

OP01 v9.7

Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines

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[Appendix 1](#)

[Appendix 1 Attachment 1](#)

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[Black Country Pathology Services Governance Arrangements](#)

[Black Country Pathology Services Operating Framework](#)

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Policy Statement

- 1.0** This policy dictates the processes that must be followed to create or review existing Trust-wide strategies, policies, procedures or guidelines and local procedures or guidelines, and the processes to remove Trust-wide strategies, policies, procedures or guidelines and local procedures and guidelines that are no longer required.
- 1.1** This policy also dictates the governance framework for strategies, policies, procedures and guidelines.
- 1.2** Local procedures and guidelines will be developed in line with local [Standard Operating Procedures attachment 11](#).
All Trust-wide strategies, policies, procedures and guidelines must be developed, approved and maintained in accordance with this policy.
Overall good governance of Local Procedures is overseen by Trust Policy Group.
- 1.3** All new and reviewed existing Trust-wide strategies, policies, procedures and guidelines must include the explicit and recorded consideration of the Conflicts of Interest Policy (OP109), taking into account whether OP109 requires specific changes to be made to bring it in line with the requirements of OP109.
- 1.4** All Trust-wide strategies, policies, procedures and guidelines will have the following paragraph inserted (as a minimum):
“All aspects of this document regarding potential Conflicts of Interest should refer first to the Conflicts of Interest Policy (OP109). In adhering to this document, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.”
- 1.5** All new and revised Trust-wide strategies, policies, procedures and guidelines will be reviewed by the Counter Fraud lead for the Trust and considerations made by the author against a [Counter Fraud Checklist attachment 9](#) with the exception of clinical policies.
- 1.6** The aims are as follows.
- Provide a clear process for developing Trust-wide strategies, policies, procedures and guidelines.
 - Ensure that where appropriate, a clear and sound evidence base is being used and that key stakeholders have been consulted.
 - Ensure that the documents are accurate, up to date and in the agreed Trust format.
 - Ensure that all documents comply with the Equality and Diversity Scheme for the Trust, Conflict of Interest and Counter-Fraud requirements.
- 1.7** Framework for the development of Trust-wide strategies, policies, procedures and guidelines.
- Stage 1 identify need
 - Stage 2 Chief Officer Sponsor approval
 - Stage 3 development of a draft document
 - Stage 4 consultation
 - Stage 5 finalisation of the draft document
 - Stage 6 approval
 - Stage 7 implementation
 - Stage 8 review

The detail of the framework is provided in OP 01 Procedure at [Attachment 1](#).

1.8 High Risk Policy Definition:

- Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of points of ligature risk in Trust premises;
- References to individually identifiable cases;
- References to commercially sensitive or confidential systems.

If a policy is considered to be high risk, it will be the responsibility of the author and Chief Officer sponsor to ensure it is redacted to the requestor.

2.0 Definitions

Throughout this document the following terms are used to differentiate different documents used for different purposes.

2.1 STRATEGY An organisational statement of intent developed to provide a framework for current and future business development of the Trust. The document should include a plan to drive its implementation and may be supported by further policies relating to differing aspects of the strategy.

2.2 POLICY An organisational statement of purpose dictating governing principles that mandate or constrain actions. A policy sets out overall aims and objectives in a particular area and the framework within which to work.

2.3 PROCEDURE A series of actions conducted in a certain order or manner e.g. the mandatory steps taken to fulfil a policy. A procedure describes the practical course of action which must be taken and can refer to protocol or practice guidelines for its reference points. ** See note below.

**For the remainder of this Policy and the management of Strategy, Policy and Procedures – the term ‘Procedure’ is used to cover items that might have previously been referred to as ‘protocols’ and/or ‘guidelines’.*

*** References made to a procedure are applicable to a protocol or practice where these are indicated. All new clinical techniques and interventional procedures MUST be approved prior to implementation by Quality Safety and Improvement Group (QSIG). See Policy OP95 Introduction of New Clinical Techniques and Interventional Procedures.*

2.4 GUIDELINE A general rule, principle, or piece of advice put forward to set a standard, determine a course of action, advise on how something should be done or what should be done. In medical terms a guideline (also called a clinical guideline or clinical practice guideline) is a document that guides decisions and defines criteria regarding diagnosis, management and treatment in specific areas of healthcare. The process and template are as per procedure above.

