Heart of England NHS
NHS Foundation Trust

Development of Controlled Documents Policy v1.0

Document reference:	POL002
Document Type:	Policy
Version:	1.0
Purpose:	This policy gives authors of Trust policies and controlled documents a comprehensive description of the requirements for HEFT and describes the process for development, approval, implementation and review.
Responsible Directorate:	Corporate Affairs
Executive Sponsor:	Director of Corporate Affairs
Document Author:	Head of Risk and Compliance
Approved by:	Policy Review Group
Date Approved:	05/09/2016
Review Date:	05/09/2019
Related Controlled documents	Clinical Guidelines Policy Controlled Documents procedure
Relevant External Standards/ Legislation	
Target Audience:	All staff who are responsible for the development of controlled documents
Further information:	Available from the Policy Assurance Officer

Paper Copies of this Document

If you are reading a printed copy of this document you should check the Trust's Policy website (http://sharepoint/policies) to ensure that you are using the most current version.

Version History:

Version No.	Date of Release	Document Author	Ratified by	Date Ratified
1.0	TBC	Head of Risk and Compliance	TBC	TBC

Summary of changes from last version:

New Policy

Table of Contents

1. Introduction / Purpose

The purpose of this policy is to ensure that the Trust's policies and procedural documents ("Controlled Documents") are developed and implemented appropriately.

This policy aims to to ensure that all Controlled Documents are:

- developed and approved through a clear process;
- developed in consultation with all relevant stakeholders;
- assessed for any impact they have on the Trust and the delivery of services;
- written clearly and succinctly, using plain language appropriate to the intended audience;
- implemented effectively by ensuring adequate awareness and providing appropriate training and support;
- are monitored effectively and in line with clear metrics;
- easily accessible to all staff and published in accordance with the Trust's Freedom of Information Act Publication Scheme; and
- reviewed and revised regularly, responding to changes in legislation, standards and good practice.

2. Policy Statement

This document ensures that authors are aware of the types of document, the overall requirements for content, style and formatting and the responsibilities of authors

Staff should:

- Use the latest Trust template for all new or reviewed policies
- Adhere closely to requirements for content and formatting
- Fully update the documentation control sheet (front page) before submission
- Ensure appropriate consultation and impact assessment on each version

Staff should not:

- Allow the existing document to exceed its review date without providing an updated version or having an imminent plan for producing one. Please note a document beyond its review date remains in force until superseded by the next version or removed.
- Assume that there have been no relevant legal or policy changes (national or local) on your subject matter since the previous version was implemented

3. Definitions

Controlled Document	Controlled Documents are documents which provide a framework for safe, effective and acceptable practice. Documents are 'Controlled' when their revision status, their approving body and date of approval is evident and they are

	protected from destruction/damage.
Controlled Document Lead	The Controlled Document Lead is the identified lead manager, nominated by the Controlled Document Sponsor, who is responsible for the development and review of the Controlled Document.
Controlled Document Register ('the Register')	A centralised system to store and revise all Controlled Documents, including title, classification, current version number, Controlled Document Lead, Controlled Document Sponsor, approval group, issue date, review date and any necessary comments.
Controlled Document Sponsor	The Controlled Document Sponsor is the identified Executive Director, who has responsibility for approving the development of the Controlled Document. For Clinical Guidelines the Controlled Document Sponsor is the Clinical Guidelines Group which acts through its chair or nominated deputy chair.
Guidelines	A guideline is a statement by which to determine a course of action. A guideline aims to streamline particular processes according to a set routine or sound practice. By definition, following a guideline is never mandatory. Guidelines are not binding and are not enforced.
Policy	A statement of intent and principles, explicitly stating individuals' responsibilities and accountabilities which provides the basis for consistent decision making, actions and resource allocation. A policy provides a documented framework enabling individuals or specific groups of staff to carry out interventions, plans or care. Compliance with policies is not open to interpretation or professional judgement and is non-negotiable.
Procedural Document	A 'Procedural Document' is a description of operational tasks to be undertaken to implement, or in support of, a policy. Procedural documents apply across the Trust to all relevant sites and services.
Reserved policies	This is a specified list of policies which require approval by the Trust Board (where approval cannot be delegated). Further guidance on reserved polices can be obtained from the Policy Assurance Officer.
Review Date	Controlled Documents will be reviewed and revised in response to changed circumstances, and in any event, at intervals of not more than three years. Shorter review periods may be stipulated by the approving body.
Stakeholders	Stakeholders are all those individuals or groups who have a stake in or may be impacted by a given Controlled Document. Accordingly, stakeholders must influence the Trust's services, policies and procedures.
Standard Operating Procedures	Standard Operating Procedures (SOPs) are a written set of instructions that staff must follow to complete a job safely,

