CONTROLLED DOCUMENT

University Hospitals Birmingham NHS
NHS Foundation Trust

Controlled Documents Policy

CATEGORY:	Policy
POLICY STATUS:	Reserved
CLASSIFICATION:	Governance
PURPOSE:	To set out the principles and framework for the development, approval and monitoring of all Controlled Documents throughout the Trust
Controlled Document Number:	001
Version Number:	9.1
Controlled Document Sponsor:	Deputy Chief Executive Officer
Controlled Document Lead:	Corporate Risk and Compliance Manager
Approved By:	Board of Directors
On:	27th October 2022
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Distribution: • **Essential Reading for:** • **Information for:**	 All Directors, Senior Managers and Department Heads All Staff

Contents

Version History

Version	Title	Issue Date
7.1	Controlled Documents Policy	30/10/2018
8.0	Controlled Documents Policy	30/10/2019
8.1	Controlled Documents Policy	06/08/2020
8.2	Controlled Documents Policy	23/02/2021
9.0	Controlled Documents Policy	06/12/2022
9.1	Controlled Documents Policy	23/02/2024

1. Policy Statement

1.1 The purpose of this Policy and its associated documents is to ensure that University Hospitals Birmingham NHS Foundation Trust (the 'Trust') has in place Policies and procedural documents ('Controlled Documents') which are controlled and implemented appropriately.

1.2 The objectives of this Policy are to ensure that all Controlled Documents are:

1.2.1 developed, approved, implemented and monitored through a clear process;

1.2.2 developed in consultation with those who fall within their scope, or who may be affected by them in accordance with the Human Rights Act 1998 and the Equality Act 2010;

1.2.3 assessed for any impact they have on the Trust and the delivery of services;

1.2.4 written clearly and succinctly, using plain language appropriate to the intended audience;

1.2.5 implemented effectively by ensuring adequate awareness and providing appropriate training and support;

1.2.6 easily accessible to all staff and published in accordance with the Trust's Freedom of Information Act Publication Scheme;

1.2.7 reviewed and revised regularly, responding to changes in legislation, standards and good practice; and compliant with Information Governance requirements.

2. Scope

2.1 This Policy applies to all Controlled Documents (as defined below) within the Trust.

3. Definitions

Types of Controlled Documents

Clinical Guidelines (CGs)	Clinical Guidelines contain evidence-based recommendations on the appropriate treatment and care of patients with specific diseases and conditions. These do not include Patient Group Directions (PGDs). Clinical Guidelines are approved by Clinical Service Leads and ratified by the Clinical Guidelines Group.
Expanded Practice Protocols (EPPs)	Expanded Practice Protocols (EPPs) are detailed plans of clinical practice which allow practitioners to expand their practice supported by a definitive set of competencies and within a definitive framework. These may apply only to a particular Specialty or be applicable Trust wide.

Patient Group Directions (PGDs)	A Patient Group Direction (PGD) is a written set of instructions for the supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. Before a PGD is developed, the Controlled Document Sponsor must ensure that the PGD is appropriate, legal and that relevant governance arrangements are in place.
Policy	A Policy is a statement of intent and principles, explicitly stating individuals' responsibilities and accountabilities which provides the basis for consistent decision making, actions and resource allocation. Policies are: Trust-wide, overarching, applicable to large groups of staff, and usually contain legal obligations. Compliance with Policies is mandatory. For the purposes of this Policy, the following are to be regarded as Policies: Code of Conduct, Standing Orders, Standing Financial Instructions, and Scheme of Delegation.
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. Any controlled document which is not a Policy is considered a Procedural Document however it may be considered Clinical or Corporate and either the Corporate Controlled documents Procedure or the Clinical Controlled Documents Procedure should be consulted.
Standard Operating Procedures (SOPs)	With the exception of local SOPs* (those which provide instructions on how to perform internal tasks/duties), Standard Operating Procedures (SOPs) are a written set of instructions that staff must follow to complete a job safely and compliantly, with no adverse effect on the personal health of the patient and staff or the environment, or on statutory requirements, and in a way that maximises operational efficiency. SOPs 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. *Local SOPs are those which affect a very small number of people, are agreed within a team/small department and are not published centrally or managed by the Controlled Documents Teams therefore are out of the scope of this Policy.
Strategies	The Trust has an overarching Strategy approved by the Board. All other Strategies within the Trust are considered to be supporting strategies. Strategies are considered to be controlled documents and prior to publication, confirmation is required that they accord to the spirit/direction of the overarching Trust Strategy.