NB before developing any document, consider the definitions above to ensure the document is given the appropriate title and content.

In some cases, local Guidelines are produced that are used/referenced in other clinical areas (e.g. CP26). In such cases, local Guidelines governance arrangements are sufficient for oversight and approval as per ‘local procedures’ below.

2.5 FRAMEWORK A framework describes the operationalising of principles of good governance. When applying these principles, it is important that the good governance of Frameworks is included.

- A Framework is a set of complex, interrelated structures, systems, processes, information and data that supports interventions applied in a health care environment.
- A Framework in this context, provides the component principles of what make a good service in health care.
- Frameworks are underpinned by the available research.

2.6 LOCAL PROCEDURE These are documents which do not overlap with an existing Trust-wide policy or procedure and relate solely and specifically to the activities of a local area, service or staff group i.e. does it only apply to one Directorate / one Division? If yes, then it needs to say so and can remain a local procedure. If no, then this needs to be a Trust-wide procedure and will need to go through the Trust Policy Group process.

2.7 FINANCIAL IMPACT ASSESSMENT A check list to identify if there are any resource implications for the Trust in adopting this new policy.

2.8 EQUALITY IMPACT ASSESSMENT An equality impact assessment (EIA) is the process of assessing the impact of existing or proposed functions or policies in relation to their consequences for Personal Protected Characteristics (PPC), both positive and negative. OP73 *Undertaking an Equality Impact Assessment* outlines the process for completion.

2.9 PERSONAL PROTECTED CHARACTERISTICS (PPC) Certain characteristics which present a legal requirement under the Equality Act 2010, to protect people from discrimination, harassment, victimisation and other prohibited conduct on the basis of that characteristic. The PPC relate to the following characteristics: age, disability, sexual orientation, gender, gender re-assignment, partnership status, marital status, race, religion or beliefs.

3.0 Accountabilities

3.1 The Trust Board (TB) is ultimately responsible for the development of strategies, policies, procedures and guidelines and expects them to be developed in line with this policy. Trust Board approves strategy documents.

3.2 The Trust Management Committee (TMC) is responsible for approving Trust-wide policies, procedures, guidelines and the review of strategies.

3.3 Trust Policy Group is responsible for making recommendations for approval of new and revised Trust-wide strategies, policies, procedures and guidelines before final approval at TMC.

3.4 Specialist Groups are responsible for evidence-based contribution and review of documents as part of the consultation and drafting process. The specialist remit of the groups will be defined by their terms of reference.

As in 2.4, some local Guideline groups will act as the governance oversight and approval mechanism in some specialism cases e.g. CP26.

The following Specialist Groups oversee governance arrangements for their specialties procedural documents:

- Black Country Pathology Services – see [Appendix 1](#)
- Radiology Services
- Nursing Clinical Procedures
- Local Procedures and Clinical Guidelines.

3.4.1 • **MP01, Prescribing, Storage and Administration of Drugs** - the procedures included within the policy have been detailed separately on InPhase with their own review dates.

3.5 Policy Management Officer will hold the index numbers for all Trust-wide strategies, policies, procedures and guidelines and maintain a review tracking database.

3.6 Policy Management Officer and Strategic Planning Directorate (for Strategic documents) are responsible for publication of approved Trust-wide strategy, policy, procedure and guidelines and local procedures and guidelines on the Trust intranet. They will hold a library of final word and pdf versions.