	with no adverse effect on personal health or the environment, and in a way that maximises operational efficiency. SOPs may be either internal (local) or external procedures. **External Standard Operating Procedures** are those required by an external body and/or which are subject to external inspection. These are treated like any other Controlled Document which means that they are registered on the Controlled Document register and published on the Trust's intranet. **Internal Standard Operating Procedures** are only applicable to local staff and are not externally inspected. They are therefore NOT registered on the Controlled Document register and NOT published on the Trust's intranet. However, the principles of this policy still apply to them. It must be identifiable when these local SOPs have been approved and when they are due for review. As a minimum they must be reviewed every 3 years.
Version Control	Version Control Numbering consists of a number followed by 'point,' then one more number. Any minor amendments will be reflected in the latter number ascending by one point. Each full review would result in the number to the left of the 'point' incrementing by one.

4. Policy Requirements

Detailed guidance on the development, formatting and approval of controlled documents can be found in the associated procedure. This section includes the policy principles that should be followed by all staff during that process.

4.1 Legislation and Guidance

Authors are responsible for ensuring that all relevant legislation and national guidance is taken into account and referenced when developing trust policy and procedures.

4.2 Impact Assessments

When authors have completed their first draft of the new (or revised) document, they must then undertake the mandatory impact assessments in accordance with the instructions in the procedure. In the event that these assessments identify further consideration or changes to the draft, such actions must then be undertaken.

4.3 Consultation

Prior to submission for the final approval processes, authors must undertake all necessary consultation. Such consultation must be meaningful and should take place with all relevant groups and individuals during policy development.

- Staff Side must be consulted about all employment related policies.

- Patients and their carers must be involved in the development and evaluation of new policies which relate to services/care that directly affect them.
- Any other external stakeholders as appropriate.

Ultimately, the executive sponsor must ensure that the full, necessary (internal and external) consultation has been undertaken, based on a case by case approach applicable to the content of the policy and/or procedure. Further advice can be obtained from the Policy Assurance Officer.

4.4 Approval Process

With the exception of urgent action taken by the Board between meetings (under the provisions of Standing Orders), all Trust policies and Trust-wide procedures must be submitted to the Policy Review Group for approval. In some cases, following agreement by the Policy Review Group, it will be necessary to submit the documents to the Board.

Some procedures are not Trust wide, for example those which are division-specific only. Such documents, (together with their implementation and monitoring plans) should follow the principles contained in this document. They may be agreed at the appropriate level within the respective division or directorate. Such procedures must not conflict with relevant Trust policies or Trust wide procedures.

4.5 Communication

The Policy Assurance Officer is responsible for posting a copy of all approved policies and trust wide procedures on the trust intranet via the SharePoint system. This posting will be announced, at the time, in the Trust's weekly electronic staff briefing and also (if appropriate) through any specific communication requirements identified within the accompanying implementation plan.. It remains the responsibility of the relevant department to undertake any specific communications. Some of these documents will also be posted on the Trust's Freedom of Information Act publications scheme.

Executive leads and authors are responsible for ensuring that they have identified those staff groups to whom the policy / procedure applies. Local managers must also make arrangements to ensure that such members of their staff have had the opportunity to be aware of the existence of the document and have the means to access, read and understand it. In the event that those members of staff do not regularly use electronic methods to access trust information, the manager is responsible for identifying alternative appropriate methods. The manager must certify that they have undertaken these actions, by completing and retaining (for audit purposes) the cover report included in the policy template.

