Policy for the Development, Approval, Management and Dissemination of Trust Controlled Documents

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Version</th>
<th>Status</th>
<th>Executive Lead(s) Name and Job Title</th>
<th>Author(s) Name and Job Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>55</td>
<td>6</td>
<td>Current</td>
<td>Neil Riley, Trust Secretary</td>
<td>Andy Challands, Assurance Manager</td>
</tr>
</tbody>
</table>

Approval Body: TEG | Date Approved: 11/01/2012
Ratified by: Board of Directors | Date Ratified: tbc
Date Issued: tbc | Review Date: tbc

Contact for Review Name and Job Title: Andy Challands, Assurance Manager
Associated Documentation:

Trust Controlled Documents:
Standing Orders
Standing Financial Instructions
Reservation and Delegation of Powers
Freedom of Information Policy
Trust Disciplinary Procedure
Incident Management Policy
Code of Practice for the Management of Records

External Documentation:


Legal Framework
Equality Act 2010
Health and Social Care Act 2001
Human Rights Act 1998
Freedom of Information Act 2000

Version History If there is insufficient space on the page to show all versions it is only necessary to show the previous 2

<table>
<thead>
<tr>
<th>Version</th>
<th>Date issued</th>
<th>Brief summary of change</th>
<th>Owner’s name</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>05/10/09</td>
<td>Major re-write</td>
<td>Andy Challands</td>
</tr>
<tr>
<td>6</td>
<td>13/9/10</td>
<td>Inclusion of process for approval of non material amendments between review dates and management of obsolete documents. Clarification of archiving arrangements. Additional guidance on monitoring compliance for the policy in contrast to controlled documents.</td>
<td>Andy Challands</td>
</tr>
<tr>
<td>7</td>
<td>tbc</td>
<td>Updated guidance to comply with Equality Act 2010 and to undertake Equality Impact Analysis. Amended scope and inclusion of an Appendix 2 on Guidance for Locally Managed Documents. Removal of TEG responsibility to designate Approval Bodies. Updated checklist – Appendix 1.</td>
<td>Andy Challands</td>
</tr>
</tbody>
</table>

Document Imprint
Copyright ©Sheffield Teaching Hospitals NHS Foundation Trust 2011: All Rights Reserved
Re-use of all or any part of this document is governed by copyright and the “Re-use of Public Sector Information Regulations 2005. SI 2005 No 1515.
Information on re-use can be obtained from:
The Department for Information Governance & Caldicott Support,
Sheffield Teaching Hospitals NFT.
Tel: 0114 226 5151. E-mail: infogov@sth.nhs.uk
Executive Summary

Policy for the Development, Approval, Management and Dissemination of Trust Controlled Documents

Document Objectives: To ensure a structured and systematic approach to the development, approval, management and dissemination of Trust procedural documents

Group/Persons Consulted: 2011 Review: Members of Trust Controlled Documents Group, Head of Patient and Healthcare Governance, Governance Improvement Manager, Trust Secretary, Equality and Human Rights Manager

Monitoring Arrangements and Indicators: This policy will be monitored for compliance via the Healthcare Governance Risk Management Audit Programme. Key Performance Indicators: As a minimum, Trust Controlled Documents must be:
- approved as per this policy
- logged on the Trust’s intranet/internet site within 10 working days of TEG ratification with any older version removed for archive
- distributed to nominated leads (as per dissemination plan) within 10 working days of TEG approval
- reviewed in a timely manner

Training Implications: None identified

Equality Impact Assessment: An initial Equality Impact Assessment, as published on the Trust’s internet site, has been reviewed by the Assurance Manager. This policy references the Equality Impact Analysis.

Resource implications: None identified.