- 3.7** The Trust has, in the spirit of open-ness and candour, begun publishing suitable policies in the public domain. These will have been approved for publication as part of the approval process and have been risk assessed. Any areas of potential risk will be redacted prior to publication.
- 3.8** Publication on the Trust Internet page of policy and procedural documents occurs following the full review process at the Trust Policy Group. Revised versions are only published following significant changes and/or completion of the review process. Minor changes and/or updates such as virtual approvals will only be published internally on the Trust's Intranet page.
- 3.9** **Chief Officer Sponsor** is an Executive Director of the Trust Board who is responsible for the management of a specific strategy, policy, guideline or procedural document. A Chief Officer Sponsor will consider and approve the development of strategies, policies, procedures and guidelines and assign an author or group to develop the document.
- 3.10** **Authors are** the individuals or groups responsible for the development of a strategy, policy, procedure, guideline or a local procedure or guideline. They ensure that new and amended Trust-wide and local documents mentioned above are developed, approved and maintained in accordance with this policy. The author is responsible for the development of an implementation plan and for ensuring that appropriate consultation has been undertaken for all new and revised strategies, policies, procedures and guidelines where appropriate. The author is responsible for ensuring that following final approval of the document it is made available for publication. The Author is responsible for the communication and implementation of Trust-wide strategies, policies, procedures and guidelines, and for the good governance of local procedure and guidelines.
- 4.0** **Policy Detail**
- 4.1** This policy dictates the process and guiding principles for the development and review of Trust-wide strategies, policies, procedures and guidelines.
- 4.2** Local procedures and guidelines will be developed in line with the requirements for Standard Operating Procedures (SOP's) given in [Attachment 11](#)
- 4.3** Before developing a strategy, policy, procedure or guideline, consider the definitions in section 2.1 – 2.4 above to ensure the document is given the appropriate title and content.
- 4.4** [Attachment 2](#) flowchart outlines the steps for each stage of the document development framework.
- 4.5** [Attachment 1](#) provides a training guide for authors.
- 4.6** [Attachment 3](#), [Attachment 4](#), [Attachment 4.1](#) and [Attachment 6](#) provide templates to be used in developing the documents, namely strategies, policies, procedures and guidelines.
- 4.7** [Attachment 7](#) provides a guidance flowchart for appropriate consultation and approval of Trust-wide strategies, policies, procedures and guidelines
- 4.8** The procedure for the development, consultation and approval of all new and revised Trust-wide strategies, policies, procedures and guidelines must be developed, consulted and approved in line with the procedure in [Attachment 1](#) and have the following documents completed. The documents detailed below will be retained by the Policy Management Officer as part of the review process. A copy of completed the Equality Analysis Proforma will be held by the Patient Experience Team and retained by the Policy Management Officer:

- [Equality Impact Assessment Proforma](#)

- Implementation plan
- Cover report [attachment 8](#)
- Counter fraud checklist (with the exception of clinical policies) [attachment 9](#).

- 4.9** New Trust-wide strategies, policies, procedures or guidelines must be approved for development by a Chief Officer.
- 4.10** All Trust-wide strategies, policies, procedures or guidelines will be numbered, and records stored in accordance with the Trust's version control system to aid tracking and retrieval.
- 4.11** The Policy Management Officer and Strategic Planning Directorate (for Strategic documents) will ensure that all Trust-wide strategies, policies, procedures or guidelines once approved are converted to PDF format, stored in a documents library and published on the Trust intranet. The intranet management team will hold a library of final word versions of the Trust-wide strategies, policies, procedures or guidelines which can be accessed by authors in order to review / update the current document.
- 4.12** Medical Illustration holds a record of all Trust-wide strategies, policies, procedures and guidelines (current and archive) for legal or other purposes.
- 4.13** Freedom of information (Fol) requests for Trust-wide strategies, policies, procedures or guidelines must be made via the formal Trust process (refer Fol policy).
- 4.14** All Trust-wide strategies, policies, procedures and guidelines will be held on the intranet under the heading relevant to the policy Group type e.g. Human Resources, and Health and Safety.
- 4.15** The Policy Management Officer and InPhase system will hold a database record of the status of all Trust-wide strategies, policies, procedures and guidelines.
- 4.16** The Trust recognises that there are a number of standard operating procedure or local guideline management systems that are required by accreditation bodies to manage procedures, for example Q Pulse is a recognised system for laboratories, looked for by their accreditors.
- 4.17** This Policy allows for the recognition of such repositories as acceptable outside of the requirements of the Policy OP01 as long as the following conditions are met through self-assessment declaration ([Attachment 13](#)).
1. The minimum version and governance process information (see Control Sheet Elements of Procedural Template).
 2. The system is formally administrated with an appropriate gateway (documents can only be changed by the Administrator of the system following an appropriate governance process).
 3. The system has been declared and is contained in the list below of recognised document systems:
 - Q-Pulse; used by Medical Physics, Clinical Engineering, Pharmacy, Radiology and Pathology.
 4. Any other systems must be declared to the Trust Policy Management Officer, self-assessed against the minimum requirements, and be reviewed and approved for use by the Trust Policy Group.
 5. Each system must have a method of regular audit identified and carried out in line with the stated audit frequency and method in the self-assessment ([Attachment 13](#)).

