Torbay and South Devon
NHS Foundation Trust

# Management of Care and Clinical and Non-Clinical Documents Policy

## Including strategies, policies, standard operating procedures, clinical guidelines, clinical protocols and other Trust documents

Document Information

This is a controlled document. It should not be altered in any way without the express permission of the author or their representative. On receipt of a new version, please destroy all previous versions.

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| Date of Issue: | 25 April 2017 | Next Review Date: | April 2021 |
| Version: | 1.2 | Last Review Date: | May 2020 |
| Author: | Company Secretary | | |
| Director Responsible | Corporate | | |
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| **Approval Route** | | | |
| **Approved By:** | | **Date Approved:** | |
| Executive Team | | 12 May 2020 | |
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| Links or overlaps with other policies: | | | |
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Amendment History

| Issue | Status | Date | Reason for Change | Authorised |
|---|---|---|---|---|
| v0.1 | Draft | October 2016 | Re-write post ICO | Corporate Governance Team |
| v 0.2 | Draft | February 2017 | Revised | Senior Nursing Team |
| v0.3 | Draft | February 2017 | Revised | Senior Nursing Team |
| V1 | Current | 25 April 2017 | Approved | Executive Team |
| V1.1 | Draft | September 2018 | Revised | Medical Director and Chief Nurse |
| V1.2 | Draft | April 2020 | Revised/updated re governance changes | Executive Team |

**Contents**

## 1. Introduction

In this policy the word 'document(s)' refers to strategies, policies, standard operating procedures, clinical guidelines, clinical protocols and other documents, as defined in Appendix 1. The purpose of this policy is to ensure a structured and systematic approach to the development, review, ratification and archiving of these documents.

1.1 It will support the evidence process for external and internal assessments e.g. Care Quality Commission (CQC) inspections, NHS Resolution and Information Governance Toolkit to ensure that all documents:

- are of a consistently high standard;
- are up-to-date and based on current best practice;
- are accessible to all staff,
- meet operational, legal, insurance and statutory obligations; and
- are approved by the appropriate committee/group as well as implemented, monitored and evaluated on a regular basis.

## 2. Policy Statement

2.1 This policy will apply to all documents as defined in appendix 1 that are produced by and for Torbay and South Devon NHS Foundation Trust (hereby known as the Trust) staff or for use within the Trust.

2.2 The implementation of this policy will ensure all ratified documents are compliant, consistent, fit for purpose and where applicable suitable for public access.

## 3. Responsibilities

3.1 The effective management of Trust documents ultimately lies with the Chief Executive Officer. The Trust has a responsibility to ensure that documents are a key part of the Board Assurance Framework (BAF).

3.2 Day-to-day responsibilities for all staff, line managers, document owners/authors/originators, Clinical Effectiveness Department, company secretary, document database administrator and ratifying committee/group librarian are outlined in appendix 2.

## 4. Writing, Reviewing, Ratifying and Monitoring

### Documents Writing Documents

4.1 The development of all documents must involve, where appropriate consultation of one or more of the following:

Patients, clients, service users, carers, relevant members of staff who hold key knowledge in subject area, stakeholders and/or partners including outside agencies.

4.2 Documents must not discriminate any person by gender, sexual orientation, marital status, race, religion, colour, age or disability and have been through an Quality & Equality Impact Assessment (QEIA) prior to being presented for ratification.

4.3 All documents will be presented in a standard structure and format and be written in a clear, concise and easy to read style. The templates that are used on ICON are locked down to ensure that only the correct formatting can be used. Any documents not in the correct template will not be ratified. For care and clinical documents the clinical effectiveness department will support with formatting. Acronyms should be avoided or clearly referenced where appropriate. All documents are to be created in black, Arial font size 11 text throughout unless referring to a link or a diagram or using footnotes etc.

4.4 All documents must be marked clearly with a 'draft' watermark until ratified by the appropriate committee/group and follow version control guidance. The 'draft' watermark must be removed once ratified and before being sent for upload to ICON and the website.

4.5 Associated or linked documents that may support or impact the policy must be listed in the 'document information' section under the heading 'links or overlaps with other policies'.

4.6 Any material/sources used in writing a document must be appropriately referenced by clearly marking the reference and then including the source and date in either the footer of that page, or as a separate section at the end of the document.

