangements for the ratified document, including provision of training.
- Ensure that adequate consultation occurs with interested parties and stakeholders; taking their views into account in developing and reviewing the document. The author will seek expert advice within the Trust, where required, ensure links to other documents are identified and the owners of these documents are included in the consultation and if necessary, other documents amended to reflect appropriate changes.
- Draft the document in line with the template provided, including consideration of the Equality Impact Assessment (for Trust Wide policies) at the start of the document development.
- Complete the required forms and checklists, preparation for ratification by the Director.
- Send the ratified document to the Information Governance team for publication.

- Signpost all relevant departments, staff groups, and post-holders to the document, providing training where necessary.

Information Governance Team

The Information Governance Team is responsible for the following in respect of Trust Wide formal documents.

- Provision of a library of up to date Trust Wide formal documents, accessible to staff and others that need to use them.
- Maintenance of an archive of out-of-date Trust Wide formal documents.
- Alerting owners when Trust Wide formal documents are within four months of their expiry date and providing further alerts in accordance with the agreed escalation process.
- Informing the ratifying Director when the formal document is out of date.
- Ensuring that documents comply with the formatting requirements set out in this document; and that they have been reviewed and ratified correctly.
- An index that includes the document's title, number and issue, owner, issue date, next review date and version control history.
- Monitoring implementation of this policy and providing assurance on compliance to the Caldicott and Information Governance Committee.
- Uploading policy documents to the Trust's Publication Scheme.

All Staff/Contractors and Stakeholders

All staff are expected to contribute to the development and update of documentation, if requested, in instances where their experience, skills and expertise are considered to be of likely benefit to the process.

All staff, contractors and stakeholders working in, or with the Trust will ensure that they will abide by the requirements set out in relevant formal documents.

Audit, Assurance and Effectiveness Team

The Audit, Assurance and Effectiveness Team is responsible for the management of clinical guidelines by:

- Maintaining a library of published guidelines and recording each guideline on a centralised indexing document.
- Ensuring that all documents presented for publication are in a suitable format with the required approvals.
- Alerting document owners two months prior to document expiry. Escalating non-response to Clinical Governance Leads and Care Groups.
- Maintaining an archive of out-of-date Clinical Guidelines.

5 Formal Document Development

Style and Format

All formal documents must adhere to the agreed corporate style as set out in this document. Owners are required to use the relevant template document when drafting their document. These are designed to comply with the agreed corporate style and identify the sections and information that must be provided.

- Documents must contain a “Key Messages” section on the front page which is an opportunity to quickly and clearly communicate the key points of the document to all staff.
- Documents should be written in “Plain English”.
- Text should be clear and concise using unambiguous terms and language.
- Unfamiliar terminology must be explained within the “definitions” section.
- Documents should be written in Arial Font Size 12 with the exception of diagrams and flow charts.
- Abbreviations and acronyms should only be used if these are set out in full the first time they are used, followed by the abbreviation or acronym in brackets.

References and Associated Documentation

All formal documents should incorporate up to date references including national guidance, legislation etc.

All documents must include a section that details any other documents that have an impact on, or are impacted upon, by that document. These relationships should be assessed whenever a full review or non-significant revision is planned.

Discovery Library staff can be contacted for assistance with searching for relevant literature - via http://discoverylibrary.org, library.mailbox@nhs.net or telephone (4)39111.

Shared Formal Documents

Collaborative working can necessitate the need for formal documents to be developed that are cross organisational. In some cases, documents are adopted from partner organisations. These documents must be subject to the principles set out in this policy. There must be a defined owner and ratifying Director who take responsibility for the document on behalf of the Trust.

Equality Impact Assessment

All public bodies have a statutory duty under the Equality Act 2010 (Statutory Duties) Regulations 2011 to provide evidence of the analysis that it undertook to establish whether its policy documents would further, or had furthered, the aims set out in section 149(1) of the Act; in effect to undertake equality impact assessments on documents and practices.

All policy documents must be subject to an assessment, using the Equality Impact Assessment Tool. This must be completed as part of the document development or document review process. The completed document must be appended to the end of the policy document.

6 Consultation Process

The consultation process should be comprehensive and robust and must include all relevant clinical and non-clinical stakeholders within the Trust. These are likely to include some of the following:

- Staff representatives, clinical and professional bodies and representatives.
- Unions.
- Human Resources and Workforce Development.
- Finance.
- External stakeholders, colleagues and commissioners.
- Patients and the wider community of service users.
- Trust management

This list is not exhaustive and should be reviewed for each document. Documents which affect staff employment and terms and conditions are reviewed by the Policy Sub Group of the Joint Staff Negotiating Committee (JSNC).

A time limit for consultation should be set, for a minimum of two weeks. Details of the consultation must be clearly documented in the submission to the group responsible for reviewing the document.