Other Definitions

Approval Body	The Board of Directors (delegated to a Board-level Committee), or the Executive Management Team. Other Controlled Documents will be approved by the relevant Controlled Document Sponsor who will be an Executive Director of the Trust specifically authorised to approve the document, as set out in the relevant Policy or elsewhere.

Code of Conduct	Code of conduct describes desired staff behaviour in a specific context.
Controlled Document	Controlled Documents are documents which provide a framework for safe, effective and acceptable practice. Documents are 'Controlled' when their revision status, their Approval 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 professional, 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 Body, issue date, review date and any necessary comments.

Controlled Document Sponsor	The Controlled Document Sponsor is the identified Director, or person to whom such responsibilities have been delegated, who has responsibility for approving the Controlled Document or ensuring its approval.
	
	• Policies are approved in three stages:
	  ○ The Executive Director who heads the area of the Trust to which the Policy most relates approves the policy to go to Policy Review Group.
	  ○ Policy Review Group then approves the policy to progress to ratification if appropriate
	  ○ The policy is then (if appropriate) ratified by the appropriate Approval Body
	• For Corporate Procedures the Controlled Document Sponsor is a nominated individual usually senior to the individual who authored it and has sufficient seniority to sign it off dependent on the contents of the document.
	• For Clinical Guidelines the Controlled Document Sponsor is the Clinical Service Lead or a nominated colleague
	• For Expanded Practice Protocols refer to the EPP SOP for the sponsor which is dependent of type of EPP.
	• For PGDs the Controlled Document Sponsor is the Medicines Management Advisory Group which acts through its Chair or nominated Deputy.
	
	Where there is any uncertainty as to the identity of a Controlled Document Sponsor for a particular Controlled Document, the Deputy Chief Executive Officer shall determine the Controlled Document Sponsor.

Reserved Policy	Policies specifically reserved to the Board of Directors for the purposes of approval as set down in Appendix D of the Corporate Governance Policy.
Review Date	Controlled Documents (except Strategies) 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.

Scheme of Delegation	The Chief Executive's Scheme of Accountability and Delegation.
Stakeholders	Stakeholders are all those individuals or groups who have a stake in or may be impacted by a given Controlled Document. These are selected by the Lead and Sponsor of the document. Accordingly, stakeholders must influence the Trust's services, Policies and procedures. Examples of stakeholders include but are not limited to internal stakeholders such as staff, Staff-side, the human resources and finance departments; potential external stakeholders are contracted service providers, Centre for Defence Medicine, Integrated Care Boards, other NHS providers, the University of Birmingham, General Practitioners (GP) consortia, patient user groups and interested members of the public.
Standing Financial Instructions	Standing Financial Instructions are designed to ensure that the Trust's financial transactions are carried out in accordance with the law, Government Policy and best practice in order to achieve probity, accuracy, economy, efficiency and effectiveness. They do not provide all the detailed procedural advice.
Standing Orders	Standing Orders, together with Standing Financial Instructions, form the regulatory framework within which the Trust conducts its business. They fulfil a dual role of protecting the interests of the Trust and those of its staff from any possible accusations of financial impropriety or malpractice.
Version Control	Version Control Numbering consists of a number followed by a 'point,' then one more number. Any minor amendments will be reflected in the latter number ascending by one point. Each full review will result in the number to the left of the 'point' incrementing by one.

4. Framework

4.1 This section describes the broad framework for the development and management of Controlled Documents. Detailed instructions are provided in the associated Procedure as set out below:

4.1.1 Corporate Documents: Guidance is found in the Corporate Controlled Documents Procedure

4.1.2 Clinical Guidelines, Expanded Practice Protocols, Patient Group Directions (PGDs), Emergency Clinical Pathways and Local Safety Standard for Invasive Procedures (LocSSIPS) the guidance is in the Clinical Controlled Documents Procedure

4.2 The Procedures may be amended from time to time by authority of the Deputy Chief Executive Officer or designated Document Sponsor, provided that such amendments are compliant with this Policy.