Intended Recipients: All staff with responsibility for controlled documents

Who should:-
- be aware of the document and where to access it: Executive Directors, Clinical Directors, Nurse Directors, General Managers
- understand the document: Executive Directors, Clinical Directors, Nurse Directors, General Managers
- have a good working knowledge of the document: Staff who develop trust controlled documents. Chairs and deputy chairs of approval bodies. Nominated directorate leads
<table>
<thead>
<tr>
<th>CONTENTS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary</td>
<td>3</td>
</tr>
<tr>
<td>1 Introduction</td>
<td>5</td>
</tr>
<tr>
<td>2 Scope</td>
<td>5</td>
</tr>
<tr>
<td>3 Purpose</td>
<td>5</td>
</tr>
<tr>
<td>4 Duties</td>
<td>5</td>
</tr>
<tr>
<td>5 Style and Format</td>
<td>7</td>
</tr>
<tr>
<td>6 Definitions</td>
<td>7</td>
</tr>
<tr>
<td>7 Development of Trust Controlled Documents</td>
<td>8</td>
</tr>
<tr>
<td>8 Consultation, approval and ratification process</td>
<td>9</td>
</tr>
<tr>
<td>9 Arrangements for review</td>
<td>10</td>
</tr>
<tr>
<td>10 Dissemination of Trust Controlled Documents</td>
<td>11</td>
</tr>
<tr>
<td>11 Implementation</td>
<td>12</td>
</tr>
<tr>
<td>12 Document control, including archiving arrangements</td>
<td>12</td>
</tr>
<tr>
<td>13 Monitoring compliance and effectiveness</td>
<td>13</td>
</tr>
<tr>
<td>14 Associated documentation</td>
<td>13</td>
</tr>
<tr>
<td>15 References</td>
<td>14</td>
</tr>
<tr>
<td>Appendix A: Checklist for the development of a Trust Controlled Document</td>
<td>15</td>
</tr>
<tr>
<td>Appendix B: Guidance for the development, approval, management and</td>
<td>15</td>
</tr>
<tr>
<td>dissemination of locally managed documents</td>
<td></td>
</tr>
</tbody>
</table>
1 INTRODUCTION
An important element of the Trust’s governance framework and system of internal controls is the provision of a robust mechanism for the development, approval, management and dissemination of procedural documents to ensure achievement of the organisation’s objectives and the promotion of its values.

2 SCOPE
2.1 Procedural documents developed, approved, managed and disseminated in accordance with this policy are referred to as Trust Controlled Documents (TCDs).

2.2 In general, TCDs have a Trust-wide application but consideration should be given to those documents that have an application across two or more directorates. The Trust Controlled Document Group (see Section 4.7) should be consulted for guidance on eligibility.

2.3 Documents that do not have a Trust-wide application shall be managed locally by the relevant department, directorate, care group or staff group and not by the Trust Controlled Documents Group. Arrangements for the development, approval, management and dissemination of such locally managed documents should follow the good practice principles outlined in this policy and summarised in Appendix 2. Locally managed documents do not require ratification by TEG or the Board of Directors.

3 PURPOSE
The purpose of this policy is to:

3.1 Set out a structured and systematic approach to the development, approval and management of TCDs which ensures that such documents are:
   (i) consistently delivered to a high standard and in accordance with statutory and mandatory requirements
   (ii) version controlled and previous versions removed from circulation with a copy archived for reference / legal reasons
   (iii) current and are systematically reviewed and updated as necessary
   (iv) presented in a standardised corporate style and format
   (v) accessible by staff (and public, as appropriate)
   (vi) assessed for training needs, resource implications and equality / human rights impact
   (vii) monitored to ensure effective implementation and use

3.2 Provide guidance to staff responsible for developing TCDs

3.3 To ensure compliance with:
   - NHS Litigation Authority (NHSLA) Risk Management Standards [1]
   - Information Governance Toolkit. [2]

4 DUTIES
4.1 The Board of Directors is ultimately responsible for all TCDs, (including this policy) but has delegated responsibility to the Trust Executive Group, as outlined below:

4.1.1 Trust Executive Group (TEG)

TEG is responsible for ratifying all TCDs that have been approved by the designated Approval Body, except for documents when TEG reserve responsibility as the Approval Body itself, in which case the TCD must be ratified by the Board of Directors.
4.1.2 Executive Director

(i) All TCDs submitted for approval and/or ratification must be sponsored by the appropriate Executive Director
(ii) If an Executive Director is responsible for developing a document, in practice they may delegate responsibility to a nominated author.

4.1.3 Approval Body

It is the responsibility of the Approval Body to:
(i) confirm it is the most appropriate Approval Body in terms of resident expertise to properly challenge and scrutinise the TCD
(ii) review the content of the TCD as the expert group
(iii) ensure that the development of the document complies with this policy
(iv) approve the document for ratification by TEG or recommend the author(s) to undertake additional work.