4.7 For care and clinical documents where hyperlinks are required for internal documents, these will be activated by the clinical effectiveness department. For external hyperlinks the date last accessed must be recorded on the document by the author.

4.8 Document authors MUST NOT post ratified documents on any departmental or team intranet sites. Links can be used for this purpose through liaison with the document librarians.

**Reviewing Documents**

4.9 Documents must be reviewed by their review date, and a new review date set, which should be agreed by the ratification committee/group. A reminder system is in place to provide designated ratifying committees/groups with regular reports on the documents that are due for review or are out-of-date.

4.10 If there are no changes to the document, the review date will be moved forward as agreed by the ratification committee/group and the amendment history is completed.

4.11 If there are minor changes to the document before a formal review, e.g. correction of spelling mistakes, change of staff roles or addresses, etc. which do not have an effect on care or clinical services, staff, users, financial or training implications the author will inform the document librarian and keep the review date as set.

4.12 If a document has major changes then it should be treated as a new document and consulted on appropriately.

4.13 The ratification committee/group must record in the minutes/notes from each meeting all documents which have been ratified.

**Ratifying Documents**

4.14 Documents should be ratified by an appropriate committee/group before being implemented within the Trust. A list of documents and the committees/groups that can ratify documents is listed in appendix 6.

4.15 The ratification committee/group must include within their terms of reference the responsibility for ratification of relevant documents. A record in the minutes/notes from each meeting must be made for all documents which have been ratified.

4.16 The ratification committee/group will determine if a document is **NOT** suitable for publication on the Trust public website and the chair will inform the document librarians.

**Adopting External Documents**

4.17 In some instances the Trust will adopt documents from external organisations / professional regulatory bodies and/or other recognised Groups where the document sets out best practice as agreed by a broad expert group e.g. Peninsula Neonatal Network, Safeguarding Boards , Chartered Society of Physiotherapy.

4.18 On occasions urgent patient presentations may require clinicians to adopt a clinical guideline from a specialist centre of excellence to ensure immediate patient safety. On such occasions the clinicians would be required to record the source of the guidance followed.

**Implementing and Monitoring Documents**

4.17 Approved documents will be distributed and implemented via the Trust's public website and ICON; additional awareness can be raised through the staff bulletin. Documents that are not suitable for the public facing website will be published on ICON only.

4.18 Audit checks will be undertaken on a regular basis by the Clinical Effectiveness Department and Corporate Document Database Administrator to ensure all ratified documents are available and accessible to staff.

4.19 All new policy documents will be reviewed within two years in the case of non-clinical documents and three years in the case of clinical documents, unless indicated otherwise. The subsequent review period will be determined according to the nature of the document. No review date should extend longer than within two years in the case of non- clinical documents and three years in the case of clinical documents.

4.20 Policies must be reviewed when there is a change to the organisation structure, legislation, evidence or best practice. This will ensure that documents are up-to-date and relevant at all times.

4.21 All draft copies of the documents should be destroyed by the author, once the document has been ratified.

4.22 Previous documents will be archived for future reference in accordance with the Trust's retention and disposal schedule.

**Flowcharts**

4.23 The process for the:

- creation and review of **non-clinical** documents can be found as at appendix 3;
- production of **care and clinical** documents and review of existing **care and clinical** documents can be found as at appendix 4; and
- review and revision of published **care and clinical** guidance can be found as at appendix 5.

## 5. Training and Awareness

5.1 Advice and support for authors of care and clinical documents will be provided by the Clinical Effectiveness Team (contact details as at section 7) in the developing, reviewing and ratifying of documents.

5.2 Training, advice and support for **non-clinical documents** will be provided by the FoundationTrust Office (contact details as at section 8) to support staff in developing, reviewing, ratifying and publishing documents on ICON and the Trust's public website.

5.3 The corporate document database administrator (CDDA) will raise awareness of this policy through the publication of information on ICON and advise staff of changes through the staff bulletin and various ratification committees/groups.

## 6. Monitoring, Auditing and Review of this Policy

6.1 The use of this policy for the development of documents will be monitored by the Foundation Trust Office in collaboration with the Clinical Effectiveness Department through the ratification procedure and the internal audit programme.

6.2 This policy will be reviewed by the Company Secretary after one year and then every three years or earlier if working practices change. This policy document will be approved by the Executive Team.

## 7. Distribution

7.1 This policy document will be made available to staff via ICON, the Trust Website and signposted in the Staff Bulletin.