7 Review Arrangements

The Information Governance team will run monthly reports to identify Trust Wide formal documents that are due for review. These reports will be used to notify owners in advance of document reviews and are escalated where review dates lapse. Initial contact will be made four months in advance of the review date to ensure there is sufficient time to consult on amendments.

Periodic Review Frequency

All approved documents must be subject to a periodic review and re-adoption process. The frequency of review will be flexible to reflect the Trust's assessment of the risk and impact of changes in factors affecting the adopted documents. These include statutory and regulatory change; technological, clinical and professional developments; and central and local priorities.

The default review period for documents should be set as five years. Non-significant changes to documents are permitted and should be made by the document owner.

The Director or the appointed group should determine the review frequency for each document. The review process can be brought forward, at any time, in response to significant developments.

The agreed review date must be reported at the front of the document.

Early Review (Significant Changes)

It may be necessary for a document to be reviewed earlier than the agreed review date. The reviewing group should be aware of changes to relevant legal and statutory requirements, NHS policy and guidance that might indicate the need for a review and revision. The owner is responsible for monitoring the development of these changes and their potential impact on the currency of the document.

The decision to carry out an early full review should be made only if the changes needing to be implemented are considered to be significant. Significant changes might be indicated by the following:

- Statutory or regulatory change that is likely to impact on the Trust's objectives and priorities.
- Procedural or organisational change that is likely to impact on the services, or function's links and relationships with other parts of the Trust. These are likely to result in a wider review of inter-related documents.

Once the document has been reviewed and updated, it must be subject to consultation, review and ratification.

Early Review (Non-Significant Changes)

Non-significant changes might be indicated by the following:

- Editorial changes to improve understanding and comprehension and minor corrections to the stated documents.
- Changes in the name of external organisations, where the relationship with the Trust, in respect of the document, is mostly unchanged.
- Changes in the name or description of staff referred to throughout the document.

Non-significant changes can be made by the owner, without the need to go through the full review process. The nature of the minor amendments must be recorded in the document version history. Each revised and re-published version will be allocated a new version number. The ratifying Director should confirm the changes are appropriate.

The planned review and revision deadline will not be extended as a result of publication of non-significant revisions.

Review Date Extensions

Extensions to document review dates must be ratified by the responsible Director and must not exceed 12 months.

8 Dissemination and Publication

Trust Wide Formal Documents

Trust Wide formal documents must be published within the Trust Documents central repository. The owner is responsible for submitting an electronic copy of the document, along with evidence of review and ratification to the Information Governance team for publication.

The Information Governance team will report to all staff, through the Trust official communication briefing, a monthly notification of all newly published or reviewed Trust Wide formal documents.

The reviewing group and the owner should identify the expected dissemination and training requirements, associated with the publication of the revised document, as part of the initial planning of the document's revision process.

There should be a clear plan for each document on how its existence, content and implications are disseminated to those staff that need to be aware of it. The reviewing group and document owner will identify the groups and individuals, within and external to the Trust, who will need to be informed of the publication. Evidence of this dissemination must be retained. Passive dissemination should not be relied on to ensure uptake of document statements/recommendations and should be accompanied by active methods to ensure staff understanding.

All Trust employees have a responsibility to familiarise themselves and keep up to date with the relevant formal documents in relation to their work. Staff may print hard copies of documents for their own use but these printed versions will not be considered "approved documents" as the content may subsequently be updated. It is the reader's responsibility to check that the version of the document they use is the current active version.

Local Formal Documents

The document owner is responsible for identifying a suitable repository for locally produced formal documents. This must be accessible to all staff who need to be aware of the content of the document.

Freedom of Information

The Freedom of Information Act 2000 mandates a requirement to proactively publish appropriate information relating to the business of the Trust. This is made available to the public via Section 5 of the Trust's Publication Scheme, on the Trust's external facing website. All Trust Wide policy documents should be published unless an exemption applies.

The Information Governance team is responsible for uploading Trust Wide policy documents to the Publication Scheme.

9 Implementation and Training

The reviewing group must ensure that adequate levels of training are provided to relevant staff. Training will range from informing staff of the existence of a document, to the provision of a formal training programme.

The reviewing group should ensure that any training requirements are discussed and planned with the Trust's Workforce Development training function. Training requirements should be communicated to staff on dissemination of the document.

10 Monitoring Compliance and Effectiveness

All adopted documents must include a section describing how compliance will be monitored. As a minimum, the monitoring must be sufficient to meet any statutory, regulatory, clinical or professional requirements. These requirements must be identified specifically. The design of the compliance monitoring process should include the following:

- Who will perform the monitoring.
- How frequently will the monitoring be performed.
- What monitoring will be performed, including targets and KPIs, if appropriate.
- How shortfalls will be addressed.
- Where the results of the monitoring will be reported. The group responsible for monitoring must receive regular reports on monitoring activity and actions taken to improve compliance.
- Follow up arrangements.
- Arrangements for disseminating learning.

