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NHS Lancashire Teaching Hospitals NHS Foundation Trust

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AUTHOR: Christine Morris	**JOB TITLE:** Associate Director of Governance	**DIVISION:** Nursing Directorate	**DEPARTMENT:** Governance and Risk
REPLACES: Development and Management of Procedural Documents Version 6.3		**HEAD OF DEPARTMENT:** David Pilsbury, Director of Governance	
VALIDATED BY: Procedural Documents Ratification Group		**DATE:** 07 August 2020	
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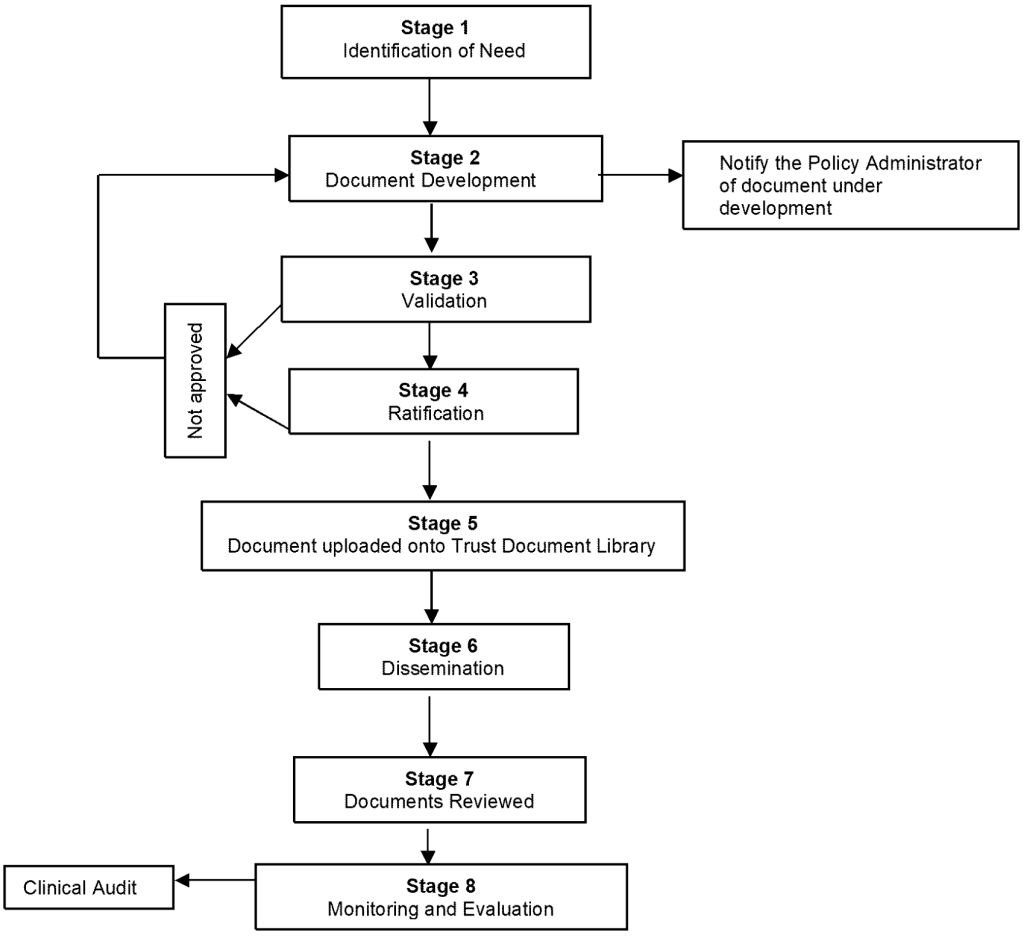
AMENDMENT HISTORY				
Version No.	**Date of Issue**	**Page/Selection Changed**	**Description of Change**	**Review Date**

Does this document meet the requirements of the Equality Act 2010 in relation to Race, Religion and Belief, Age, Disability, Gender, Sexual Orientation, Gender Identity, Pregnancy & Maternity, Marriage and Civil Partnership, Carers, Human Rights and Social Economic Deprivation discrimination? Yes
Document for Public Display: No
Evidence reviewed by Library Services 24/07/2020

CONTENTS

1. SUMMARY



The following procedure sets out the arrangements for developing and managing approved documentation. It is important that staff understand how approved documents impact on their work and how such documents are developed, approved and their content distributed and communicated.

Well-maintained documentation will improve the quality of patient care and general safety, by reducing, as far as is reasonably practicable, the risks of staff working from outdated procedural documents. The Trust is committed to ensuring that there are appropriate procedural documents in place for all staff and that they meet all statutory, legal, organisational and NHS requirements.

2. PURPOSE

The purpose of this procedure is to provide an approved framework and procedural document template to facilitate a consistent, structured and systematic approach to the development and management of procedural documents which supports best practice.

Where 'procedural documents' is referred to within this procedure, this term covers all categories of document.

Types of document include:

- Procedure;
- Policy;
- Protocol;
- Strategy;
- Guideline;
- Standard Operating Procedure (SOP);
- Plan;
- Manual;
- Patient Group Direction (PGD);
- Pathway.
- LocSSIP

The aim of this procedure is to ensure that:

- There is a process whereby procedural documents are consistent in format, compilation and dissemination.
- All procedural documents are agreed via a formal route and process, and are subject to a clear system of consultation and ratification. See Appendices 1 and 2 for flowcharts for the Development and Management of new Procedural Documents and those due for Review.
- Duplication of procedural documents is avoided and a genuine need for any new procedural document is established.
- Equality Impact Assessments and Privacy Impact Assessments are undertaken on all procedural documents in order to meet the organisation's statutory duties.
- Documents are reviewed at regular intervals.
- There is an effective system for the control of documents, including version control and archiving arrangements.
- Documents are made accessible as deemed appropriate according to the documents content.
- A process for monitoring the compliance and effectiveness of this procedure is established.

3. SCOPE

This procedure applies to all staff employed by Lancashire Teaching Hospitals NHS Foundation Trust who are developing and reviewing a procedural document produced for use within the Trust.

4. PROCEDURE

4.1 Duties and Responsibilities

4.1.1 Policy Administrator supported by library services is responsible for:

- The management, implementation and continuous monitoring of the Development and Management of procedural documents.
- Monitoring that new and revised procedural documents meet the requirements set out in this procedure, informing authors when this is not the case and advising on the changes required.
- Reviewing procedural documents prior to their presentation at relevant meetings to ensure that they are in line with the requirements of this procedure.
- Establishing and maintaining an effective system for the control of procedural documents.
- Uploading procedural documents onto the Trust Procedural Document Library (TPDL) following ratification.
- Archiving previous versions of procedural documents.
- Notifying all staff of all new / revised procedural documents uploaded to the TPDL by way of a link in the Trust's Monthly Policy, Procedure and Guideline Round-up.
- Monitoring procedural document review dates, notifying authors of upcoming reviews 3 months in advance.