4.6 Review and Archiving

All policies and Trust wide procedures should be reviewed and equality impact assessed within a maximum of three years of their publication. They should be revised, updated, subjected to consultation and resubmitted for approval in accordance with this policy. Some policies may have to be reviewed annually for accreditation purposes and the same process should be followed. There is nothing to

prevent a policy or trust wide procedure being reviewed before its programmed review date, if circumstances dictate.

4.7 Variation

The Trust may need to develop some policies and procedural documents in conjunction with partner organisations. In these circumstances the principles set out within this policy must still be adhered to. However, there is some flexibility for variation from the associated procedure. This must be approved by the Director of Corporate Affairs.

5. Responsibilities

5.1 Chief Executive

Will approve all new and revised policies, other than Reserved Policies, and reserve the power to debate in full any policy presented for approval; and cancel policies (other than the reserved policies) that are no longer required.

5.2 Director of Corporate Affairs

- Will provide assurance to the Board of Directors on compliance with this policy and will present an annual report on the development and management of Controlled Documents to the Audit Committee for consideration;
- Will approve any minor changes to policies not requiring a full stakeholder consultation;
- Will chair the Policy Review Group.

5.3 Corporate and Clinical Directors

Executive Directors are responsible for ensuring that they have identified those staff groups to whom the policy / procedure applies and that relevant staff are made aware of policies and other relevant documents that impact on them.

5.4 Local Managers

It is the responsibility of all managers and those with responsibility for supervising the work of others to make sure that their staff are aware of and understand the Controlled Documents which apply to them, their employment and work activities. Managers and supervisors must also make sure that staff are alerted to new and revised Controlled Documents and know how to access them. Managers and supervisors who also act as Head of Departments/Team Leaders must further ensure that any SOPs they have approved have appropriate document and version control in place and are published in the appropriate departmental/team folder where all relevant staff can access them.

All managers and superviors must further ensure that all local SOPs have a robust review process in place, and that they are reviewed every 3 years at a minimum.

5.5 Controlled Document Sponsor

Development of any policy must be approved by the Board Director who heads the area of the Trust to which the policy most relates. This person will be the Controlled Document Sponsor for that policy. Development of procedural documents must be approved by the relevant Controlled Document Sponsor who will be the Director/officer of the Trust specifically authorised to approve the development of the Procedural Document, as set out in the relevant Policy or elsewhere.

Where there is any uncertainty as to the identity of a Controlled Document Sponsor for a particular Controlled Document, the Director of Corporate Affairs shall determine the Controlled Document Sponsor

5.6 Controlled Document Leads

Each Controlled Document lead is responsible for the development and management of the document. This includes:

a) Obtaining the approval of the appropriate Controlled Document Sponsor for the drafting of a new Controlled Document;
b) Assessing the justification for the development of the document;
c) Identifying the people who need to be involved in the development of the document;
d) Making sure that there is appropriate consultation with all key stakeholders including any relevant committees/ groups;
e) Ensuring that appropriate impact assessments have been undertaken and that the results of the assessments are made available at the time of approval;
f) Preparing a plan for the dissemination of the document;
g) Arranging for the document to be presented for review/approval. The Controlled Document Lead or their representative will attend the review to answer any questions raised; and
h) Advising staff on the implementation of the document.

The Controlled Document Lead will make sure that each Controlled Document is reviewed and revised at appropriate intervals. This includes assessing the need for policy change as a result of changes in legislation, guidance etc. and for initiating and co-ordinating the process of review and revision and subsequent submission for approval, and taking action for the rescission of Controlled Documents which are no longer required.