5.0 Financial Risk Assessment

- 5.1** No financial risks have been identified at the time that this policy is developed.

6.0 Equality Impact Assessment

6.1 The initial Equality Impact assessment has identified a low impact affecting one PPC (Disability – visual impairment). To address this issue the policy has included a standard statement within the document control sheet offering the document in larger print where necessary. This statement is to be replicated in all Trust-wide strategies, policies, procedures and guidelines.

7.0 Maintenance

7.1 This policy will be reviewed every three years or earlier if warranted by a change in Standards or if changes are deemed necessary from internal sources.

8.0 Communication and Training

8.1 Approved Trust policy can be found on the Trust intranet pages and a number of specific and approved documents will be available on the Trust's Internet page for access by the general public.

8.2 Advice and guidance on the development of Trust-wide strategies, policies, procedures and guidelines can be obtained from the Policy Management Officer. [Attachment 1](#) provides a training guide for authors.

8.3 New or updated Trust-wide strategies, policies, procedures and guidelines are flagged on the intranet policies page.

8.4 Trust managers will be informed of new / revised strategies, policies, procedures and guidelines via a monthly all user bulletin, via meeting presentations and subject training.

9.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Committee
Style and format	Legal Services	Quality assurance audit	Annual	Policy Group
Consultation process	Legal Services	Policy review	3 yearly	Policy Group
Ratification process	Legal Services	Policy review	3 yearly	Policy Group
Review arrangements	Legal Services	Policy management reports to	Monthly Annual	Policy Group
Audit Programme	Clinical Audit	Any relevant Clinical Audit from Clinical Audit Programme	Annual	Policy Group
Divisional oversight of Audits	Divisional Management Teams	Any relevant Audits from Divisional Audit Programmes	Annual	Policy Group
Trust wide audit of Policy Audits – Dissemination and Awareness	Company Secretary's office	Annual Survey	Annual	Policy Group

10.0 References

Department of Health Information Governance Standards
NHSLA (2011) Risk management Standards

Care Quality Commission fundamental standards of care of all Health & Social Care

Providers (April 2015)
Department of Health Records retention and destruction schedule

NHS England. Equality, diversity and health inequalities. Available at [www.legislation.gov.uk / ukpga](http://www.legislation.gov.uk/ukpga)

The Employment Equality (Religion or Belief) Regulations 2003. London: Stationery Office. Available at [www.legislation.gov.uk / ukpga](http://www.legislation.gov.uk/ukpga)

Health and Social Care Act 2001. London: Stationery Office. Available at [www.legislation.gov.uk / ukpga](http://www.legislation.gov.uk/ukpga)

Human Rights Act 1998. London: Stationery Office. Available at [www.legislation.gov.uk / ukpga](http://www.legislation.gov.uk/ukpga)

Race Relations (Amendment) Act 2000. London: Stationery Office. Available at [www.legislation.gov.uk / ukpga](http://www.legislation.gov.uk/ukpga)