4.1.2 Authors of Trust Wide and Departmental Procedural Documents are responsible for:

- Ensuring the procedural document is required and does not duplicate other local work, and for confirming the need with relevant line management or working group.
- Ensuring that the document is in the correct template and that the correct structure and style for the procedural document is used.
- Ensuring that key stakeholders are consulted with and involved in the development of the document.
- Ensuring the Policy Administrator is consulted with and involved in the development of the document.
- Ensuring that the content of the procedural document is aligned with the requirements of the Care Quality Commission (CQC) and other relevant regulations (see Section 7).

- Liaising with Library & Knowledge Services (LKS) to check that the content references up-to-date, evidence-based practice (where appropriate), see Section 4.3.2.
- Undertaking a Data Protection Impact Assessment (DPIA) (as required).
- Following the agreed validation and ratification processes.
- Ensuring the document is appropriately disseminated and communicated.
- Ensuring that the procedural document is reviewed within the required timescales and that any document on the TPDL under their responsibility is valid and in date.
- Ensure that any amendments to the document within the three year lifecycle are carried out in a timely manner in consultation with the Policy Administrator.
- Ensure that the integrity of any hyperlinks is maintained throughout the lifecycle of the document.

4.1.3 Divisional Procedural Document Group (DPDG) is responsible for:

- Ensuring that responsibility for developing / reviewing a procedural document for a division or department is assigned to the most appropriate person or team.
- Ensuring that all procedural documents submitted for validation comply with the Development and Management of procedural documents procedure.
- Reviewing, providing validation, and recommending ratification of relevant Departmental procedural documents by the Divisional Governance Group (DGG) as part of the document's pathway through to final ratification.
- Reviewing and recommending validation of relevant Trust Wide procedural documents by the DGG as part of the document's pathway through to final ratification.
- Ensuring the Policy Administrator receives relevant minutes for further action, e.g. adding to the agenda of Corporate committees where appropriate for ratification.

4.1.4 Divisional Governance and Assurance (DGG) in clinical divisions is responsible for:

- Reviewing and providing ratification (based on recommendation from the Divisional Procedural Document Group (DPDG)) of relevant Departmental procedural documents.
- Reviewing and providing validation (based on recommendation from the DPDG) of relevant Trust Wide procedural documents as part of the document's pathway through to final ratification.
- Ensuring the Policy Administrator receives relevant minutes for further action.

4.1.5 Procedural Documents Ratification Group is responsible for:

- Reviewing and ratifying procedural documents prior to publication to:
  - Ensure that all procedural documents follow the Trust ratification process.
  - Review the accuracy and content of the procedural document.

- Ensure that relevant consultation has taken place.
- Identify deficiencies and opportunities for the development of procedural documents.

4.1.6 Clinical Governance Leads are responsible for:

- Raising awareness of newly published and amended documents.
- Monitoring adherence with relevant departmental and Trust Wide procedural documents.
- Act as a point of contact for the Policy Administrator and Authors of local procedural documents to ensure that the agreed validation and ratification process is followed.

4.1.7 Ward, Department Managers and Clinical Leads are responsible for:

- Ensuring that all staff are informed of new and amended departmental and Trust Wide procedural documents.
- Implementing the procedural documents for the areas in which they apply.
- Enabling staff to be released for any training required to successfully implement the procedural documents.
- Providing advice to all new and existing staff on how to access both current and archived Trust procedural documents.
- Ensuring that all staff have access to the Trust's Procedural Document Library (TPDL) on the Intranet.
- Ensuring that all staff, contractors and others are aware of their responsibility in maintaining compliance with Trust procedural documents.

4.18 Associate Director of Safety and Governance

- Advising procedural document authors of the requirements for inclusion within procedural documents to ensure processes are auditable.
- Checking procedural documents to ensure compliance with Risk Management Standards prior to their submission for ratification.
- Supporting the Policy Administrator in undertaking their responsibilities for the management, implementation and monitoring of 'Development and Management of Procedural Documents'.

4.1.9 Trust's Company Secretary is responsible for:

- Advising document authors of statutory requirements for inclusion within procedural documents to be ratified by the Board.

Some policies require Board of Directors' approval as defined in the document 'Reservation of Powers to the Board':

"policies having wide ranging strategic and/or financial implications for the Trust, which are likely to affect the financial viability of the Trust and are fundamental to

the Trust's business", or require Board of Directors' approval in order to comply with statutory or regulatory requirements.

Contact the Company Secretary for further advice, extension 2010.

4.1.10 All Trust Employees are responsible for ensuring that they:

- Co-operate with the development and implementation of procedural documents.
- Read, comply and maintain up-to-date awareness of procedural documents, as laid down in job descriptions and contracts of employment.
- Attend training as required, to familiarise themselves and enable compliance with procedural documents relevant to their role and responsibilities.

4.2 Equality Act (2010) – Equality Impact Assessment and Privacy Assessment

Equality Impact Assessment

All documents must be developed taking into consideration the Equality Impact Assessment Process in order to comply with the requirements of the Equality Act 2010 and ensure all procedural documents eliminate unlawful racial discrimination, promote equality of opportunities and promote good race relations. This is carried out using the Equality Impact Assessment Tool which must be attached as the last appendix in all procedural documents.

The overall aim of an assessment is to identify whether there is an adverse impact upon any particular group or community so that action can be taken to minimise the detrimental impact.

To find out if the Procedural Document is compliant to the Equality Act 2010 we must identify the main aims, collect information and decide if the Procedural Document is relevant using the Trust approved Equality Impact Assessment included in the Procedural Document template. All evidence from Equality Impact assessments identifying adverse impact should be held by the policy author locally for the purposes of audit. This should be reviewed each time the Procedural Document is due for renewal.

The completion of the Equality Impact Assessment (EIA) should identify if the Procedural Document has any consequences for service users and if these consequences differ according to people's needs, experiences or priorities.

For assistance and additional guidance on completing the EIA please contact the Equality and Diversity Lead on extension 7282.

Privacy Impact Assessment

Data Protection Impact Assessments (DPIAs) are a tool to help you identify and minimise the data protection risks of existing/new projects. They form part of your accountability obligations under the GDPR, and an integral part of the 'data protection by default and by design' approach.

The DPIA will allow you to demonstrate how any potential privacy data threats and the likelihood of them happening were reduced at the start of a project.

For assistance and additional guidance contact Information Governance x4159.