5. Principles of Controlled Document Development

Controlled Documents must adhere to the following principles:

5.1 Their development must be authorised by an appropriate Controlled Document Sponsor;

5.2 They must be equality impact assessed in line with the Controlled Document Procedure;

5.3 Controlled Documents must be subject to a stakeholder consultation, led by the Controlled Document Lead, when the Controlled Document is first developed, as part of its three-yearly review or before if the document is reviewed before the review date (see below);

5.4 Minor amendments to Controlled Documents approved by the Chair of the Medicines Management Advisory Group (MMAG) do not require a full stakeholder consultation, unless they are in their 3 yearly review, first being developed or the document being submitted for approval is the Patient Group Directions Policy. Please refer to the Medicines Policy and to the Procedure for the Development and Management of Controlled Documents.

5.5 They must be approved as follows:

- Policies must be approved by Policy Review Group then ratified by either the appropriate Approval Body in accordance with Appendix D of the Corporate Governance Policy; and
- all other Controlled Documents must be approved by the Controlled Document Sponsor.

5.6 All Controlled Documents must be logged on the appropriate register which is held within the relevant team. These registers will catalogue all Controlled Documents by document type, issue date and document control number.

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

- are still required
- remain accurate
- continue to comply with the appropriate template;
- comply with any relevant legislation or guidance; and
- comply with any associated Trust Controlled Documents

5.8 With the exception of PGDs and Clinical Guidelines, Controlled Documents will remain in force until such time that they are replaced or removed. The version of a Controlled Document held on the intranet shall be the definitive version to which reference must be made. The Version Control number is subdivided into two parts as stated in section 3. Further guidance on this is available in the associated Corporate Controlled Documents Procedure.

5.9 Departments that undergo regular quality control assessments (including, but not limited to, Regional Radiation Physics and Protection Service, Nuclear Medicine, Immunology, IT Services, and Pathology) hold their own specific Document Register, called Q-Pulse, which is maintained by the respective Quality Control Lead and which allows for similar document Version Control.

5.10 When Controlled Documents are amended, superseded or cancelled, they will be removed from the intranet and archived in accordance with the Controlled Document Procedure.

5.11 Controlled Documents may be cancelled and archived if they are no longer required. Whenever this occurs, evidence to this effect must be obtained from the Controlled Document Sponsor. This may be in the form of an email, or minutes of a meeting where the Controlled Document Sponsor was present.

5.12 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 Deputy Chief Executive Officer.

5.13 Monitoring

Controlled Documents are part of the control framework that supports the effective and efficient management of risk across the Trust. As such assurance is required in relation to compliance with the document and outcomes being achieved. The Document Sponsor must ensure that each document has an appropriate monitoring framework that identifies the relevant standards. They are also responsible for ensuring the policy is monitored and reported upon according to the monitoring framework.

6. Duties

6.1 Board of Directors

The Board of Directors will:

6.1.1 Delegate the authority to approve any new and revised Policies reserved to the appropriate Approval Body dependent on the status of the policy recorded in the Corporate Governance Policy, Annex B).

6.1.2 The Board will decide whether policies are to be considered as Reserved or Ordinary.

6.2 Deputy Chief Executive Officer

The Deputy Chief Executive Officer will:

6.2.1 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;

6.2.2 Approve any minor changes to Policies not requiring a full stakeholder consultation; and

6.2.3 Chair the Policy Review Group or delegate as appropriate.

6.3 Chair of the Policy Review Group

The Chair of the Policy Review Group (PRG) is responsible for:

6.3.1 Ensuring current Terms of Reference are in place for the Group.

6.3.2 Reviewing new and revised Policies and, where considered fit, recommending such Policies to the Chief Executive or, in the case of Reserved Policies, the Board of Directors, for approval;

6.3.3 Reviewing the overdue Controlled Document report and identifying any action that needs to be taken;

6.3.4 Ensuring all Policies adhere to the template in the Controlled Document Procedure before any documents are approved; and

6.3.5 Ensuring that the consultation and ratification process is followed for all Controlled Documents which are presented to the Group