4.1.4 Author(s)

It is the responsibility of the author(s) of a TCD to ensure the document is developed in accordance with this policy.

4.1.5 Line Managers

It is the responsibility of line managers to:
(i) ensure that their staff are aware of and have access to TCDs that are relevant to their working environment and are notified of any new or re-issued TCDs
(ii) ensure staff have access to any training identified as necessary for effective implementation of the TCD
(iii) ensure that current and/or superseded or withdrawn TCDs stored as hard copy or on local PCs, shared drives or websites within their areas are removed. Only under exceptional circumstances (e.g. when staff do not have access to the intranet) can hard copy TCDs be stored locally and in such circumstances the line manager is responsible for ensuring the hard copy TCDs are current.

4.1.6 Staff

It is the responsibility of staff (including contractors and agency staff) to be aware of and to comply with relevant TCDs.

Please note:
(i) Information regarding the failure to comply with TCD, for example because of lack of training or inadequate equipment, must be reported to the Line Manager and the incident reported according to the Incident Management Policy
(ii) Failure to comply with relevant TCDs that are mandatory will be dealt with in accordance with the Trust Disciplinary Procedure.

4.1.7 Trust Controlled Documents Group

The Trust Controlled Documents Group (TCDG) is responsible for:
(i) providing advice and support on aspects of this policy
(ii) administering the development and approval process in line with this policy
(iii) maintaining and developing the STH Corporate Policies and Related Documents intranet site and associated databases
(iv) completing or updating relevant sections on the template document Control Sheet
(v) uploading new or reissued TCDs on to the intranet (and internet site, as appropriate) and maintaining an archive of superceded or withdrawn TCDs
(vi) maintaining and developing an effective and timely system for the dissemination of new and reissued TCDs
(vii) maintaining and developing an effective and timely system for reviewing TCDs

5 STYLE AND FORMAT

5.1 TCDs should be written in a style which is concise and clear using unambiguous terms and language. Abbreviations should be written in full, followed by the abbreviation in brackets, in the first instance of use. Flowcharts, algorithms and diagrams should be used to aid understanding.

5.2 Consideration should also be given to producing TCDs in languages other than English, dependent upon the target audience. Author(s) should contact the TCDG for further advice.

5.3 Style

To ensure a corporate style, TCDs must use:
(i) Arial Font 11 point for the main body text
(ii) single line spacing
(iii) outline numbering with headings highlighted in bold
(iv) a footnote on all pages (except the front sheet) with title, version number and page number of total.

5.4 Format

(i) All TCDs should follow a standard format. A Microsoft Word copy of the TCD template with standard headings is available on the STH Corporate Policies and Related Documents intranet site.
(ii) If a TCD is developed in Portable Document Format (pdf), the original pdf document must be made available to the TCDG before it is disseminated.

6 DEFINITIONS

Trust Controlled Documents are documents that have been developed, approved and ratified in accordance with this policy. They include strategies, policies, procedures, protocols and guidelines which aim to provide direction to staff:

Strategy - A medium- or long-term plan of action designed to achieve a particular goal. The content of strategy documents will tend to be high level and concise, presenting a vision of what it is intended to achieve and why, what benefits are intended to accrue from the strategy and how it is to be achieved over a defined period – usually 3 to 5 years.

Policy - A statement of corporate intent explicitly stating responsibility and accountability. It is not open to interpretation or professional judgment and is non-negotiable. It may result from national or local directives and provides a framework within which individuals or specific groups must work.

Procedure - This must follow from a particular policy. It is a description of the way in which a policy is implemented. A set of actions, which is the official or accepted way of doing something. Alternatives may be specified within a procedure but deviation from the procedure is not an option.

Protocol - The way of prescribing exactly what must be done and documented in a specific situation. An agreed approach and / or description of roles and responsibilities mostly employed in clinical settings. It does not allow deviation from the agreed practice.
**Guideline** - This gives systematically developed recommendations for practice, which are based on evidence and referenced (if possible). It guides professionals and allows individuals to use their professional judgment and decision-making skills. It is flexible and acts as a support and guide, it is not prescriptive.

**Standard** - A means of describing the level of quality that organisations or individuals are expected to meet or to aspire to. The performance of organisations or individuals can be assessed against this level of quality.