5.7 Policy Assurance Officer

The Policy Assurance Officer is responsible for:

- Maintaining the main Controlled Document Register;
- Overseeing the revision of overdue Controlled Documents listed in the main register;
- Maintaining the Trust's electronic library of Controlled Documents (save for any Clinical Guidelines) and for publishing new and revised versions;
- Advising the Controlled Document Leads on implementing the process for the approval of Controlled Documents;

- Preparing reports for the Policy Review Group and the Audit Committee on compliance with the Policy; and
- Provide assurance to the Director of Corporate Affairs of compliance of Controlled Documents.

5.8 All Staff

It is the responsibility of all staff to make sure that they are familiar and adhere to the Controlled Documents which apply to them, their employment and work activities. Incidences of non-adherence to a Controlled Document will be investigated and therefore may be subject to disciplinary procedures.

All staff have a duty to report non-compliance with Trust Controlled Documents as soon as possible.

Staff must always refer to Controlled Documents electronically to ensure they are the most up-to-date version. If a paper copy is referred to staff must always check the review date to ensure it is the most current document. If the paper copy is out-of-date it must be disposed of and the current document must replace any paper copies and must not be circulated to staff.

5.9 The Policy Review Group

Is responsible for reviewing new and revised policies and, where considered fit, recommend such policies to the Chief Executive or, in the case of Reserved Policies, the Board of Directors, for approval and reviewing the overdue Controlled Document report and identifying any action that needs to be taken

5.10 Audit Committee

The Audit Committee will receive an annual report on the development and implementation of Controlled Documents which will include any non-compliance with this policy and its associated procedures.

6. Training

The Policy Assurance Officer will provide ongoing support and advice to controlled document leads.

Specific training will be provided quarterly

7. Monitoring Matrix

See **Appendix A**

8. References

None Applicable

APPENDIX A

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Style and Format				
All Controlled Documents adhere to the correct style and format including referencing and associated documents	Document Lead	Policy Review Group and Policy Assurance Officer/Document Sponsor	The PRG will ensure all policies adhere to the Template in the Controlled Document Procedure before any documents are approved. For all other Controlled Documents the Document Sponsor must ensure it complies with the Controlled Document Procedure and the Policy Assurance Officer will not publish any document that does not.	As required (e.g. when the document is approved)
Consultation and ratification process				
That the consultation and ratification process is followed for all Controlled Documents (other than Clinical Guidelines and SOPs)	Document Lead	Policy Review Group and Policy Assurance Officer/Document Sponsor. BD Minutes and CEAG Minutes	The PRG will not accept any policies that are not accompanied by the cover sheet which summarises the consultataion process. Any non-adherence to the implementation plan will be reported to the PRG by exception. For all other Controlled Documents the Policy Assurance Officer will not publish any document where the cover sheet has not been submitted along with written proof from the document sponsor that they have approved the document.	As required (e.g. when the document is approved)
The consultation and ratification process is followed for all Controlled Documents (other than Clinical Guidelines and SOPs)	Policy Assurance Officer	Audit Committee	Minutes from the BoD and CEAG show that policies are approved appropriately and this information is detailed in the Controlled Document Annual Report. A review of the documents approved within the last year will also be undertaken to ensure they comply with the Controlled Document procedure and any non-adherence will be identified in the Controlled Document Annual report	Annually

Review process				
Ensure that Document Leads are reviewing and getting their Controlled Documents approved before the review date	Policy Assurance Officer	Policy Review Group	A report (which is an extract of the policy register filtered by overdue documents) is submitted to the Policy Review Group. The comments box in the policy register details which actions have been taken.	Monthly
Control, including archiving arrangements				
Control of documents including archiving arrangements	Policy Assurance Officer	Audit Committee	The policy register details which document versions are currently in use and the archive tab details when previous versions have been in use.	As required
Associated documents/supporting references				
To ensure that each Controlled Document have an associated documents and supporting references section	Document Lead	Policy Review Group and Policy Assurance Officer/Document Sponsor	The PRG will ensure all policies adhere to the Template in the Controlled Document procedure before any documents are approved. For all other Controlled Documents the document sponsor must ensure it complies with the Controlled Document procedure and the Policy Assurance Officer will not publish any document that does not.	As required (e.g. when the document is approved)