Part A - Document Control

Reference Number and Policy name: OP01 Governance of Trust-wide Strategy, Policy, Procedure and Guidelines and Local Procedure and Guidelines	Version: 9.7 March 2023	Status: Final		Author: Group Company Secretary Chief Sponsor: Chief Nurse
Version/ Amendment History	Version	Date	Author	Reason
	1	November 2002	Trust Governance Manager	Original Policy
	2	February 2005	Head of Governance and Legal Services	NHSLA requirements
	3	April 2007	Head of Governance and Legal Services	NHSLA requirements
	4	October 2009	Head of Governance and Legal Services	Review and amendments
	5	November 2011	Head of Governance and Legal Services	Review of Policy and process
	5	August 2012	Head of Governance and Legal Services	MinorAmendApp_PoCAug12 Minor amendments <ul style="list-style-type: none"> - Audit Section updated - Archiving arrangements section. - Slight wording adjustments to ensure clarity on instructions. - April 13 v5.2 minor
	6	March 2015	Compliance Manager	Planned review of policy and process
	6.1	June 2015	Compliance Manager	Minor amendment-addition of guidance to template in relation to approval of any forms developed.
	7.0	January 2018	Head of Governance and Legal Services	Full review

	8.0	March 2019	Company Secretary	Full review
	8.1	January 2020	Company Secretary	Minor updates.
	8.2	June 2020	Company Secretary	Minor update regarding definition of high risk policies.
	8.3	December 2020	Company Secretary	Minor update to Attachments 1, 3, 4 5 and 10 and inclusion of new attachments 1.1 and 4.1.
	8.4	March 2021	Company Secretary	Minor update to section 3.4 – Specialist Groups and hyperlinks within attachments 3 and 5. Minor updates made to Attachments 1, 4, 4.1 and 9.
	8.5	April 2021	Company Secretary	Minor updates to hyperlinks in Attachments 1, 3 and 5 due to update of EA Policy (OP73)
	8.6	May 2021	Company Secretary	Minor updates regarding publishing requirements made to Attachments 3, 5 and 7
	8.7	June 2021	Company Secretary	Minor updates to Attachment 7, Cover Report
	8.8	July 2021	Company Secretary	Update included regarding publications of procedural documents on the Public Internet page. Updated Attachment 8
	9.0	December 2021	Company Secretary	Three Yearly Review
	9.1	March 2022	Company Secretary	Minor updates to Attachments 3 and 6
	9.2	April 2022	Company Secretary	Minor update to section 4.8 of policy
	9.3	November 2022	Company Secretary	Minor updates to policy, attachments 1, 3, 6 and 8
	9.4	December 2022	Group Company Secretary	Minor update to attachment 8
	9.5	December 2022	Group Company Secretary	Minor updates to attachment 4 – Enabling Strategy Template
	9.6	January 2023	Group Company Secretary	Minor updates to Attachments 1 and 11
	9.7	March 2023	Group Company Secretary	Inclusion of Attachment 14 – Policy, Procedure, Local Procedure and Guideline Risk Assessment for Extensions (Approved at

				TMC Feb. 2023)
Intended Recipients: All staff with responsibility for generating Trust policies and procedural documentation (including strategies)				
Consultation Group / Role Titles and Date: Divisional Management Teams. Executive Director, Trust Secretary, Trust Policy Group, Chairs for approving Committees.				
Name and date of Trust		Trust Policy Group – January 2022 – V9.0		
Level group where reviewed		Trust Policy Group Virtual Approval – March 2023 – V9.7		
Name and date of final approval committee		Trust Management Committee – January 2022		
Date of latest issue		March 2023		
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)		January 2025 (three yearly)		
Training and Dissemination: Launched via Senior managers briefing, Divisional Governance and Management forums, communicated through the chairs or approving committees, via the Intranet and guidance provided by the central governance team. Equality Impact Assessment (EIA) training provided by the Equality and Diversity Officer. Quality assurance on formatting will be undertaken by the Trust level/Specialist committee prior to approval by Trust management team.				
Publishing Requirements: Can this document be published on the Trust’s public page:				
No				
If yes you must ensure that you have read and have fully considered it meets the requirements outlined in sections 1.9, 3.7 and 3.9 of OP01, Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines, as well as considering any redactions that will be required prior to publication.				
To be read in conjunction with: OP73 Undertaking an Equality impact assessment, Corporate Record Management Procedure, OP95 Introduction of New Clinical Techniques and Interventional Procedures				
Initial Equality Impact Assessment (all policies): Completed				
Yes Full Equality Impact assessment (as required): Completed:				
If you require this document in an alternative format e.g., larger print please contact Policy Administrator				
Monitoring arrangements and Committee		Policy Quality Assurance audit – annual Director Policy Report – monthly to Executive Directors.		
Document summary/key issues covered. This policy directs the management of strategies, policies, procedures and guidelines. It directs the steps to be taken in the development, consultation approval and review of Trust-wide strategies, policies, procedures and guidelines.				
Key words for intranet searching purposes			OP01, Policy, Procedure, Strategy, Development, Procedural, Guidelines, Frameworks, Template.	