7.2 Awareness will be raised through Equality Impact Assessment training, all ratifying committees/groups, policies and procedures training and ICON.

## 8. Key Contacts

| | | |
|---|---|---|
| Care and Clinical documents | Clinical Effectiveness Team | 01803 655802 |
| Non-clinical documents | Foundation Trust Office | 01803 655705 |

## 9. Appendices

Appendix 1 Definitions

Appendix 2 Responsibilities

Appendix 3 Creation and review of **non-clinical** documents

Appendix 4 Process for production of **care and clinical** documents and review of existing **care and clinical** documents

Appendix 5 Process for review and revision of published **care and clinical** guidance

Appendix 6 Committee/group ratification structure

**Appendix 1**

## Definitions

**Strategy**
- Defines an overall outline and direction that will help co-ordinate long term planning and decision making;
- Supports an overarching NHS or Social Care Strategic Plan and presents what is to be achieved;
- Is time limited, although the time line can be decades and the strategy can be reviewed at any time;
- Usually has an action plan and identifies risks to the organisation.

**Policy**
- Is an overarching statement of intent which explicitly states who is responsible and accountable for the subject of the policy;
- It states how to comply with relevant legislation, guidelines and good working practices;
- It may include specific expectation of what is to be achieved and why.
- It may include a plan or course of action that is intended to influence and determine decisions, actions;
- It provides a safe environment for individuals or specific groups to work within
- It is not open to interpretation or professional judgment and it is non-negotiable.

**Standard Operating Procedure (SOP)**
- Is the way that a named policy is implemented;
- Can cover one aspect of care;
- Is a step-by-step method of how to do something;
- Based on best practice;
- Provides clarity and consistency;
- Deviation is not an option although alternatives may be specified.

**Code of Practice**
- Supports a named policy;
- Is a documented procedure operated by public bodies to enable them to comply with legislation e.g. NMCs Code of Professional Practice.

**Clinical Guideline/Guidance**
- The term ‘guideline(s)’ is intended when it is recognised that there is not an exclusive course of action to take, but they represent known best practice and compliment any existing standard.
- Supports the named policy or strategy;
- Is not prescriptive;
- Is a systematically developed evidence-based statement;
- Is flexible and acts as a support and guide;
- Allows individuals to use their professional judgement and decision-making skills concerning the appropriate care or delivery of service;
- Supports the improvement of care in all aspects of the service;
- Is prescriptive when used by unregistered health and care staff as the registered member of staff retains accountability and they alone can change the guidance.

**Clinical Protocol**

- Written as a practical education resource for health professionals and as a core component of disease management initiatives;
- Does not allow deviation, except by registered staff if the action and reason is clearly documented and based on an evidence base;
- Shows delegation and clear accountability;
- Standardises a safe approach to a task or intervention related to specific skills and knowledge required;
- Is designed to protect both staff and patients.

***NB: It is important when using a protocol or guideline to document clearly any reason why in the case of an individual patient/client/service user it has not been followed. They should be developed using the current available evidence, expert opinion or accepted current best practice.***

**Standard**

- Underpins a procedure, guideline or protocol;
- Is a minimum performance/outcome which is widely recognised or employed because of its level of excellence or attainment;
- Is sometimes included as part of a policy, procedure, guideline or protocol.

**Competency Frameworks**

- Defines the knowledge and practical experience required to be demonstrated by a Healthcare Professional to undertake a specific intervention. In some cases it acts as the assessment documentation/evidence of competence.

**Care Pathways**

- A hybrid document combining sequenced clinical guidance/actions, with areas for clinical recording for the management of a specific disease or condition, along an anticipated pathway of care.

  Like a Clinical Protocol it does not allow deviation, except by registered staff if the action and reason is clearly documented and based on an evidence base and clinical judgement relating to the clinical situation.

**Clerking Proformas**

- A document for clinical recording for the management of a specific disease or condition in an emergency situation, along an anticipated pathway of care. It may have some clinical guidance, but in a much more limited format than the Care Pathway.

**Patient Group Direction (PGD)**

- Definition in (Patient Group Directions Policy ref 1782)

  "A PGD is a specific written instruction for the supply or administration of a licensed named medicine including vaccines to specific groups of patients who may not be individually identified before presenting for treatment".