4.3 Development of a Procedural Document

4.3.1 Identification of Need

Before starting development of a procedural document, it is the responsibility of the author/s to ensure that no similar document currently exists before starting development, to avoid duplication of effort across the Trust. A search on the Trust's Procedural Document Library should identify any existing internal procedural documents. The Policy Administrator and Library and Knowledge Services can also be contacted to check against the procedural document database.

Procedural documents must be evidence-based and referenced, wherever possible. Reference must also be made to any associated national policies, standards, guidelines, Acts of Parliament etc.

References and associated documents must be checked when reviewing an existing procedural document, to ensure they are still current and relevant.

Where national guidance is available, this should be adapted for local practice. Examples of national guidance would include National Institute for Clinical Excellence (NICE), Royal College of Obstetricians and Gynaecologists (RCOG), Scottish Intercollegiate Network (SIGN), NHS Litigation Authority (NHSLA). This list is not exhaustive.

The validity of evidence is directly-related to the comprehensiveness of the literature search. It is therefore important that authors liaise with Library and Knowledge Services.

Tel: 01772 522763 Email: library.rph@lthtr.nhs.uk to check that the content references up-to-date, evidence-based practice (where appropriate).

References which support the development of the document must be listed in Section 7 of the procedural document template.

4.3.2 Identification of Stakeholders

The author will identify the stakeholders to be consulted with, and after drafting, will circulate the procedural document to this identified group for comment.

Stakeholders are any individuals and / or groups with an interest in a procedural document and who can contribute, comment and agree to the content of that document. The relevant stakeholders and their appropriate level of involvement will need to be identified. They may be:

- Individual Colleagues
- Budget holders
- Whole departments which will be directly affected
- Particular staff groups
- Trade Unions
- Staff side representatives
- Partner organisations
- Patient groups
- Individual patients and their families
- The public

Please see Appendix 4 for guidance on type of stakeholder and document categories.

4.3.3 Consultation with Stakeholders

Consultation with relevant stakeholders will improve the accuracy and quality of the procedural document and facilitate effective implementation when ratified.

Names and job titles of those involved in the consultation process must be listed in Section 9 of the procedural document template.

4.3.4 Adoption of Documents

Sometimes it may be necessary to adopt another organisation's procedural document. Documents approved by the Trust may be adopted, but must still be ratified at the Procedural Documents and Information Leaflet Group before uploading to the TPDL.

4.4 Structure and Format of the Document

The structure and format of procedural documents are shown in Appendix 3 – all procedural documents must follow this, apart from the following exception:

- Patient Group Directions (PGDs)

For guidance on completing a PGD please contact Judith Argall, Lead Pharmacist, Medicines Governance.

Telephone: GRO-C

Email: Judith.Argall2@ GRO-C

4.5 Accessible Formats

The Trust will endeavour to make documents available on request in Braille, large print, symbols, or languages other than English in line with Creating Patient Information Leaflets for Patients, Relatives, Carers and Staff (see Section 6).

4.6 Validation (Approval) Process

It is the responsibility of the author and Policy Administrator to ensure that the document has been submitted in the correct format.

4.6.1 Departmental Documents

The Policy Administrator/Author(s) will submit relevant **non-clinical** departmental procedural documents to the either the departmental senior manager or divisional/departmental meeting for validation.

The Policy Administrator/ Author(s) will submit relevant **clinical** departmental procedural documents to the DPDG for validation.

4.6.2 Organisational (Trust Wide) documents

The Policy Administrator/ Author(s) will submit all **non-clinical** organisational (Trust Wide) documents to the divisional/departmental meeting for validation and then to the Policy Administrator for ratification.

Corporate procedural documents (e.g. Finance, Governance) must be validated by the Departmental senior manager. The Policy Administrator/ Author(s) will submit all **clinical** organisational (Trust Wide) documents to the DPDG meeting for review, prior to validation at DGG, and then to the Policy Administrator for ratification.

Any amendments to be made to the procedural document will be recorded in the minutes and documented following agreement that:

- Approval of the document is subject to the amendments made.
  Or,
- The validating committee requests to review the procedural document following amendments made.

If any amendments are to be made prior to ratification, the Policy Administrator will liaise with the Author to ensure any amendments are made to the document and relevant action taken.

Copies of divisional / departmental minutes or an email from the author's line manager confirming validation will be required before the procedural document can be progressed.

Following the validation of a procedural document, the Policy Administrator will record the validation date on the front page of the procedural document.

4.6.3 Patient Group Directions (PGDs)

Patient group directions (PGDs) are written instructions to enable supply or administration of medicines to patients, when the patient is not individually identified on a prescription.

(Please consult with your divisional Lead Pharmacist to establish a clear plan and to assure that a PGD is still appropriate for your specialist area)

PGDs should be put together by a multi-disciplinary group including a doctor, a pharmacist and a representative of any professional group expected to supply the medicines under the PGD (e.g. nurse or physiotherapist).

The department wishing to produce / review the PGD should review it against the most up to date evidence and complete all sections of the PGD template.

- They require a review by lead clinician and other users of the PGD.
- They then need to be approved by the relevant group meeting and documented in the minutes as approved.
- Official copies will need to be printed and signed by the Lead Clinician and divisional lead nurse, then forwarded to the lead pharmacist for PGDs for review.
- The Pharmacy Department will arrange for sign off by Chief Pharmacist and nominated Trust PGD signatory.
- The pharmacist will scan the official sign off page and send to the Policy Administrator.
- The signed copy must be kept in the department.
- Each unit that uses the PGD will need to print off a copy and have their nurse's sign up to the PGD before use.

The PGD will be sent to the Library and Knowledge Services team for publishing on the Heritage library system.

4.7 Ratification Process

4.7.1 Departmental Documents

For **non-clinical** documents, the Policy Administrator/ Author(s) submits all Departmental procedural documents to the appropriate divisional / departmental meeting who have designated authority for ratification of procedural documents.

For **clinical** documents, the divisional Governance Lead or other representative from the DPDG submits all Departmental procedural documents to the Divisional Governance Group (DGG) for ratification.

The procedural documents that are ratified are formally recorded in the minutes of the appropriate committee or DGG meeting.

The chair of the committee will inform the Policy Administrator if any amendments are to be made to the divisional / departmental procedural document and this will be recorded in the minutes as follows:

- Approval of the document is subject to the amendments made.
  Or,
- The ratifying committee requests to review the procedural document following amendments made at the next committee meeting.

The Policy Administrator will liaise with the Author(s) to ensure any amendments are made to the divisional / departmental procedural document and the same ratification process will be followed.

Following the ratification of a divisional / departmental procedural document, the Policy Administrator will record the ratification date and name of ratification committee on the front page of the procedural document.

The Policy Administrator will upload the newly ratified divisional / departmental procedural document onto the Document Library within 4 weeks of the ratification.