<p>High Risk Policy?</p> <p>Definition:</p> <ul style="list-style-type: none"> • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. <p>If a policy is considered to be high risk it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee.</p>	<p>No (delete as appropriate)</p> <p>If Yes include the following sentence and relevant information in the Intended Recipients section above –</p> <p>In the event that this is policy is made available to the public the following information should be redacted:</p>
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(Part B)

Ratification Assurance Statement

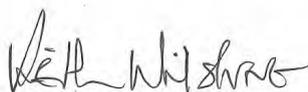
Name of document: Governance of Trust-wide Strategy, Policy, Procedure and Guidelines and Local Procedure and Guidelines

Name of author: Keith Wilshere Job Title: Company Secretary

I, Keith Wilshere the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines (OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:



Date: December 2021

Name of Person Ratifying this document (Chief Officer or Nominee):

Job Title: Chief Nurse

Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to:
The Policy Management Officer

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version OP01 version 9.0	Policy Title: Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure Guidelines	
Reviewing Group	Trust Policy Group	Date reviewed: December 2021
Implementation lead: Print name and contact details: Keith Wilshere 01902 307999 x4294		
Implementation Issue to be considered (add additional issues where necessary)	Action Summary	Action lead/s (Timescale for completion)
Strategy; Consider (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	N/A	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	N/A	
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record MUST be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept/accessed/stored when completed	N/A	
Strategy/Policy/Procedure communication; Consider 1. Key communication messages from the policy/procedure, who to and how?	To all staff via Intranet	One month from approval
Financial cost implementation Consider Business case development	N/A	
Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation	N/A	

Procedure for the Development and Control of Trust-wide Strategies, Policies, Procedures and Guidelines

1.0 Procedure Statement

As per statement OP01 Policy Statement

2.0 Accountabilities

As per Policy OP01

3.0 Procedure Detail / Actions

The flowchart in [attachment 2](#) provides a step-by-step outline of the Trust-wide strategy, policy, procedure and guideline framework.

Before developing a strategy, policy, procedure or guideline, consider the definitions in section 2 of the Policy Statement above to ensure the document is given the appropriate title and content.

3.1 Stage 1 Identify need

Check if such a strategy, policy, procedure or guideline, or one that is very similar, already exists via the Intranet or liaise with the Policy Management Officer. If there is, consider liaising with the author to amend the existing document.

3.1.1 There is an increasing number of people/services who have realised that using documents already written and adopted elsewhere makes more sense than either writing your own and/or re-writing what someone else has already done.

The 3 main sources of these documents:

1. National – usually a national organisation or similar e.g., NICE, Royal Colleges.
2. Regional – usually West Midlands or Black Country network based e.g. West Midlands Cancer Network.
3. Local – usually agreed with commissioners at the ICB or with other providers.

As with existing practice regarding local documents, in each case we will require some form of evidence of the good governance of these by the producers. In each case this is likely to be something like:

1. Publication on NICE or Royal College web site.
2. A minute from a meeting providing evidence of a process and approval e.g. WMCA Minute, web site publication.
3. A minute/note/action point from an appropriate local governance meeting providing evidence of a local process and approval e.g., ED Governance Group.