  Health Service Circular 2006 https://www.nice.org.uk/guidance/mpg2 ***(updated March 2017)***

**Patient Specific Direction (PSD)**

- A Patient Specific Direction (PSD) is a written instruction, signed by a prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. In practice, a PSD is may be referred to as a "prescription" by those who write and follow them because this indicates that it is written by a prescriber.

https://www.rcn.org.uk/clinical-topics/medicines-management/patient-specific-directions-and-patient-group-directions

**Appendix 2**

## Responsibilities
**(*Day-to-day responsibilities for all staff, line managers, document owners/authors/ originators, Clinical Effectiveness Department, company secretary, document database administrator and ratifying committee/group*)**

### All Staff

Have a responsibility to:

- read and understand and align working practice with all documents relating to their areas of work and role.
- report any changes relating to best working practice to their manager, so that the document can be reviewed and updated.

### All Line Managers

Have a responsibility to ensure staff have:

- access to all relevant documents
- working environments, processes and practices that meet the requirements of the documents
- received any relevant training and education to support them in aligning their work with Trust documents
- a responsibility for ensuring that staff who are authorised for developing documents are fully trained and aware of this policy and the process involved (appendix 5).

### Document Owner/Author/Originator

Have a responsibility to:

- ensure that the document does not exceed its review date and undertaking any creations, reviews or amendments, ensuring that the document is fully consulted upon and meets with the current document format;
- supply information source references as required
- submit an "Quality & Equality Impact Assessment Form" (QEIA) prior to its ratification
- liaise directly with the Trust Equality and Diversity Lead in relation to any potential impact identified through the QEIA form.
- ensure that documents are presented for ratification two weeks prior to relevant ratification committee/group meeting. Once ratification has been completed, documents can be published in accordance with appendix 3.
- For non-clinical documents follow guidance in Appendix 3. For care and clinical documents follow guidance in Appendix 4.

**For Care and Clinical documents**

- The ratification process for care and clinical documents includes approval by directorate meeting eg cardiology, specific Group eg Infection Prevention and Control Group or Trust wide Care and Clinical policy Group.
- Signature approval is also required from the relevant Clinical Director/Committee Chair and/or Executive Level sign off.
- Additional ratification is required from the Director of Pharmacy if the content makes reference to the use of drugs or drug dosages.
- Ratified documents require a 2 yearly review and the Clinical Effectiveness department inform the relevant Integrated Service Unit (ISU) and department 4 months in advance of the review due date. Re-ratification will then be required with the exception of date change only and/or logistic changes eg. Telephone contact details.

**The Clinical Effectiveness Department**

Have a responsibility to:

- support the document originator in the formatting of new and revised documents into the agreed Trust format
- maintain a publication history of the document with version numbering
- publish new and revised ratified documents onto the intranet and public websites on a weekly basis, and also publish notification of changes to all relevant staff groups
- maintain the metadata related to each document
- notify originators of the requirement to review their documents (every 3 years, unless otherwise agreed) approximately 4 months prior to the review date; and
- manage and report monthly on the notification of documents to ISU or relevant department which remain un-reviewed post expiry, and the escalation of these to the executive.

**Company Secretary**

Responsible for the management of the corporate records system and has responsibility for overseeing corporate document creation, review, ratification and publication for all corporate documents. The Company Secretary will produce reports to ratifying committees/groups identifying documents due for review in the next three months and for those that are out of date and may pose a risk to the Trust.

**Corporate Document Database Administrator (DDA)**

Has a responsibility to create and publish reports from the document database for the ratifying committees' librarians, uploading ratified documents to the database and ensuring it is maintained.

All documents will be published on the Trust public website as part of our responsibilities under the Freedom of Information Act 2000.

There will be a small number of documents which will not be suitable for public viewing; these will be agreed by the ratification committee/group. These will be made available on the Trust's intranet site.