Minutes of the ratification committee identifying the ratified divisional / departmental procedural document will be held electronically by the Policy Administrator/Archivist.

4.3.5 Organisational (Trust Wide) Documents

The Policy Administrator submits all corporate procedural documents and clinical guidelines to the Trust Procedural Document Ratification Group for ratification. The Board ratifies procedural documents which are a specific risk and have a potential Corporate implication to the Trust e.g. Risk Management Strategy.

The following process will be followed:

The Policy Administrator will add all corporate procedural documents and clinical guidelines for ratification to the Trust Procedural Document Ratification Group for ratification and also add to the agenda.

The chair of the committee will inform the Policy Administrator if any amendments are to be made to the corporate procedural document and this will be recorded in the minutes as follows:

- Approval of the document subject to the amendment's made;
  Or
- The ratifying committee requests to review the procedural document following amendments made at the next committee meeting.

The Policy Administrator will liaise with the Author(s) to ensure any amendments are made to the corporate procedural document / clinical guideline and the same ratification process will be followed.

Following the ratification of a corporate procedural the Policy Administrator will record the ratification date and name of ratification committee on the front page of the procedural document.

The Policy Administrator will upload the newly ratified corporate procedural document / clinical guideline onto the Document Library within 4 weeks of ratification.

Minutes of the Trust Procedural Document Ratification Group for ratification identifying the ratified corporate procedural document / clinical guideline will be held electronically by the Policy Administrator/Archivist.

4.3.6 Informing the Author following Ratification

An email will be sent to the Author on upload to the TPDL with the web link to the 'recently approved' ratified procedural document.

Please Note:
If any 'minor' amendments need to be made following approval of the procedural document, this can be undertaken by the author and will not be subject to the ratification process. The amended procedural document will be checked by the author.

4.8 Chair's Action

In the event that a procedural document needs to be approved urgently, the chair of the appropriate group/committee, or in their absence an Executive Director, will give Chair's Action subject to stakeholder engagement of the procedural document. It must be noted in the subsequent group/committee minutes that Chair's Action has been given for the particular procedural document and dated.

4.9 Recording, Storing and Controlling Procedural Documents on the Trust Procedural Document Library (TPDL)

4.9.1 Document Library of Procedural Documents

When procedural documents are ratified the Policy Administrator and library team will upload the document onto Heritage.

The Policy Administrator will be responsible for storing the master copy in Word (or PDF) within relevant Divisional/Departmental folders.

All ratified procedural documents will be located on the TPDL intranet page, and only current ratified versions will be held for staff to access.

The Policy Administrator will be responsible for managing and maintaining the TPDL of procedural documents for the Trust.

4.9.2 Sensitive Procedural Documents

In exceptional circumstances, it may be identified that the viewing of a procedural document will be inappropriate for other members of staff outside a department to view. In these circumstances, the following process will be undertaken:

The procedural document will follow the same process outlined above; however, following validation of the procedural document at the Divisional Meeting, the procedural document will be ratified by the relevant Divisional Manager.

The Policy Administrator will be informed that the document is not to be displayed on the document library. The title of the procedural document will be uploaded and identified as 'sensitive'. Staff wishing to access these documents will be requested to contact the relevant Author / Department.

4.9.3 Archiving Arrangements

Following ratification of a revised procedural document the previous version will be archived.

The archived electronic procedural document will be stored in an ARCHIVE folder on the T: Drive Local Area. All previous versions of the document will be stored in the relevant Division/Directorate folder. In accordance with the Records Management Code of Practice for Health and Social Care (2016) and the Trust's Records Managements Strategy, procedural documents must be retained for a period of the life of the organisation plus 6 years.

The version number of the archived procedural document will be recorded on the document proforma.

When a procedural document becomes inactive, library team will delete this document from Heritage and the policy administrator will store the last version of that document in an ARCHIVE folder on the T: Drive Local Area, along with the request for removal as evidence.

When a procedural document is amalgamated with another procedural document the Policy Administrator will record this on the document pro forma for both documents.

4.10 Process for the Retrieval of Archived Procedural Documents

On request, the Policy Administrator will obtain copies of archived documents. For contact details of the Policy Administrator, see the HOME page of the Trust Procedural Document Library on the Trust intranet.

4.11 Review/Revision Arrangements

The review date for each procedural document developed must be documented on the front page of the procedural document template.

This must also include the author/originator and title and the division/department that will be responsible for the reviewing of the procedural document. However, as the author may leave the Trust or change jobs, the ownership of the procedural document will remain with the division/department and not the individual.

All procedural documents which are reviewed must be approved according to the process described in Sections 4.3 to 4.8 (above).

The accurate dating of a procedural document and a clinical guideline must ensure the correct process has been followed.

When reviewing a procedural document or any other clinical guideline, it is the responsibility of the member of staff to ensure that they have the correct version to update by downloading the current version from Heritage.

Documents must be reviewed at least every 3 years. The review date may alter if significant changes are made. Changes to a procedural document may be required due to implementation of actions following an incident or complaint, or the receipt of new national evidence.

The Policy Administrator will facilitate the process of review and ensure that all documents are submitted to the Author for review prior to their review dates.

The author and relevant Manager will be alerted on 6 months prior to the review date and asked to review the content. This is to ensure that the procedural document remains valid.

If the review date has elapsed and the author does not respond with notification of changes or to republish, then the procedural document will be deemed out-of-date. Alerts will continue to be sent to the author until the document is reviewed or extended. Notification of out-of-date documents will be escalated to the Director of Governance, who will contact the author to ascertain the reason for allowing the procedural document to lapse.

4.11.1 Extension of Document Validity

Occasions may arise where it is necessary to extend the life of a document beyond the review date. This must be requested on the 'Request to Extend Procedural Document Validity' form (see Appendix 6) and returned to the Policy Administrator.

Such requests will be considered at the next Procedural Document Ratification Group meeting for approval, or approval will be given by Chair's Action in exceptional circumstances.

The following are carried out by the Policy Administrator/Archivist:

- The decision on whether to extend the procedural document validity will be communicated back to the author. Only one extension will be permitted. Any documents breaching the extended review date will be removed from Heritage.
- The extended document must have the following text appended to the Review Date on the front cover if approval is given for an extension:
- **(Extended – Form XXX/YYYY)**
- Where XXX/YYYY is the reference number of the extension form.
- Also, the Amendment History should be amended within the document to reflect the change in review date, and the version number increased as per a minor amendment (i.e. increase the version number by 0.1 – see Section 4.12).

4.12 Version Control

Version control enables appropriate control of documents configuration to be maintained. Normally, a draft document will have version 0.1, 0.2 and so on during its development until it is ratified and published as version 1.0.