**Patient Group Direction** - A written instruction for the supply and/or administration of named medicines in an identified clinical situation which applies to groups of patients who may not be individually identified before presenting for treatment (see Patient Group Directions Protocol).

Please note: The above list is not exhaustive.

7 DEVELOPMENT OF TRUST CONTROLLED DOCUMENTS

This section is supported by the TCD Flowchart (see Appendix A)

7.1 Prioritisation of Work

7.1.1 Author(s) responsible for developing a TCD must inform the TCDG at the outset (see New Document Online Notification Form).

7.1.2 Author(s) must:
(i) ensure that a new TCD is not duplicating other work, either locally or nationally
(ii) secure any necessary outline support for developing a new TCD, including sponsorship by the appropriate Executive Director
(iii) identify the Approval Body (Authors should contact the TCDG and/or the sponsoring Executive Director for guidance concerning an appropriate Approval Body)
(iv) contact the chairperson of the Approval Body to notify them that the TCD is under development and to confirm the Approval Body is willing and able to act in that capacity
(v) ensure a new TCD is consistent with corporate and relevant directorate strategies, service priorities and other existing TCDs
(vi) confirm that implementation is achievable within existing resources or that enabling resources have been secured.

7.1.3 In some cases, the development of a TCD will have been recommended by an external body (e.g. NHS Litigation Authority, the National Patient Safety Agency, etc). This should be made explicit within the document. It may influence the frequency of review or the Approval Body.

7.2 Identification of Stakeholders

7.2.1 The author(s) should identify all relevant stakeholders who should be involved in the development or consultation phases of the document.

[A stakeholder is anyone with an interest in a TCD and includes staff (at all levels), staff side organisations, governors, departments, directorates, committees, patients and the public, external stakeholders and/or people with specialist skills or knowledge such as the Local Counter Fraud Specialist. Stakeholders can contribute to or comment on the content of a document and may recommend additional stakeholders.]

7.2.2 As appropriate, patients and the public may be involved in the development or consultation phases. Contact the Head of Patient Partnership for further advice and support.
7.3 Equality Impact Analysis and Human Rights

7.3.1 As a public body, the Trust has a legal responsibility under the Human Rights Act not to breach human rights. Authors must consider if a TCD has the potential to impact on human rights. Further guidance on human rights is available on the Equality and Human Rights intranet site.

7.3.2 Similarly, the Trust has a legal responsibility under the 2010 Equality Act to comply with the Public Sector Equality Duty which requires the Trust to have due regard to

- eliminate discrimination, harassment and victimisation
- advance equality of opportunity between people who share a relevant protected characteristic\(^1\) and people who do not
- foster good relations between people who share a relevant protected characteristic and people who do not.

7.3.3 Having due regard means equality issues must be consciously considered in the process of decision-making by the Trust. This requirement is met through Equality Impact Analysis (EIA) which aims to identify and address real or potential inequalities and discrimination resulting from the development and implementation of TCDs and/or identify how equality can be promoted.

7.3.4 An EIA must be undertaken as part of the development of TCDs in accordance with Equality Impact Analysis Policy (add hyperlink).

7.3.5 A summary of the EIA must be documented in the relevant section of the template document Control Pages. Author(s) are responsible for the validity of any statement made. TCDs that do not have this section completed may not be ratified.

7.4 Executive Summary

Authors must produce an Executive Summary of the TCD.

8 CONSULTATION, APPROVAL AND RATIFICATION PROCESS

8.1 Consultation Process

8.1.1 The consultation process should be comprehensive and should include the stakeholders identified in accordance with Section 7.2. The draft TCD should be circulated to stakeholders with instructions about what they are expected to do, a clear deadline and a named contact for feedback.

8.1.2 The appropriateness of consulting with stakeholders should be guided by the nature of the document being developed or reviewed.

8.1.3 Some TCDs have mandated consultation, for example:

- human resources or health and safety TCDs must include consultation with staff side through the Joint Negotiating and Consultative Committee.
- the development of Patient Group Directions must involve a senior pharmacist and antibiotic PGDs must involve a consultant microbiologist
- specific policies that must be reviewed by the Local Counter Fraud Specialist

(Please note: This list is not exhaustive)

\(^1\) There are 9 Protected Characteristics: Age, Race, Religion and belief, Disability, Sex, Gender Reassignment, Sexual Orientation, Pregnancy & Maternity, Marriage & Civil Partnership
8.1.4 In circumstances when the TCD includes accompanying documentation intended to be used in the patient record, such documentation must be consistent with the Trust Design Standards. Author(s) are responsible for ensuring that any such documentation is approved by the New Documents Sub-Group as part of the TCD approval and ratification process. Author(s) should contact the Medical Records Manager for further advice and support.