6.4 Executive Directors and Nominated Controlled Document Sponsors

Executive Directors and Nominated Controlled Document Sponsors are responsible for:

6.4.1 Approving any procedural documents for their areas of responsibility; however Clinical Leads are responsible for approving Clinical Guidelines, prior to submission to the Clinical Guidelines Group;

6.4.2 Ensuring that all procedural documents approved by them (with the above exception) are compliant with Trust Policies;

6.4.3 Ensuring they have identified those staff groups to whom the controlled document applies and that relevant staff are made aware of Policies and other relevant documents that impact on them; and

6.4.4 Ensuring that all Controlled Documents within their area of responsibility are reviewed at least every three years and/or when changes in legislation, guidance etc occur.

6.5 Clinical Leads

Clinical Leads are responsible for approving Clinical Guidelines, prior to submission to the Clinical Guidelines Group.

6.6 Corporate Risk and Compliance Manager

The Corporate Risk and Compliance Manager is responsible for:

6.6.1 Overseeing the Corporate Controlled Document Register and associated library ensuring only approved documents are published;

6.6.2 Overseeing the revision of overdue Corporate Controlled Documents listed in the Corporate Controlled Documents Register;

6.6.3 Advising Corporate Controlled Document Leads on implementing the process for the approval of Corporate Controlled Documents;

6.6.4 Preparing reports for Policy Review Group and Audit Committee on compliance with this Policy;

6.6.5 Providing assurance to the Deputy Chief Executive Officer of compliance of Corporate Controlled Documents

6.7 Head of Clinical Governance and Patient Safety

The Head of the Clinical Governance and Patient Safety Team is responsible for:

6.7.1 Maintaining the Controlled Document Register for all Clinical Guidelines and EPPs.

6.7.2 Maintaining the Trust's electronic library of Clinical Guidelines and EPPs and for publishing new and revised documents; and

6.7.3 Advising the Controlled Document Leads on implementing the process for the approval of Clinical Guidelines in accordance with this Policy and the Clinical Guidelines Procedure.

6.8 Chair of the Clinical Guidelines Group

The Chair of the Clinical Guidelines Group are responsible for:

6.8.1 Overseeing the revision of overdue Clinical Guidelines;

6.8.2 Ratification of new or revised Clinical Guidelines following approval by Clinical Service Leads, and

6.8.3 Receiving any Clinical Guidelines exception reports on non-compliance with this Policy and the Clinical Controlled Documents Procedure.

6.9 Controlled Document Sponsor

Each Controlled Document Sponsor is responsible for ensuring that the Controlled Document is only developed where there is a need with regard to:

6.9.1 Service priorities;

6.9.2 Whether the proposed Controlled Document duplicates national work or other work within the Trust, including existing Controlled Documents

and other Controlled Documents under development;

6.9.3 Whether implementation will be achievable within the resources of the Trust;

6.9.4 Which individual will become the Controlled Document Lead;

6.9.5 That the consultation and ratification process is followed for all Controlled Documents (other than Clinical Guidelines and Local SOPs); and

6.9.6 Ensuring all associated Procedures adhere to the template in the Controlled Document Procedure before any documents are approved.

6.10 Controlled Document Leads

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

6.10.1 Assessing the justification for the development of the document;

6.10.2 Identifying the people who need to be involved in the development of the document;

6.10.3 Obtaining the approval of the appropriate Controlled Document Sponsor for the drafting of a new Controlled Document;

6.10.4 Ensuring that Controlled Documents have associated documents and supporting references section;

6.10.5 Making sure that there is appropriate consultation with all key stakeholders including any relevant committees/groups;

6.10.6 Ensuring that appropriate impact assessments have been undertaken and that the results of the assessments are made available at the time of approval;

6.10.7 Attending, or nominating a representative, to attend the Policy Review Group to present and answer any questions raised;

6.10.8 Arranging for the document to be presented for review/approval to the relevant Approval Body;

6.10.9 Preparing a plan for the dissemination of the document;

6.10.10 Advising staff on the implementation of the document; and

6.10.11 Making sure that each Controlled Document is reviewed and revised at appropriate intervals. This includes, but is not limited to, assessing the need for updating Controlled Documents as a result of changes in legislation or guidance, initiating and coordinating the process of review, revision and subsequent submission for approval, and taking action for the removal of Controlled Documents which are no longer required.