In each case a copy will be required in a pdf file of the documentation in an appropriate form and where a review date has been determined, log this on In-phase.

Where links are provided to external web sites to source a document, we need to ensure staff can access them e.g., access is not restricted by a log-in/registration

and/or pay-wall.

3.2 Stage 2 Chief Officer Sponsor approval

- 3.2.1 The proposer must inform the appropriate subject Chief Officer to obtain approval to develop a new document or amend an existing document.
- 3.2.2 This approval should be in writing and a copy of approval must be forwarded to the Policy Administrator (guidance on the appropriate chief officer can be obtained from the Policy Management Officer).

3.3 Stage 3 – Development of a draft document

- 3.3.1 [Attachment 2](#) provides a training guide for authors in the form of a flowchart.
- 3.3.2 The author of the strategy, policy, procedure or guideline is responsible for the following:
 - 3.3.2.1 drafting the strategy, policy, procedure and guideline in line with style, format and minimum content as per strategy, policy, procedure and guideline template [Attachment 3, Attachment 4, Attachment 4.1 and Attachment 6.](#);
 - 3.3.2.2 collating consultation information supplied by stakeholders;
 - 3.3.2.3 if there are new forms or training requirements, liaising with appropriate departments to ensure delivery of these e.g., Education and Training, Clinical Illustration etc.;
 - 3.3.2.4 implementation and monitoring considerations.

All aspects of this document regarding potential Conflicts of Interest must refer first to the Conflicts of Interest Policy (OP109). In adhering to this document, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

3.4 Stage 4 – Consultation

- 3.4.1 The author is responsible for distribution of a draft document for consultation. Where necessary the Chief Officer Sponsor will advise on the appropriate consultees.
- 3.4.2 A summary of Specialist and Trust Groups to consult and approve documents is seen in the flow chart at [Attachment 7](#) (NB the flowchart pertains to Trust-wide strategies, policies, procedures and guidelines).
- 3.4.3 Where appropriate, patient and, or public involvement and consultation can be sought through liaison with the Communications and Stakeholder Engagement Team. Alternatively, where there is an appropriate patient group, e.g., relative to a condition, then if deemed appropriate their views can be sought.
- 3.4.4 Once the document has been through consultation, the author sends a final draft with the completed equality impact assessment ([Equality Impact Assessment Proforma](#)), counter fraud checklist (with the exception of clinical policies), cover report ([attachment 8](#)) to the Policy Group for review. All completed documentation must be forwarded in accordance with the Trust's Policy Group Process to the Policy Management Officer. Any documents forwarded after the specified dates within said process will be subject to the Group's discretion as to whether they will be added to that Policy Group Meeting agenda or will have to wait until the next Policy Group meeting. Nominated readers will need sufficient time to review the documents.
- 3.4.5 [Attachment 7](#) provides a flowchart for the process of impact assessment. The

following link ([Equality Analysis Proformas](#)) provides the proforma for assessing Trust-wide strategies, policies, procedures and guidelines. In some cases, a full EIA may be required in addition (refer OP 73 Undertaking an EIA).

- 3.4.6 If the implementation of a strategy, policy, procedure or guideline requires financing that cannot be achieved through local changes and negotiation, then the financial elements must be taken through the appropriate route for the formulation of a business case. Where the necessary funding is not available, consideration must be given as to whether it constitutes a risk and whether it will be put on the Trust Risk Register.

3.5 Stage 5 Finalisation of a draft document

Once the document has been finalised, the author must forward all draft documentation to the Policy Management Officer prior to the approval stage.