8.1.5 Persons and groups consulted with during the development or review of a TCD must be listed in the Groups/Persons Consulted section on the template document Control Pages.

8.2 Contact for Review

Author(s) must identify a Contact for Review which must be documented in the relevant section on the template document Control Pages. If a specific member of staff is named as the contact, their full job title and/or role must also be documented.

8.3 Approval and Ratification Process

8.3.1 The Approval Body as designated by the Author(s) should review and approve the TCD.

8.3.2 TCDs that have been approved by the designated Approval Body must be ratified by TEG (except those policies specified in the Scheme of Reservation and Delegation as requiring Board approval or TCDs that TEG choose to escalate on an ad hoc basis to the Board for approval and ratification).

8.3.3 In ratifying an approved TCD, TEG must consider and endorse the appropriateness of the Approval Body or recommend a more appropriate Approval Body prior to ratification.

8.3.4 Some documents are developed outside the Trust, for example national guidelines or city-wide policies. In order to be adopted as TCDs they should be approved and ratified in accordance with this policy and appended to the standard template. In these circumstances the Control Pages should still be completed in full but the status will be changed to adopted and an operational sponsor will be identified in place of the author.

9 ARRANGEMENTS FOR REVIEW

9.1 Existing TCDs will remain in force until updated on the TCD intranet site or withdrawn, even if the review date has been passed.

9.2 Unless otherwise stated, TCDs must be reviewed and re-issued within 3 years from the date of issue / last re-issue. However, TCDs should be reviewed immediately, irrespective of the review date, in response to:
   (i) new guidance following changes in legislation, policy or practice
   (ii) a recommendation following a Serious Untoward Incident or other governance findings
   (iii) changes in partnership working

9.3 Specific TCDs must be reviewed annually, e.g. Health and Safety Policy Statement, Standing Orders, Standing Financial Instructions and Scheme of Delegation. (Please note: This list is not exhaustive).

9.4 Using an automated alert system triggered by the review date, the TCDG will inform the nominated Contact for review that the TCD is due for review 6 months before the review date with a reminder at 3 months. The designated Executive Director will be copied in as a failsafe to ensure that a new reviewer be identified in case the original contact is no longer responsible.
9.5 The review process should be undertaken according to the same procedure as for new TCD development. However, under exceptional circumstances such as alerts about drugs or equipment, the Executive Director, Trust Secretary or TCDG chairperson can authorise amended versions to be circulated immediately pending retrospective confirmation of approval and ratification.

9.6 The author(s) responsible for the review should ensure that the TCD is up-to-date and fit for purpose and should consider the impact of changes in legislation, guidance and organisational structure since the document was developed or last reviewed.

9.7 A summary of the main changes to the TCD following the review should be clearly identified in the Version History section the template document Control Pages. When the review does not result in any change this should be documented as No changes were made to the document following the review.

9.8 It is sometimes necessary to make minor revisions to TCDs outside the approved review dates (for example, to update changed organisational arrangements, job titles, etc., or to correct spelling mistakes). The TCDG chairperson will forward all requests to revise TCDs outside the approved review dates for consideration by the Trust Secretary. If the suggested revision is not considered material, the Trust Secretary is authorised to approve the revision without recourse to the standard Approval and ratification processes. In such circumstances the TCD will not be disseminated but will be updated on the Trust's TCD intranet site. The TCDG will update the version number and version history accordingly and will notify TEG. The author(s) will notify staff of relevant changes, as appropriate.

9.9 If the author(s) undertaking the review conclude that a TCD is obsolete (for example, in response to changes in legislation, service provision, etc) they may request that the TCD be removed from view from the Trust's TCD intranet site. This decision must be approved by the Approval Body. The author(s) is responsible for informing the TCDG which will arrange for its removal from the intranet site and will inform TEG.

9.10 For TCDs that are adopted but cannot be maintained as current via hyperlinks, the operational sponsor is responsible for ensuring there are robust mechanisms in place to notify them of any changes and to arrange for the TCD to be amended and reissued.