If any 'minor' amendments needs to be made following approval of the procedural document, this can be undertaken by the author and will not be subject to the ratification process. The version number will be amended to indicate the change, i.e. version 2.1.

A full review of a procedural document increases the version number to the next consecutive whole number. The review date of the procedural document will only change when a full review of the document is completed and ratified by the Committee responsible.

4.13 Dating

The following dates must be completed on the front page as identified in the list below:

- Validation Date (see Section 4.6).
- Ratification Date (see Section 4.7).
- Review Date (see Section 4.11).

4.14 Dissemination and Implementation across the Trust

All procedural documents will be publicised via a link on the Intranet homepage and Weekly News. This will show a list of 'Documents uploaded in the last 30 days'.

It is the responsibility of the author to ensure that the requirements of the procedural document are communicated to relevant staff.

The author(s), together with the divisions/departments to whom the document applies, will bring it into practice supported by planned management of change, education and training activities, and allocation of resources if required.

4.15 NHS Constitution

The Trust has a legal duty to 'have regard to' the NHS Constitution (the Constitution) in exercising its NHS functions. It should evidence that this occurs.

The Author must consider the NHS Constitution when performing its NHS functions, especially in relation to all policies, practices and procedures, and, importantly, to record that it has done so.

The Author on developing or reviewing a procedural document must complete the sections stated on the front sheet, 'Which Principles and Staff Pledges of the NHS Constitution Apply?' so that this clearly identifies an endorsement that the Trust has had regard to the NHS Constitution.

Links to the 'NHS Constitution - Principles that guide the NHS' and 'NHS Constitution – Staff Pledges' can be found on the HOME page of the Trust Procedural Document Library on the Trust intranet.

4.16 Process for Monitoring Compliance

The process for monitoring compliance with this procedure is identified in Appendix 7.

This will be monitored through audit together with a single Key Performance Indicator which identifies the number of procedural documents which are out-of-date on the Trust Procedural Document Library.

Adherence to this procedure may also be periodically audited by the internal audit department as part of the review of internal controls.

5. AUDIT AND MONITORING

See Appendix 7.

6. TRAINING

TRAINING Is training required to be given due to the introduction of this policy? No		
Action by	**Action required**	**Implementation Date**

7. DOCUMENT INFORMATION

ATTACHMENTS	
Appendix Number	Title
Appendix 1	Flowchart for the Development and Management of a New Procedural Document
Appendix 2	Flowchart for the Development and Management of a Procedural Document for Review
Appendix 3	Procedural Document Template – Structure and Format
Appendix 4	Matrix for Stakeholder Consultation
Appendix 5	Procedural Document Approval Process (Trust Wide and Departmental Documents)
Appendix 6	Request to Extend Procedural Document Validity
Appendix 7	Process for Monitoring Compliance table
Appendix 8	Equality and Diversity Impact Assessment Tool

OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	Title and web links from the document library

SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS **References in full**	
Number	**References checked by library 24/7/2020 DG**
1	Department of Health DoH (2010) NHS Constitution: NHS belongs to us all The NHS Constitution
2	Information Governance Alliance IGA (2016) Records Management Code of Practice for Health and Social Care https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016
3	Equality and Human Rights Commission http://www.equalityhumanrights.com/
4	CQC Guidance about Compliance http://www.cqc.org.uk/sites/default/files/documents/gac_-_dec_2011_update.pdf
Bibliography	

DEFINITIONS / GLOSSARY OF TERMS	
Abbreviation or Term	Definition
Business Continuity Plans	Business Continuity Plans are a framework to ensure the resilience of organisations and businesses to any eventuality, to help ensure continuity of service to key users and customers and the protection of the NHS brand and reputation
Consultation	Who is consulted during the process outlined in Section 9
Document Author	The person nominated to prepare the draft of a specific procedural document
Guideline/ Clinical Guideline	An aid to decision making, they are not hard and fast rules. Applying guidelines to individual practice is always likely to require judgement, even when recommendations are properly linked to evidence. Guidelines will, therefore, need to be interpreted sensibly and applied with discretion, i.e. Helps us decide what we have to do
Integrated Care Pathway	An integrated Care Pathway (ICP) is an outline or plan of anticipated clinical practice for a group of patients with a particular diagnosis or set of symptoms. The ICP provides a multidisciplinary template of the plan of care, leading each patient towards a desired objective. An ICP determines locally agreed, multidisciplinary practice based on guidelines and evidence where available. It forms all or part of the clinical record documents the care given and facilitates the evaluation of outcomes for continuous quality improvement.
LAN	Local Area Network/T: Drive
Manual	A source of information
NHSLA	National Health Service Litigation Authority
NICE	National Institute for Health and Care Excellence
PGD	Patient Group Direction - The legislation (Statutory Instrument, 2000a) states that 'Patient Group Direction means – in connection with the supply of a prescription only medicine… a written direction relating to the supply and administration of a description or class of prescription only medicine… or a written direction relating to the administration of a description or class of prescription only medicine, and which in the case of either is signed by a doctor… and by a pharmacist; and relates to the supply and administration, or to administration, to persons generally (subject to any exclusions which may be set out in the Direction).'
Plan	Provides a plan of action to be taken
Policy	A policy is a statement of what the Trust plans to do and the principle upon which it will act to carry out its responsibilities in relation to an activity. i.e. what we have to do and ideally should be no more than two pages long
Policy Administrator	Ensures that all documents are co-ordinated through the validation/ratification process, up to date, publicised and accessible by relevant staff.
Principle	Fundamental truth or belief on which a policy is founded
Procedural	Documents that provide instructions on how to carry out certain

Document	tasks and can be any of the following:- Strategy ,Policy/Procedure, Protocol/Guideline, Clinical Guideline, Plan, Standard Operating Procedure (SOP), Scheme or Manual
Procedure	A procedure may be defined as a set process to be followed, often set out as a step-by-step list of actions/instructions that describe the required working method to achieve high standards and ensure consistency and accuracy.
Protocols	A protocol is a formal set of procedures which are to be followed in order to achieve specific outcomes. Protocols must be adhered to.
Ratification	The 2nd (final) approval by a more senior committee
Regulation	Governing direction or law imposed on an individual and /or organisations
Rule	A principle or regulation governing conduct, actions, procedures or arrangements
Schemes	Provide instructions for staff to follow
SOP	Standard Operating Procedures are an agreed set of instructions for performing a particular task, usually in a clinical setting, e.g. a clinical diagnostic test or screening procedure.
Stakeholder	Any individuals and / or groups with an interest in a procedural document and who can contribute, comment and agree to the content of that document. The relevant stakeholders and their appropriate level of involvement will need to be identified.
Strategy	A strategy is a long term plan of action which is designed to achieve stated goals or objectives It is usually a broad statement which outlines how the organisation plans to reach the intended outcome.
Validation	The 1st formal approval by an expert committee/Manager