6.11 All Managers and Supervisors

6.11.1 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, understand and have any necessary training required to implement the Controlled Documents which apply to them, their employment and work activities.

6.11.2 Managers and Supervisors must also make sure that staff are alerted to new and revised Controlled Documents and know how to access them.

6.11.3 Managers must discourage the printing of, and use of printed hard copies as these may become out of date. The electronic version of the Controlled Document as registered on the Controlled Document Register is the most current version.

6.11.4 Ensure that any out-of-date Controlled Documents kept locally (either electronically or hard copies) are destroyed when replaced with revised versions.

6.11.5 Managers and Supervisors must further ensure that any Local SOPs they have approved:

a) have appropriate document and version control in place;
b) are published in the appropriate departmental/team folder where all relevant staff can access them; and
c) have a robust review process in place, and that they are reviewed every 3 years at a minimum.

6.12 All Staff

6.12.1 It is the responsibility of all staff to make sure that they are familiar with and adhere to the Controlled Documents which apply to them, their employment and work activities.

6.12.2 All staff have a duty to report non-compliance with Controlled Documents as soon as possible to their immediate Line Manager.

6.12.3 Staff must always refer to electronic versions of Controlled Documents on the intranet to ensure they are the most up-to-date version. Staff are discouraged from relying on a printed hard copy as this might not be the most current version.

6.13 Stakeholders

The interests of potential stakeholders must be considered by the Controlled Document Lead and appropriate consultative mechanisms must be agreed. Stakeholders have a duty to respond in a constructive manner and within the timescales of the consultation process.

7. Implementation and Monitoring

7.1 Implementation

7.1.1 This Policy will be available on the Trust's intranet site. The Policy will also be disseminated through the management structure within the Trust.

7.1.2 The Corporate Governance Team will provide advice and support to Controlled Document Leads about the implementation of this Policy.

7.1.3 Templates for different types of Controlled Documents will be available on the Trust's Intranet.

7.2 Monitoring

Appendix A provides full details on how this Policy will be monitored by the Trust.

8. References

- Equality Act 2010
- Human Rights Act 1998
- Data Protection and Security Toolkit

9. Associated Policy and Procedural Documentation

- Chief Executive's Scheme of Accountability and Delegation
- Clinical Laboratory Services Quality Management System Document Control Manual (QMS Manual)
- Clinical Laboratory Services Quality Management System Document Control (Q-Pulse) Manual
- Corporate Governance Policy
- Medicines Policy
- Controlled Documents Procedure
- Clinical Controlled Documents Procedure

Appendix A: Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Consultation and ratification process				
Clinical Guidelines are reviewed on a timely basis	Clinical Governance and Patient Safety Team	Clinical Quality Management Group	Annual report on exceptions (i.e. out of date guidelines) is approved by the Chair of the Clinical Guidelines Group and presented to CQMG.	Annual
Clinical Guidelines are reviewed on a timely basis	Clinical Governance and Patient Safety Team	Site Quality and Safety Group	A summary report is submitted to Site Quality and Safety Group meetings setting out the status of all Clinical Guidelines.	Quarterly
Review process				
Policy Leads are reviewing and ensuring their Controlled Documents are approved before the review date	Corporate Risk and Compliance Manager	Policy Review Group	An update report is submitted to the Policy Review Group, setting out the status of all Policies which are due for review, or beyond their review date.	Quarterly
Leads for other corporate documents are reviewing and ensuring their Controlled Documents are approved before the review date	Corporate Risk and Compliance Manager	Individual Directors	The Corporate Compliance Framework contains this information and a director specific update is sent on a quarterly basis.	Quarterly
Policy compliance with monitoring matrices	Corporate Risk and Compliance Manager	Deputy Chief Executive Officer	Exception report – status Policy monitoring matrices and compliance therewith to be reported to ensure Policies are effectively monitored.	Quarterly
Compliance				
Report on the development and implementation of Corporate Controlled Documents	Corporate Risk and Compliance Manager	Audit Committee	To include any non-compliance with this Policy and its associated procedures.	Annual