10 DISSEMINATION OF TCDs

10.1 New and reissued TCDs are disseminated to staff via the Trust’s intranet site.

10.2 The TCDG is responsible for uploading new and revised TCDs on to intranet site. The TCD may also be published on the Trust’s internet website. The TCDG will liaise with the Communications Department to decide whether to publish on the internet site. Consideration will be given to the need to promote transparency and to reduce the number of Freedom of Information requests to the Trust.

10.3 The TCDG is responsible for maintaining an up to date electronic database of nominated leads in directorates and departments to notify them of new and revised TCDs. The leads are responsible for cascading notification to their staff as appropriate. The TCDG notifies the leads via a standard email. A record of circulation is kept as an audit trail.

10.4 Author(s) of new and reissued TCDs must identify the target audience in the Intended Recipients section of the template document Control Pages and must liaise with TCDG to advise on email circulation to the nominated leads to ensure a focused and targeted audience and reduce the burden of unnecessary notification.
10.5 The standard email to nominated leads includes:
   (i) details of the TCD (i.e. title, author and Executive Lead)
   (ii) hyperlinks to the executive summary and the full document
   (iii) directions to confirm receipt, as appropriate

11 IMPLEMENTATION

11.1 Training

A Training Needs Analysis must be undertaken which considers the training required to implement the TCD and must be detailed in the Training Implications section on the template document Control Pages. It should highlight if the training is mandatory, the regularity of the training, implications for new employees and whether it affects all staff or specific staff groups only, (including senior managers and Board members).

11.2 Resource implications

The need for additional resources (including training costs) to implement the TCD must be assessed and the Resource Implications section on the template document Control Pages must be completed to confirm that:
   (i) implementation is achievable within existing resources or
   (ii) additional resources have been secured, (giving brief details).

12 DOCUMENT CONTROL INCLUDING ARCHIVING ARRANGEMENTS

12.1 Document Control

The TCDG will ensure robust document control (as recorded on the Control Pages) by:
   (i) allocating a unique Reference Number to all newly ratified TCDs
   (ii) allocating a Version number to all newly ratified TCDs, which will be updated:
      o following a non-material change to the document as indicated by an increase in the number after the decimal point
      o following a review, (even if the review does not result in a change to the document), as indicated by an increase in the whole number
   (iii) ensuring the Version History section is updated following any change or review
   (iv) designating the Status of the majority of TCDs as either draft or current or adopted. [Please note: The template document Control Pages is defaulted to draft status to facilitate electronic sharing for review, consultation purposes. The TCDG is responsible for changing the Status to current only when the TCD is ratified and uploaded on to the intranet].
   (v) completing/updating the Date Approved; Approval Body; Date Ratified, Ratifying body; Date Issued; Review Date and Contact for Review sections.

12.2 Register/Library of Trust Controlled Documents

The TCDG will maintain an up-to-date and controlled database of all TCDs and associated documentation, which will be made accessible via the STH Corporate Policies and Related Documents intranet site.

12.3 Archiving Arrangements

Superseded and obsolete TCDs are retained and managed electronically on the database by the TCDG and are accessible as an archived copy in the Superseded and Obsolete Document section on STH Corporate Policies and Related Documents intranet site.
12.4 Process for managing external requests for archived TCDs

Any external requests for archived TCD documents under the terms of the Freedom of Information Act will be processed in accordance with the Trust’s Freedom of Information Policy.

13 MONITORING COMPLIANCE AND EFFECTIVENESS

13.1 Monitoring compliance and effectiveness of TCDs

(i) The Trust is committed to ensuring compliance with all TCDs and will actively monitor the effectiveness of such documents.

(ii) Should it become evident, through the monitoring process, that the document is not being followed or that staff are unaware of its existence, the lead Executive Director is responsible for implementing appropriate measures to address the situation.

13.1.1 Process for Monitoring Compliance and Effectiveness of TCDs

(i) Monitoring arrangements and Key Performance Indicators (or standards) to demonstrate compliance and effectiveness must be detailed in the Monitoring Arrangements and Indicators section on the template document Control Pages. The section should identify:
   • who is responsible for undertaking the monitoring
   • the method to be used
   • frequency of monitoring
   • how the results will inform or improve practice

(ii) Common monitoring approaches to assess knowledge, implementation and experience include:
   • Audits (including Internal Audit)
   • Patients’ views and experiences surveys (existing or bespoke)
   • Benchmarking
   • Staff surveys (existing or bespoke)
   • Staff appraisals
   • Impact analysis
   • Complaints monitoring
   • Trend analysis
   • Incident reporting and monitoring
   • External agency visits, inspections and accreditations.