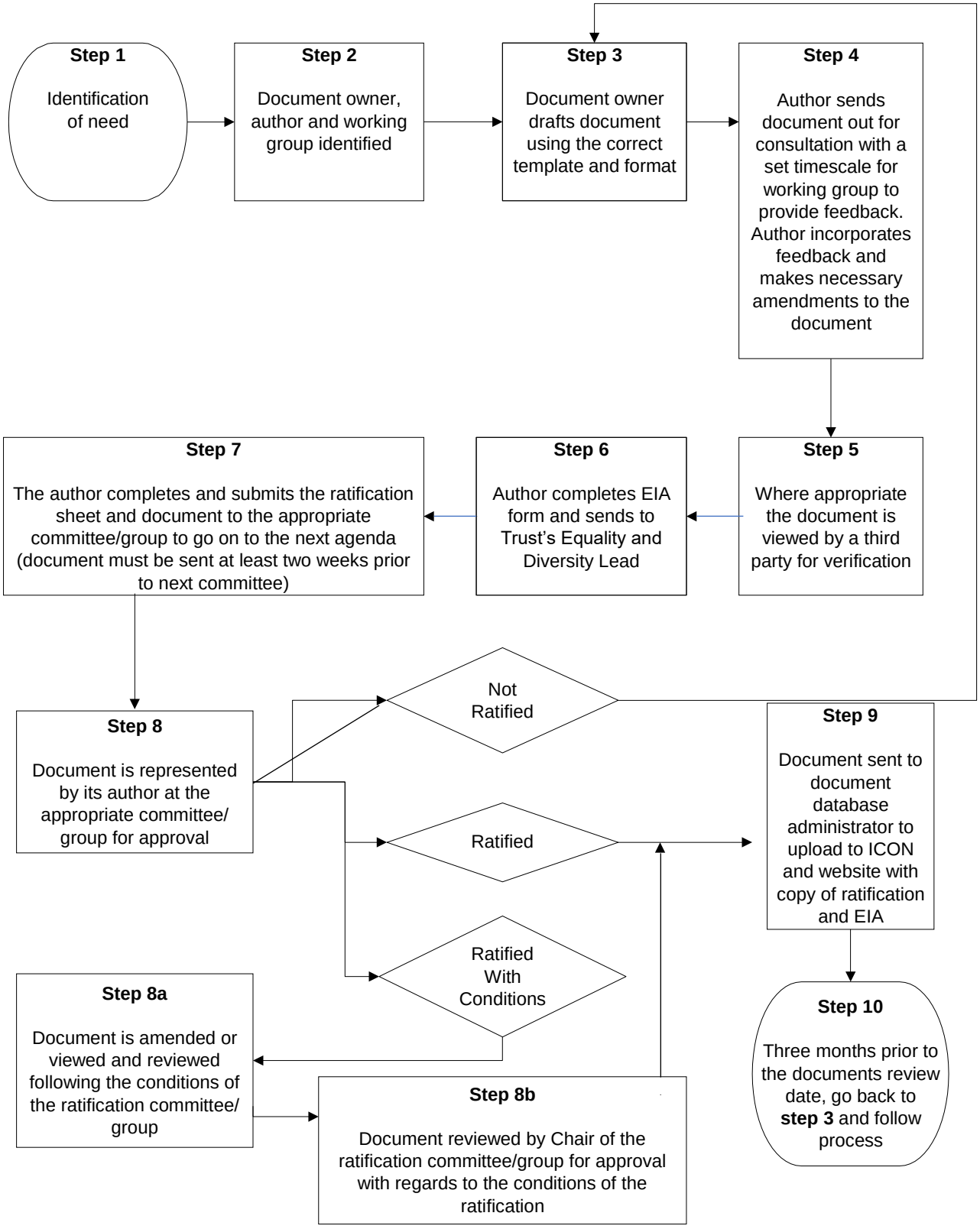
**Ratifying Committee/Group Librarian**

Have a responsibility to:

- receive a monthly report from the DDA identifying documents due for review in the next three months and/or overdue to ensure that these have been allocated a document owner/author for review;
- identify any areas of risk relating to the document and record there on the risk register; and
- assist the Chair of the committee/group to ensure all documentation is in the correct format/template and are fit for purpose before ratification and publication through the DDA.