CONSULTATION WITH STAFF AND PATIENTS

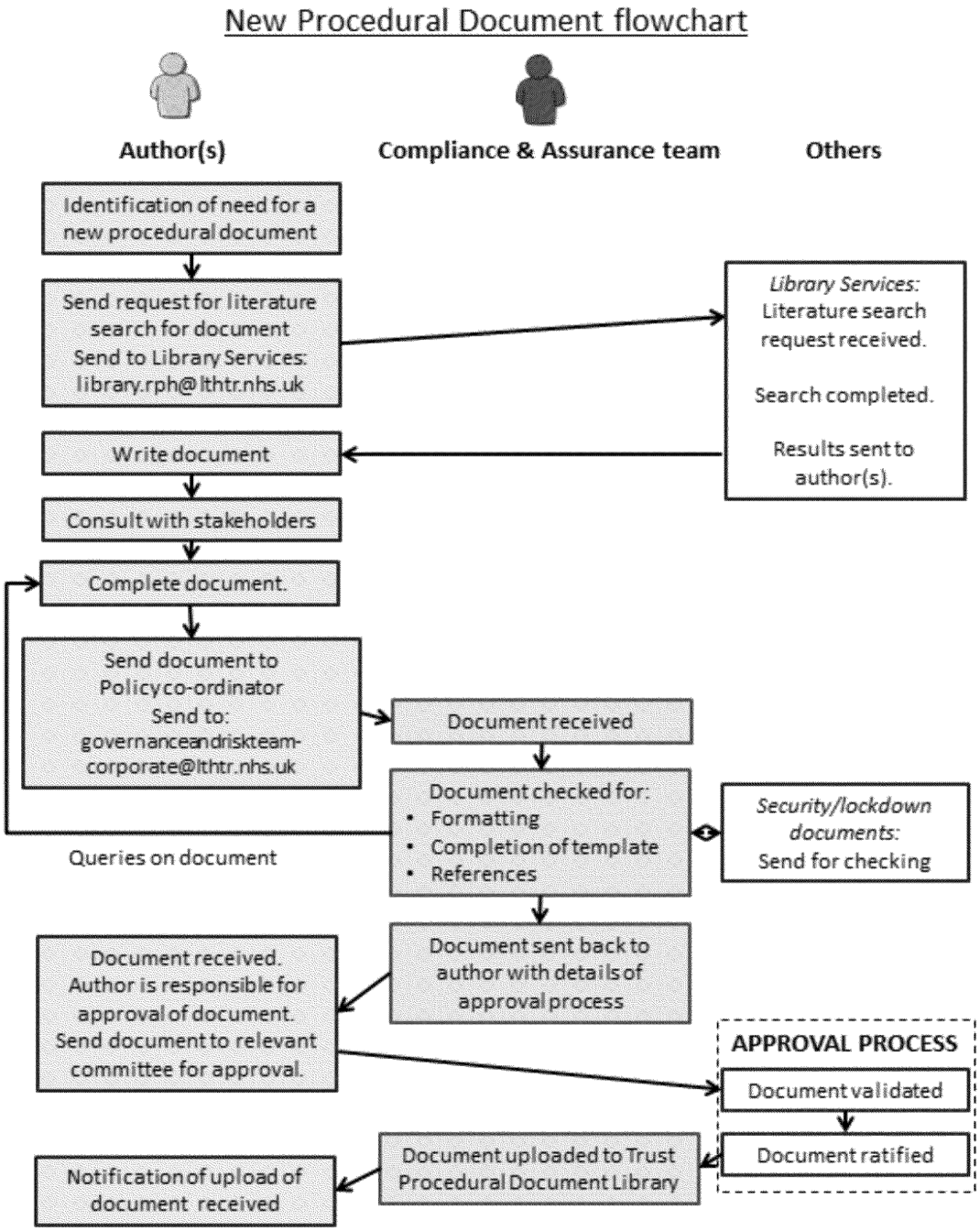
Enter the names and job titles of staff and stakeholders that have contributed to the document

Name	Job Title	Date Consulted
Clare Shaw	Policy Administrator	21 July 2020

DISTRIBUTION PLAN	
Dissemination lead:	Christine Morris
Previous document already being used?	Yes
If yes, in what format and where?	Electronic, heritage library system, hard copy
Proposed action to retrieve out-of-date copies of the document:	Knowledge and library to replace with updated version. Any paper copies to be removed and placed in confidential waste.
To be disseminated to:	Trust wide
Document Library	
Proposed actions to communicate the document contents to staff:	Include in the LTHTR weekly Procedural documents communication– New documents uploaded to the Document Library