13.2 Monitoring compliance and effectiveness of this policy

Compliance with this policy is monitored through the Healthcare Governance Risk Management Audit Programme which will be launched and co-ordinated by the Patient and Healthcare Governance Department each year. The audit schedule, guidance and documentation are posted on the Patient and Healthcare Governance intranet site. The Healthcare Governance Committee will review the audit results.

14 ASSOCIATED DOCUMENTATION

14.1 Supporting or linked TCDs

(i) Relevant policies, procedures, guidelines, etc., that the document should be read in conjunction with, must be listed in the Associated Documentation section on the template document Control Pages.

(ii) If the supporting or linked TCD is cited in the document, it should be hyperlinked to the source. The TCDG will be responsible for activating and maintaining hyperlinks.
14.2 Relevant legislation should be listed in the *Legal Framework* section on the template document Control Pages.

15 **REFERENCES**

15.1 Evidence or sources cited in a TCD should be referenced using Harvard style at the end of the document (click [here](#) for guide).

15.2 The references cited in this policy are:

# Appendix A

## CHECKLIST FOR THE DEVELOPMENT OF A TRUST CONTROLLED DOCUMENT

### STAGE 1 – DECISION TO DEVELOP A TRUST CONTROLLED DOCUMENT (TCD)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Executive Director to nominate author OR authors to secure relevant Executive Director support</td>
</tr>
<tr>
<td>2</td>
<td>Author to inform Trust Controlled Document Group (TCDG) of intention to develop TCD</td>
</tr>
</tbody>
</table>
| 3 | Prioritisation:  
  - develop outline case which should be linked to local and/or corporate strategy and/or priorities  
  - identify support  
  - check TCD is not duplicating existing STHFT TCD or national work  
  - ensure TCD can be delivered within existing resources OR that enabling resources are secured |
| 4 | Read the “Policy for the Development, Approval, Management and Dissemination of Trust Controlled Documents” and download TCD Template from Controlled Documents Web Site on the Intranet |
| 5 | TCDG or Executive Director to advise author on appropriate Approval Body |
| 6 | Author to contact chairperson of Approval Body. Check outline support and agree timetable |

### STAGE 2 – DEVELOP DRAFT TCD

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identify and involve stakeholders, as appropriate</td>
</tr>
</tbody>
</table>
| 2 | Initiate:  
  - Equality Impact Analysis (contact the Equality and Human Rights Manager or visit the Equality and Human Rights intranet site)  
  - Training Needs Assessment (contact Learning and Development) |
| 3 | Develop draft TCD – ensuring relevant expertise is used. If relevant, initiate approval process for supporting information e.g. patient information (contact Patient Information Manager), patient documentation (visit New Documents Sub-Group website) |
| 4 | Complete Executive Summary |
| 5 | Send out draft TCD for consultation and amend as necessary, in response to feedback |
| 6 | Complete the relevant sections of Control Pages |

### STAGE 3 – APPROVAL AND RATIFICATION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Author to submit TCD for approval to the Approval Body. Amend as necessary on recommendation from Approval Body and re-submit for approval.</td>
</tr>
<tr>
<td>2</td>
<td>Send approved document with evidence of approval to TCDG for quality control check. (NB TCDG will NOT assess the content of the TCD but will check style / format and adherence to policy)</td>
</tr>
<tr>
<td>3</td>
<td>TCDG will submit approved TCD with evidence of approval to TEG (or Board) for ratification.</td>
</tr>
</tbody>
</table>

### STAGE 4 – DISSEMINATION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TCDG complete document control sections of Control Pages e.g. Reference Number, Version Number, etc., and upload to STHFT intranet websites and STHFT internet website, as appropriate.</td>
</tr>
<tr>
<td>2</td>
<td>TCDG to circulate new TCD to Nominated Leads in Clinical Groups and Corporate Directorate. (NB Responsibility for cascading TCD to intended recipients rests with Nominated Leads)</td>
</tr>
<tr>
<td>3</td>
<td>TCDG to discuss disseminated TCD with Communications Team for inclusion in Team Brief and consider additional publicity as appropriate</td>
</tr>
</tbody>
</table>