**Appendix 3**

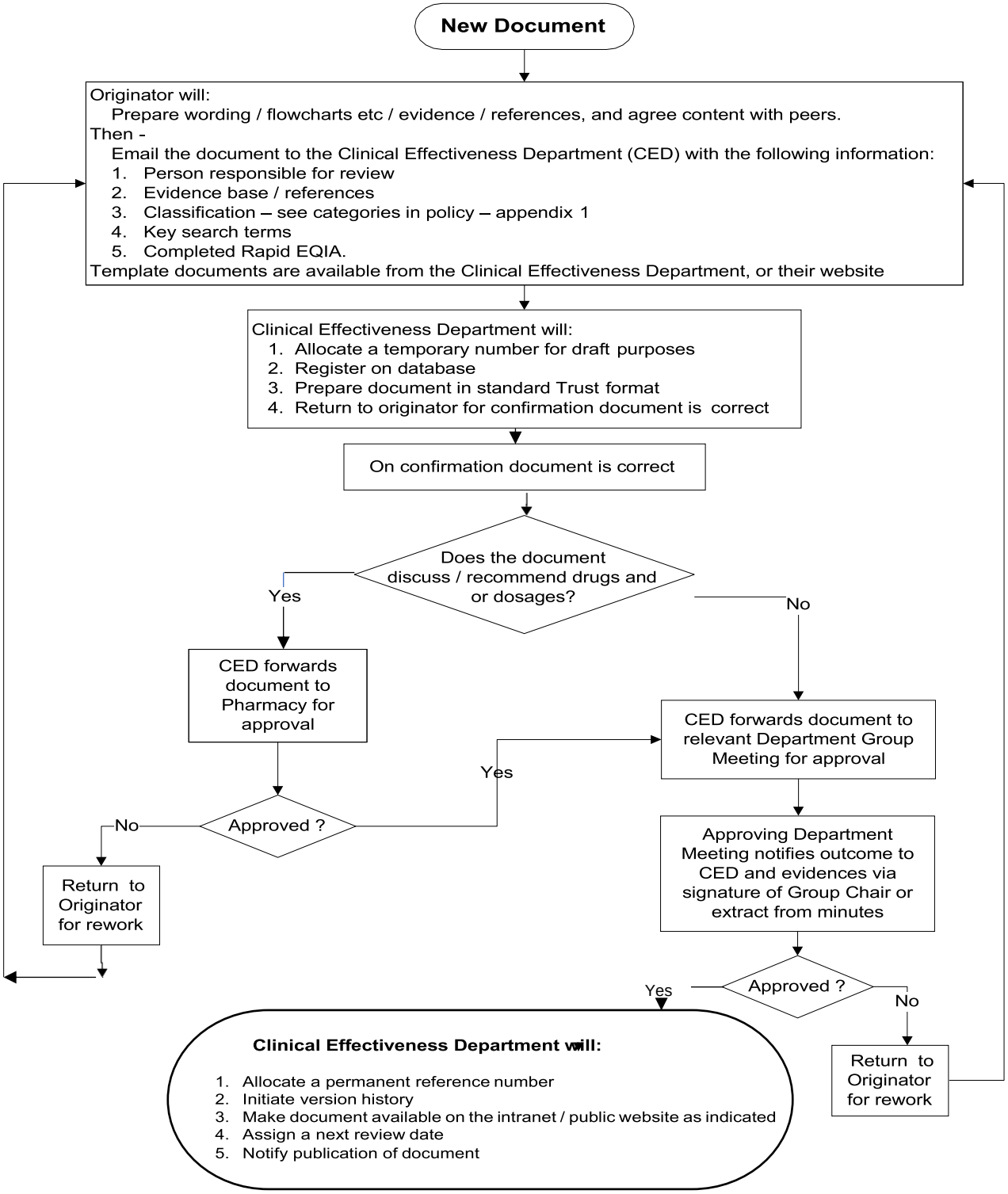
## Creation and review of Non-Clinical Documents