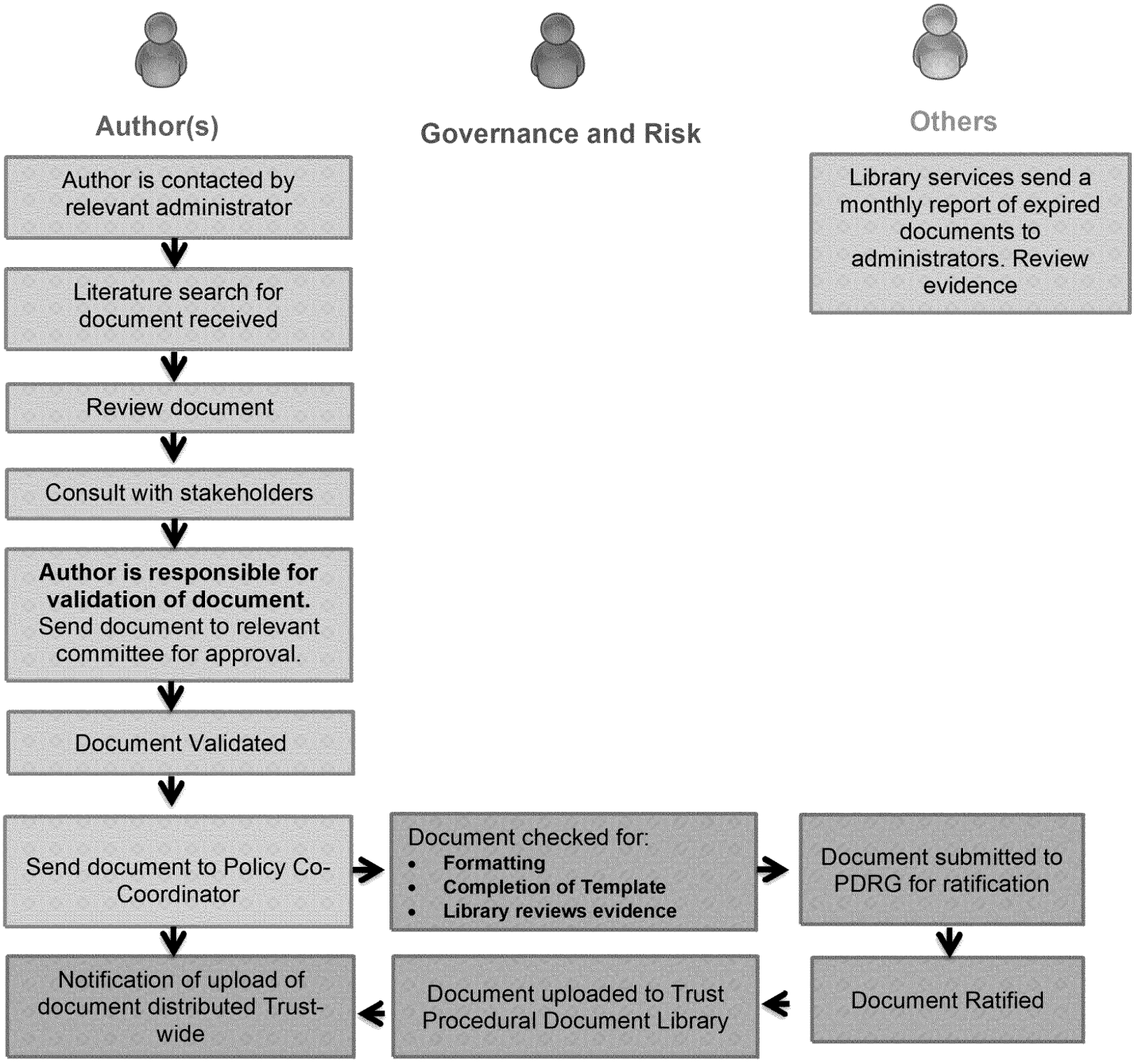
Appendix 1

Flowchart for the Development and Management of a New Procedural Document



Appendix 2

Flowchart for the Development and Management of a Procedural Document for Review



Appendix 3

Procedural Document Template

See Procedural Document Template

Appendix 4

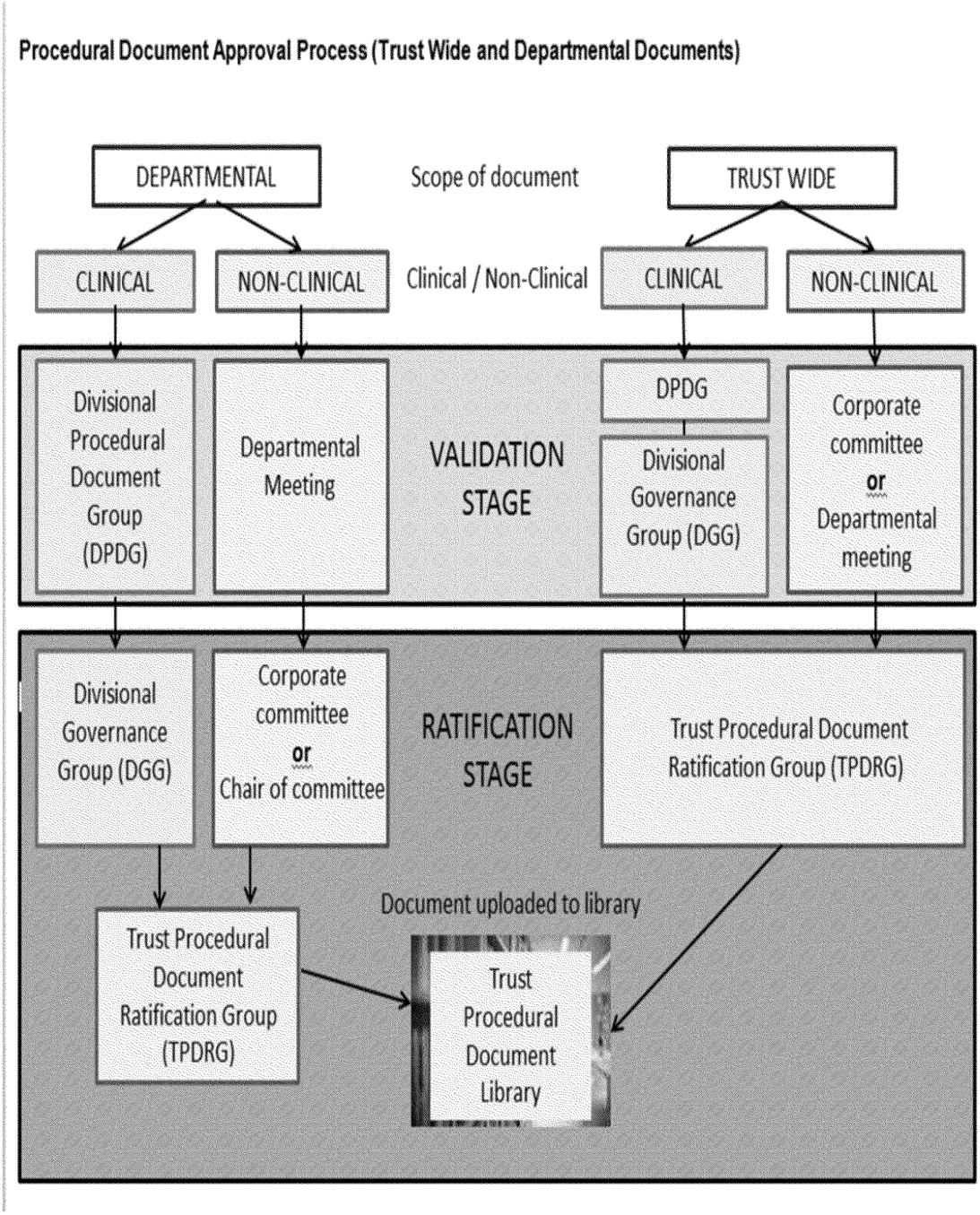
Matrix for Stakeholder Consultation

Document Category	Type of Stakeholder
Clinical (General , Infection Control, Medicines, and Safeguarding	Governance Leads Safeguarding Adults / Children Team Infection Prevention Team Pharmacy Health, Safety Lead Information Governance Team Equality and Diversity Lead Clinical Librarian Policy Administrator/ Archivist Staff Side
Health, Safety and Security	Health, Safety Lead Local Security Management Specialist Counter Fraud Specialist Governance Leads Human Resources / Organisational Development Team Information Governance Team Equality and Diversity Lead Safeguarding Adults / Children's Team Patient Safety Lead Policy Administrator/Archivist Staff Side
Finance	Head of Financial Management Deputy Director of Finance Counter Fraud Specialist Health, Safety Lead Information Governance Mental Capacity Act Lead Policy Administrator/Archivist
Human Resources	HR Business Partners Counter Fraud Specialist Equality and Diversity Lead Staff Side Governance Leads Policy Administrator/Archivist
Information Governance	Counter Fraud Specialist Governance Leads Human Resources / Organisational Development Team Policy Administrator/Archivist
Mental Health Legislation (including Mental Capacity Act)	Governance Leads Equality and Diversity Lead Information Governance