### STAGE 5 – REVIEW

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TCDG will inform nominated Contact for Review (by email) when review is due. Copy to Executive Director.</td>
</tr>
<tr>
<td>2</td>
<td>Contact for review is responsible for ensuring review and approval, as per guidance for new TCDs. Reviewed TCDs must summarise key changes or notify if no changes on Control Pages</td>
</tr>
<tr>
<td>3</td>
<td>TCDG is responsible for ratification and dissemination, as per guidance for new TCD</td>
</tr>
</tbody>
</table>

### STAGE 6 – MONITORING EFFECTIVENESS

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TCDG will performance manage the monitoring arrangements and key performance indicators detailed in the Monitoring Arrangements and Indicators section of the Control Pages</td>
</tr>
</tbody>
</table>
GUIDANCE FOR THE DEVELOPMENT, APPROVAL, MANAGEMENT AND DISSEMINATION OF
LOCALLY MANAGED DOCUMENTS

Background:
This guidance recognises that some documents will be developed, approved, managed and
disseminated at a local level i.e. team(s), department(s), service(s), directorate(s), care group(s) or
staff groups. Examples include departmental protocols, office procedures, standard operating
procedures, patient information, clinical guidelines, care guidelines, etc.

Scope
This guidance covers locally managed documents that do not have a Trust-wide application, as
defined in the Policy for the Development, Approval, Management and Dissemination of Trust
Controlled Documents.

Format
Locally managed documents should follow best practice guidance as outlined in the Policy for the
Development, Approval, Management and Dissemination of Trust Controlled Documents.

Author
(i) The relevant manager or professional lead is responsible for nominating the Author(s) and for
identifying the necessary resource to facilitate the development and implementation of the
locally managed document.
(ii) Locally managed procedural documents should only be developed if the local situation requires
procedures or processes additional to those set out in an existing TCD. The author is
responsible for ensuring any new local document does not duplicate or contravene an existing
TCD.
(iii) Authors are responsible for ensuring that a locally managed document does not breach the
Human Rights Act and meets the Public Sector Equality Duty of the Equality Act, as outlined in
the Policy for the Development, Approval, Management and Dissemination of Trust Controlled
Documents.
(iv) Authors are responsible for identifying the target audience for dissemination and for considering
the implications for training.

Approval
The Trust recognises three levels of approval for locally managed documents:
(i) If document is only relevant to one area (department, ward, etc ) it can be developed, approved
and maintained by the manager
(ii) If document is relevant to two areas (department, ward, etc) it can be developed and
maintained by one manager but must be approved by the other manager
(iii) If document is relevant to more than two areas it should be approved by the relevant directorate
forums such as Directorate Management Teams or Directorate Governance Groups (or
equivalent) and maintained by a nominated directorate
(iv) If a document is relevant to staff group(s) it can be developed and maintained by a professional
lead and approved by relevant professional forum.

Depending upon the level of approval, locally managed documents must identify the name and job-
title of the approving manager(s) or the professional lead or the name of the Approval Body.

Review
Local documents must include the date of approval and a review date. The relevant manager or
professional lead is responsible for initiating and managing a timely review.
Management

(i) Whilst arrangements for managing local documents are at the discretion of the relevant directorate, care group or professional group, such documents must be stored and managed electronically with clear version control, including electronic retention of superseded versions. For further guidance on the electronic management of locally managed documents contact the Trust Controlled Documents Group.

(ii) Depending upon the relevance to a wider audience in the Trust, directorates, care groups or professional group should consider posting local documents on their website, if applicable. The intranet version should be hyperlinked to the electronically stored version to ensure the intranet version is current. As above, contact the Trust Controlled Documents Group for further guidance.

(iii) The relevant manager or professional lead is responsible for ensuring that requisite training identified by the author is in place and funded.

Dissemination and monitoring implementation

The relevant manager or professional lead is responsible for disseminating the locally managed document to staff as recommended by the author.

Monitoring compliance and effectiveness

It is the responsibility of the relevant manager or professional lead to monitor compliance and the effectiveness of locally managed documents.