University Hospitals Birmingham NHS
NHS Foundation Trust

CONTROLLED DOCUMENT

Policy for the Development and Management of Controlled Documents

CATEGORY:	Policy
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:	1
Version Number:	7
Controlled Document Sponsor:	Director of Corporate Affairs
Controlled Document Lead:	Associate Foundation Secretary
Approved By:	Board of Directors
On:	October 2016
Review Date:	October 2019
Distribution: • **Essential Reading for:** • **Information for:**	 All Directors, Senior Managers and Department Heads All Staff

Contents

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

1.2.8 are compliant with Information Governance Toolkit.

2 Scope

This policy applies to all Controlled Documents (as defined below) within the Trust. Controlled Documents in existence prior to the issue of this policy will remain in effect until such time as they are reviewed, replaced or cancelled, even if the review date has passed.

3 Framework

3.1 This section describes the broad framework for the development and management of Controlled Documents. Detailed instructions are provided in the associated Procedure for the Development and Management of Controlled Documents (Controlled Document Procedure). The Procedure may be amended from time to time by

authority of the Director of Corporate Affairs, provided that such amendments are compliant with this Policy.

3.2 Definitions

Approval Body	The Board of Directors (BOD), Chief Executive (CEAG) or any Committee to whom approval of a particular type of Controlled Document has been delegated.
Code of Conduct or Practice	Codes of conduct describe desired staff behaviour in a specific context.
Clinical Guidelines (CG)	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.
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 (Executive) Director, or person to whom such responsibilities have been delegated, who has responsibility for approving the development of the Controlled Document. • Policies: Development of any policy must be approved by the Board Director who heads the area of the Trust to which the policy most relates • For Clinical Guidelines the Controlled Document Sponsor is the Clinical Guidelines Group which acts through its chair or nominated deputy chair. 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.
Expanded Practice Protocols (EPPs)	Expanded Practice Protocols 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 particular divisions or be applicable Trust wide.
Guidelines	Guidelines are evidence based best practice statements which determine a course of action by a healthcare professional who is allowed to use professional judgement. If the healthcare professional wishes to deviate from a Guideline, this must be documented in the patient records together with the reasons for variance and any actions taken.
Patient Group Directions (PGD)	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. Compliance with policies is mandatory.
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 Policy	Policies specifically reserved to either the Board of Directors or the Chief Executive Advisory Group
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.

Scheme of Delegation	A Scheme of Delegation identifies which authority will be retained by the Board of Directors or be delegated to the Chief Executive.
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. 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 Consort Healthcare, Centre for Defence Medicine; ambulance services, 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.
Standard Operating Procedures (SOP)	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.
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.

3.3 Controlled Documents must adhere to the following principles:

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

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

c) Save for Controlled Documents approved by the chair of the Medicines Management Advisory Group (MMAG) (see Medicines Policy), they must be subject to a stakeholder consultation, led by the Controlled Document Lead, when the Controlled Document is first developed or as part of the 3 yearly review (see (f) below);

d) They must be approved as follows:

(i) Policies must be approved by either the Chief Executive or the Board of Directors in accordance with Appendix B of the Corporate Governance Policy; and
(ii) All other Controlled Documents must be approved by the Controlled Document Sponsor.

e) All Controlled Documents must be logged onto the Trust's main Register which is held within the Risk and Compliance Team. This Register will catalogue all Controlled Documents by document type, issue date and document control number.

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

(i) are still required;
(ii) remain accurate;
(iii) continue to comply with the appropriate template;
(iv) comply with any relevant legislation or guidance; and
(v) comply with any associated Trust Controlled Documents.

g) With the exception of PGD's 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 3.2. Further guidance on this is available in the associated Procedure for the Development and Management of Controlled Documents.

h) Departments who undergo regular quality control assessments (including but not limited to Radiation, 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.

i) When Controlled Documents are amended, superseded or cancelled, they will be removed from the intranet and archived in accordance with the Controlled Document Procedure and the Q-Pulse Manual.

j) Controlled Documents may be cancelled and archived if they are no longer required. Wherever 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.

3.4 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.

4 Duties

4.1 Board of Directors

The Board of Directors will:

4.1.1 Approve any new and revised policies reserved to the Board of Directors for approval (Reserved Policies – see Corporate Governance Policy, Annex B) and may debate in full any policy presented to it; and

4.1.2 Approve the cancellation of reserved policies that are no longer required.

4.2 Chief Executive

The Chief Executive will:

4.2.1 Approve all new and revised policies, other than Reserved Policies, and reserve the power to debate in full any policy presented for approval; and

4.2.2 Cancel policies, other than reserved policies, that are no longer required. This duty may be delegated to Directors or Controlled Document Sponsors

4.3 Director Of Corporate Affairs

The Director of Corporate Affairs will:

4.3.1 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;

4.3.2 Approve any minor changes to policies not requiring a full stakeholder consultation; and

4.3.3 Chair the Policy Review Group.

4.4 Members of the Policy Review Group

Members of the Policy Review Group (PRG) are responsible for:

4.4.1 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;

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

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

4.4.4 That the consultation and ratification process is followed for all Controlled Documents (other than Clinical Guidelines and Internal SOPs)

4.5 Members of the Audit Committee

The members of 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.