**Appendix 4**

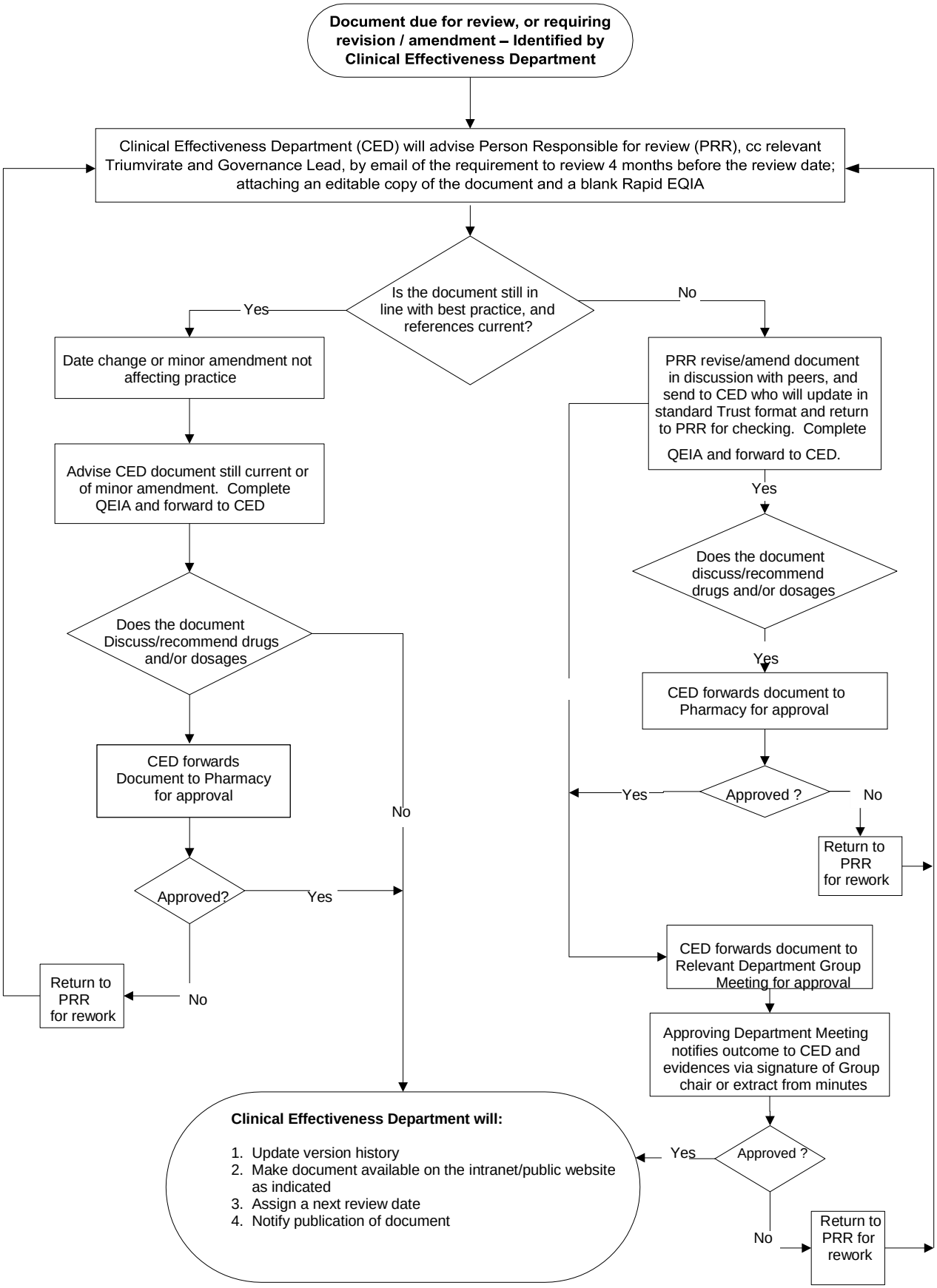
## Process for Production of Care and Clinical Documents and Review of Existing Care and Clinical Documents

NB. Patient Group Directions (PDG) are also published by the Clinical Effectiveness Group onto the intranet, in conjunction with Pharmacy, who manage the production of these documents and ratification through the Medicines Management Group.



**Appendix 5**

## Process for Review and Revision of Published Clinical Guidance



**Process for management of <u>care and clinical</u> documents overdue for review:**

- Responsibility for the management of care and clinical documents falling overdue for review rests with the triumvirate* of the ISU in which the author of the document is located.
  *(Triumvirate consists of the ISU System Director; the Associate Director of Nursing and the relevant Medical Director).

- The Clinical Effectiveness Department holds the responsibility of maintaining records relating to the progress of documents through the notification of requirement to review, updating of documents, and progress through approval and ratification. From this information a suite of reports and tools are supplied on a monthly basis to the ISU triumvirate and governance leads to enable their management of documents.

- The ISU should review the risk and impact of the out of date documentation being made available on the intranet (and in some cases public website), and consider adding to their divisional risk register.

**Appendix 6**

## Ratification Structure

All documents should be ratified as set out below unless there is a requirement for the document to be ratified by the Board of Directors, e.g. CQC, NHS Resolution, Information Governance Toolkit or other standards which the Trust is reporting on.

Please note that policies should be passed through the relevant steering/working groups for comment prior to submission to the ratification committee/group.