11 Development and Management of Clinical Guidelines

Clinical Guidelines are managed by the Audit, Assurance and Effectiveness Team. Key information relating to the governance of Clinical Guidelines is detailed below:

To publish a Clinical Guideline:

- The document must be in the Clinical Guideline template (which can be obtained from the Clinical Guidelines section in the Document Library) or suitable alternative which has been agreed in advance by the Audit, Assurance and Effectiveness Team.

- The Trust logo must be present in the top right hand corner.

- The document must be presented to an appropriate group/committee for review.

- The document must be ratified by a suitable person (e.g. Clinical Governance Lead/Subject Expert/Service Line Clinical Director/Care Group Director).

- The document must have a defined review date which must not exceed five years.

12 Key information regarding this document

Overall responsibility for this document

The Director of Corporate Business is responsible for ratifying this document on behalf of the Trust Board. The Head of Clinical Systems Governance is the document owner and the Caldicott and Information Governance Assurance Committee is the reviewing group.

Dissemination and training in respect of this document

This document will be publicised in the Trust's weekly staff news briefing. All Service Line Managers and formal document owners will have the document sent to them and the document will be available in the Trust Documents central repository. The Information Governance Team will run a small number of familiarisation sessions, to acquaint key staff with the document.

Monitoring Compliance

The Information Governance team is responsible for reviewing documents presented for publication, to ensure that they are compliant with the requirements set out in this policy. Compliance with this policy will be monitored by subjecting all policies to a quality assurance review prior to publication. The team will maintain a record of its review process, as part of the document history. This record will include:

- Details where documents have to be returned to the owner for amendment.
- Evidence that the document has been approved, adopted and ratified correctly.
- Details of overdue documents and the archiving of previous versions.

An annual report will be presented to the Caldicott and Information Governance Group, summarising the results of the compliance monitoring process. As a minimum, this will report, the following:

- The number of documents held.
- The number of documents falling overdue for review.

- Action taken to improve the level of compliance.

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	The Development and Management of Formal Documents
Date Finalised	November 2016
Previous Documents	
Action to retrieve old copies	To be managed by the Information Governance Team.

Dissemination Plan			
Recipient(s)	**When**	**How**	**Responsibility**
All Trust staff	November 2016	Vital Signs	Information Governance Team
All Document Owners/SLMs	November 2016	Electronic	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
Rationale	Are reasons for development of the document stated?	Yes
Development Process	Is the method described in brief?	Yes
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	Yes
Content	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the intended outcomes described?	Yes
	Are the statements clear and unambiguous?	Yes
Evidence Base	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited and in full?	Yes
	Are supporting documents referenced?	Yes
Approval	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	Yes
	Does the document identify which Executive Director will ratify it?	Yes
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	Yes
Document Control	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes
	Is there a plan to review or audit compliance with the document?	Yes
Review Date	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	November 2016
Title	The Development and Management of Formal Documents
What are the aims, objectives & projected outcomes?	The purpose of this document is to provide a standard corporate approach to the development and management of Trust wide and local formal documents. This will ensure that appropriate information is presented in a standard format and is accessible to staff, patients and other stakeholders; and that the drafting, approval and review process is clear to all.

Scope of the assessment
All Trust staff will use this document as standard when compiling any formal documents so that all are developed and managed in a comprehensive and consistent manner. The compliance and effectiveness of the document will be managed by means of audits of documents published or reviewed over the previous 12 month period. The document includes an approval and review checklist to be completed by the owner prior to ratification.

Collecting data	
Race	This is mitigated as the policy can be made available in alternative languages.
Religion	The document has no impact in this area.
Disability	This is mitigated as the policy can be made available in alternative formats.
Sex	The document has no impact in this area.
Gender Identity	The document has no impact in this area.
Sexual Orientation	The document has no impact in this area.
Age	The document has no impact in this area.
Socio-Economic	The document has no impact in this area.
Human Rights	The document has no impact in this area.
What are the overall trends/patterns in the above data?	There are no trends/patterns in this data.
Specific issues and data gaps that may need to be addressed through consultation or further research	Formal documents can be made available in a number of different formats and languages if requested. No further research is required as there are no further equality issues.

Involving and consulting stakeholders	
Internal involvement and consultation	The policy owner is the Head of Clinical Systems Governance. Assistance has been provided by the Director of Corporate Business. The policy has been circulated Trust Wide for consultation.
External involvement and consultation	This policy has been developed with reference to the practices of other NHS Trusts.
Impact Assessment	
Overall assessment and analysis of the evidence	This assessment has shown that there could be an impact on race or disability groups. However, this document can be made available in other formats and languages if requested. The document does not have the potential to cause unlawful discrimination. The document does not have any negative impact.

Action Plan

Action	Owner	Risks	Completion Date	Progress update
Provide document in alternative formats and languages if requested.	Head of Information Governance and Library Services	Potential cost impact.	Ongoing	This action will be addressed as and when the need occurs.