	Policy Administrator/Archivist
NHSLA Procedural Documents	Governance Leads Policy Administrator/Archivist
Estates and Facilities	Estates and Facilities team Health, Safety Lead IT Team Policy Administrator/Archivist
Governance	Governance Leads Safeguarding Adults / Children Team Infection Prevention Team Pharmacy Health, Safety Lead Information Governance Team Equality and Diversity Lead Clinical Librarian Policy Administrator/ Archivist Staff Side

Appendix 5

Procedural Document Approval Process (Trust Wide and Departmental Documents



Appendix 6

Request to Extend Procedural Document Validity

Appendix 7

Process for Monitoring Compliance

Minimum Requirement to be Monitored		Process for monitoring e.g. audit	Responsible individual/ group/ committee	Frequency of monitoring	Responsible individual/ group/ committee for review of results	Responsible individual/ group/ committee for development of action plan	Responsible individual/ group/ committee for monitoring of action plan and Implementation
1	KPI: Number of out of date documents on the Document Library	Monitored on a monthly basis and recorded on the Quality Dashboard	Policy Administrator / Archivist	Monthly	Trust Procedural Documentation Ratification Group Governance Committee	Policy Administrator / Archivist	
2a)	style and format	Audit	Trust Procedural Documentation Ratification Group	Annually	Trust Procedural Documentation Ratification Group	Trust Procedural Documentation Ratification Group	Trust Procedural Documentation Ratification Group
2b)	an explanation of any terms used in documents developed	Audit					
2c)	consultation process	Audit					
2d)	ratification process	Audit					
2e)	review arrangements	Audit					
2f)	control of documents, including archiving arrangements	Audit					
2g)	associated documents	Audit					
2h)	supporting references	Audit					

Appendix 8

NHS
Lancashire Teaching Hospitals
NHS Foundation Trust

Equality, Diversity & Inclusion Impact Assessment Form

Department/Function	Governance			
Lead Assessor	Christine Morris			
What is being assessed?	Development and Management of Procedural Documents			
Date of assessment	July 2020			
What groups have you consulted with? Include details of involvement in the Equality Impact Assessment process.	Equality of Access to Health Group	☐	Staff Side Colleagues	☐
	Service Users	☐	Staff Inclusion Network/s	☐
	Personal Fair Diverse Champions	☐	Other (Inc. external orgs)	☐
	Please give details:			

1) What is the impact on the following equality groups?			
Positive: ➢ Advance Equality of opportunity ➢ Foster good relations between different groups ➢ Address explicit needs of Equality target groups		**Negative:** ➢ Unlawful discrimination, harassment and victimisation ➢ Failure to address explicit needs of Equality target groups	**Neutral:** ➢ It is quite acceptable for the assessment to come out as Neutral Impact. ➢ Be sure you can justify this decision with clear reasons and evidence if you are challenged
Equality Groups	**Impact** (Positive / Negative / Neutral)	**Comments:** ➢ Provide brief description of the positive / negative impact identified benefits to the equality group. ➢ Is any impact identified intended or legal?	
Race (All ethnic groups)	Neutral		
Disability (Including physical and mental impairments)	Neutral		
Sex	Neutral		
Gender reassignment	Neutral		
Religion or Belief (includes non-belief)	Neutral		
Sexual orientation	Neutral		
Age	Neutral		

Marriage and Civil Partnership	Neutral	
Pregnancy and maternity	Neutral	
Other (e.g. caring, human rights, social)	Neutral	

2) In what ways does any impact identified contribute to or hinder promoting equality and diversity across the organisation?	

3) If your assessment identifies a negative impact on Equality Groups you must develop an action plan **to avoid discrimination and ensure opportunities for promoting equality diversity and inclusion are maximised.**

- This should include where it has been identified that further work will be undertaken to further explore the impact on equality groups
- This should be reviewed annually.

ACTION PLAN SUMMARY

Action	Lead	Timescale

HOW THE NHS CONSTITUTION APPLIES TO THIS DOCUMENT

WHICH PRINCIPLES OF THE NHS CONSTITUTION APPLY? Click here for guidance on Principles	Tick those which apply	WHICH STAFF PLEDGES OF THE NHS CONSTITUTION APPLY? Click here for guidance on Pledges	Tick those which apply
1. The NHS provides a comprehensive service, available to all.	☐	1. Provide a positive working environment for staff and to promote supportive, open cultures that help staff do their job to the best of their ability.	√
2. Access to NHS services is based on clinical need, not an individual's ability to pay.	☐	2. Provide all staff with clear roles and responsibilities and rewarding jobs for teams and individuals that make a difference to patients, their families and carers and communities.	√
3. The NHS aspires to the highest standards of excellence and professionalism.	√	3. Provide all staff with personal development, access to appropriate education and training for their jobs, and line management support to enable them to fulfil their potential.	☐
4. The patient will be at the heart of everything the NHS does.	√	4. Provide support and opportunities for staff to maintain their health, wellbeing and safety.	☐
5. The NHS works across organisational boundaries.	☐	5. Engage staff in decisions that affect them and the services they provide, individually, through representative organisations and through local partnership working arrangements. All staff will be empowered to put forward ways to deliver better and safer services for patients and their families.	☐
6. The NHS is committed to providing best value for taxpayers' money.	☐	6. To have a process for staff to raise an internal grievance.	☐
7. The NHS is accountable to the public, communities and patients that it serves.	√	7. Encourage and support all staff in raising concerns at the earliest reasonable opportunity about safety, malpractice or wrongdoing at work, responding to and, where necessary, investigating the concerns raised and acting consistently with the Employment Rights Act 1996.	☐

WHICH AIMS OF THE TRUST APPLY? Click here for Aims	Tick those which apply	WHICH AMBITIONS OF THE TRUST APPLY? Click here for Ambitions	Tick those which apply
1. To offer excellent health care and treatment to our local communities.	√	1. Consistently deliver excellent care.	√
2. To provide a range of the highest standard of specialised services to patients in Lancashire and South Cumbria.	√	2. Great place to work.	☐
3. To drive innovation through world-class education, teaching and research.	☐	3. Deliver value for money.	☐
		4. Fit for the future.	√