4.6 Directors and Divisional Directors

Directors and Divisional Directors are responsible for:

4.6.1 Approving any procedural documents for their areas of responsibility;

4.6.2 Ensuring that all procedural documents approved by them are compliant with Trust policies; and

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

4.7 Members of the Directorate of Corporate Affairs

Members of the Directorate of Corporate Affairs are responsible for:

4.7.1 Maintaining the Controlled Document Register;

4.7.2 Overseeing the revision of overdue Controlled Documents listed in the main Register;

4.7.3 Maintaining the Trust's electronic library of Controlled Documents (save for any Clinical Guidelines) and for publishing new and revised versions;

4.7.4 Advising Controlled Document Leads on drafting and obtaining appropriate approval for all clinical Controlled Documents and ensuring compliance with this Policy;

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

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

4.7.7 Preparing reports for PRG and the Audit Committee on compliance with the Policy;

4.7.8 Provide assurance to the Director of Corporate Affairs of compliance of Controlled Documents;

4.7.9 Arrange for the publishing of all approved Controlled Documents; and

4.7.10 Prepare an Annual Report for the Audit Committee detailing all Controlled Documents approved within the last year to ensure they comply with the Controlled Document procedure and any non-adherence will be identified in the Controlled Document Annual report.

4.8 **Clinical Guidelines Group**

Members of the Clinical Guidelines Group are responsible for:

4.8.1 Overseeing the revision of overdue Clinical Guidelines;

4.8.2 Approving new or revised Clinical Guidelines; and

4.8.3 Receiving any Clinical Guidelines exception reports on non-compliance with this policy and the Controlled Document Procedure.

4.9 **Controlled Document Sponsor**

Each Controlled Document Sponsor is responsible for:

4.9.1 Ensuring that the Controlled Document is only developed where there is a need having regard to:

a) Service priorities;

b) Whether the proposed Controlled Document duplicates national work or other work within the Trust, including existing Controlled Documents and other Controlled Documents under development;

c) Whether implementation will be achievable within the resources of the Trust;

d) Which individual will become the Controlled Document Lead;

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

f) Ensuring all associated procedures adhere to the template in the Controlled Document Procedure before any documents are approved.

4.10 **Controlled Document Leads**

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

a) Assessing the justification for the development of the document;

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

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

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

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

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

g) Arranging for the document to be presented for review/approval to the relevant Approval Body; and

h) Preparing a plan for the dissemination of the document; and

i) Advising staff on the implementation of the document.

4.10.2 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 co-ordinating the process of review, revision and subsequent submission for approval, and taking action for the removal of Controlled Documents which are no longer required.

4.11 All Managers and Supervisors

4.11.1 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.

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

4.11.3 Managers must discourage the printing of hard copies as these may have become out of date. The electronic version of the

Controlled Document as registered on the Controlled Document Register is the most current version.

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

4.12 **All staff**

4.12.1 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.

4.12.2 All staff have a duty to report non-compliance with Controlled Documents as soon as possible to their immediate line manager.

4.12.3 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.

4.13 **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.

5 Implementation of this policy

5.1 Implementation

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

5.1.2 The Corporate Governance Team will provide advice and support to controlled document leads about the implementation of this policy.

5.1.3 Templates for different types of Controlled Document will be available on the Trust's intranet via the Procedure for the Development and Management of Controlled Documents.

5.2 Monitoring

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

6 References

Equality Act 2010

Human Rights Act 1998

Information Governance Toolkit

7 Associated Controlled Documents

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

Procedure for the Development and Management of Controlled Documents

Appendix A **Monitoring Matrix**

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	Document Lead	Policy Review Group (PRG) and Corporate Governance 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 Controlled Document Sponsor must ensure overall compliance with the Controlled Document Procedure.	As required (e.g. when the document is approved)
Consultation and ratification process				
The consultation and ratification process is followed for all Controlled Documents	Document Lead	Policy Review Group and Corporate Governance Officer/Document Sponsor. BOD Minutes and CEAG Minutes	The PRG will not accept any policies that are not accompanied with an Equality Impact Assessment (EIA). Any non-adherence to the implementation plan will be reported to the PRG by exception. All policies will be reported to the BOD or CEAG and evidence of this will be in the minutes. The Corporate Governance team annually audit a sample of their Controlled Documents to ensure compliance.	As required (e.g. when the document is approved)
The consultation and ratification process is followed for all Clinical Guidelines	Risk and Compliance Unit	Clinical Guidelines Group	Receiving any reports by exception on non-compliance.	By exception
Review process				
Compliance that Document Leads	Corporate	Policy Review Group	An update report is submitted to the	As required

are reviewing and ensuring their Controlled Documents are approved before the review date	Governance Team		Policy Review Group, setting out the status of all policies. An update report is submitted to Divisional Clinical Quality Group meetings setting out the status of all Clinical Guidelines.	