Documents will be categorised as follows:

| Category | Area | Consultation Groups | Ratification |
|---|---|---|---|
| Strategy | All strategies which are developed due to national policy and/or legislative requirement and relevant for more than three years to be ratified by the Board of Directors.<br><br>All other strategies to be ratified as per list below. | • Directors<br>• Head of services/directorates<br>• Professional leads<br>• Managers<br>• Appropriate working /steering groups | • Board of Directors |
| | Human resources, volunteers, workforce and education strategies. | • Joint Consultative and Negotiating Committee (JCNC) | • People Committee |
| | Quality related strategies which relate to care and treatment e.g. quality strategy and end of life strategy. | • As appropriate including Quality Improvement Group | • Quality Improvement Group plus<br>• Quality Assurance Committee as appropriate. |
| | Partnership agreement. | • As appropriate | • Board of Directors |
| | Learning disability strategy. | • Head of services/directorates<br>• Professional leads as appropriate | • Safeguarding / Inclusion Group |
| Care and Clinical | Care and clinical quality related documents. | • Head of services/directorates<br>• Professional leads<br>• Care governance groups<br>• Care teams affected by the document. | • ISU specific Integrated Governance Group Speciality specific - Specialties/ Directorates meetings/ committee<br>• Trust wide – Care and Clinical Policy Group |
| Estates and Facilities | All documents that relate to estates and facilities excluding health and safety and security (please see Health and Safety section below) | • Head of services/directorates<br>• Infection Prevention and Control Group<br>• Professional leads<br>• Authorising Engineers<br>• Estates and Facilities Team | • Capital Infrastructure and Environment Group<br>• Health and Safety Committee<br>• Infection Prevention and Control Group |

| Category | Area | Consultation Groups | Ratification |
|---|---|---|---|
| | | • Joint Consultation and Negotiating Committee | |
| Finance | All documents that relate to financial systems and processes for the Trust. | • Head of services/directorates<br>• Finance team<br>• Internal and external auditors | • Finance, Performance and Digital Committee |
| Human Resources | Policies relating to the employment of staff. | • Managers and appropriate working groups. | • Joint Consultative and Negotiating Committee |
| Health and Safety including security | Documents relating to health and safety related issues including security. | • Head of services/directorates<br>• Professional leads<br>• Appropriate working group<br>• JCNC<br>• External experts | • Health and Safety Committee |
| Safeguarding / Inclusion | Safeguarding of adults and children as well as more widely applied equality and disability discrimination acts. | • Adult Safeguarding Group<br>• Children's Safeguarding Group<br>• Dementia Group<br>• Disability Awareness Action Group<br>• Domestic Violence Group<br>• Experts by Experience Group<br>• Joint Equalities Cooperative<br>• Serious Case Review Group | • Safeguarding / Inclusion Group |
| Corporate policies | Policies that do not fall into any of the above categories e.g. IT, information governance, etc. | • Head of services/directorates<br>• Care teams<br>• Appropriate working groups, committees | • Information Management and Technology Group<br>• Executive Team |
| Corporate procedures, guidelines etc. | Documents that do not fall into any of the above categories e.g. ICT, information governance, etc. | • Head of services/directorates<br>• Care teams<br>• Appropriate working groups, committees | *To appropriate steering/working group. See list below*. |

Corporate procedures, guidelines, protocols, standards, etc. which sit under a ratified policy can be ratified by one of the appropriate groups, subject to appropriate consultation, as listed below.

| Documents | Ratification |
|---|---|
| Estates and Facilities | Capital Infrastructure and Environment Group |
| Finance | Finance, Performance and Digital Committee |
| Health and Safety including Security | Health and Safety (reports to Risk Group) |
| Human resources | Joint Consultative and Negotiating Committee and/or People Committee |
| Infection prevention and control | Infection Prevention and Control Group |
| Information Management and Information Technology (IM&IT) | IM&T Group |
| Information governance | Information Governance Steering Group and/or IM&T Group |
| Resuscitation | Resuscitation Group |
| Risk management | Risk Group |
| Safeguarding / Inclusion | Safeguarding / Inclusion Group |

If your document does not fit into one of the above categories or are unsure as to where it should go for ratification, please contact the Corporate Document Database Administrator on 01803 654630 / Internal 54630. For Care and Clinical documents please contact the Clinical Effectiveness Team on 01803 655802.