3.6 Stage 6 – Approval

- 3.6.1 The 2 stages of strategy, policy, procedure and guideline approval are Policy Group and Trust Management Committee.
- 3.6.2 If only minor changes to existing strategies, policies, procedures or guidelines have been made, they can be approved at Policy Group without ratification by TMC. In this case the author must inform the Policy Management Officer of the amendment who will then upload the document to the intranet once approved at Policy Group.
- 3.6.3 An extension to a document can be granted virtually on the approval of Chief Officer Sponsor under adverse circumstances only. Any extension applied for should be on the basis of a realistic timescale for the completion. Multiple extensions are discouraged.
- 3.6.4 An urgent tabletop review can take place with the authority and signature of the Chief Officer Sponsor when a potential risk is identified, and action has to be taken immediately.
- 3.6.5 A suspension to a document can be applied on the approval of the Chief Officer Sponsor in exceptional circumstances – a period of no more than 6 months should be applied at a time.
- 3.6.6 The Policy Group will review the documents along with a completed equality impact assessments ([Equality Impact Assessment Pro-forma](#)), counter-fraud checklist and cover report. As part of the implementation and review of documents Authors are encouraged to take advantage of the help and support that is available via the Policy Management Officer for Trust-wide procedural document queries and the Equality, Diversity, Inclusion and Engagement Officer for Equality Analysis queries to Authors of Trust-wide procedural documents that are being reviewed/updated and created. Once the Policy Group is satisfied it then recommends for final approval at TMC or determines final approval in the case of minor changes.
- 3.6.7 Approval must be subject to an adequate quality assurance assessment by the Policy Group.
- 3.6.8 For strategies, policies, procedures and guidelines needing TMC approval, the author is responsible for making any final amendments proposed by the group and submitting a final version to the Policy Management Officer for presentation at TMC or Trust Board as appropriate.

- 3.6.9 The author must provide a standard cover report for TMC ([attachment 8](#)).
- 3.6.10 Trust Strategies and Schemes will be signed off by the Trust Board after assurance by the Policy Group and TMC. Strategies associated with Emergency Planning or the Civil Contingency Act require sign off by the Chief Executive Officer in addition to the Trust approval process described in this procedure.
- 3.6.11 Virtual approval of any Trust-wide strategy, policy, procedure or guideline will only be agreed with the Chair's approval.
- 3.6.12 Chairperson approval is decided upon at the discretion of the Chair and consulted group members.

3.7 Stage 7 Implementation

- 3.7.1 The author is responsible for development of a realistic implementation plan and for liaising with the appropriate action leads identified within the plan. The implementation plan must be realistic in timescale and include appropriate leads for action.
- 3.7.2 Where the effectiveness of the document is reviewed, the implementation plan and action leads may be reviewed to make improvements or identify failures at implementation stage.
- 3.7.3 An implementation plan must be completed for all documents. Any new documents that are developed for use and retention within the clinical case-note must be approved by the Health Records Group prior to being rolled out.
- 3.7.4 The implementation plan must address the need for targeted communication of the document to ensure that employees or other stakeholders who will be affected by the document are proactively informed and made aware of any changes in practice that will result.
- 3.7.5 The implementation plan must be held and monitored by the author for assurance on delivery of the document. A copy of the implementation plan submitted is held by the Policy Management Officer.

3.8 Stage 8 Review

- 3.8.1 All documents must have a review date that does not exceed 4 years (The standard review frequency is 3 yearly unless otherwise indicated). The review date is determined by the Chief Officer Sponsor or the Author. The document may be reviewed sooner if the need arises. All other review dates are set from the date the policy et al was recommended for approval by the Trust Policy Group to the next Trust Management Committee of the Board.
- 3.8.2 When reviewing a strategy, policy, procedure or guideline, the author must review the evidence base to determine whether the standards have changed.
- 3.8.3 The reviewed document must go through the same approval process as the new document.
- 3.8.4 With each review, the author must revisit the existing quality assurance checklist, implementation plan and EIA for necessary changes resulting from the document or procedural change and record the outcome in the relevant group report.
- 3.8.5 All aspects of this document regarding potential Conflicts of Interest must refer first to the Conflicts of Interest Policy (OP109). In adhering to this document, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

3.9 Publication Management

- 3.9.1 The Policy Management Officer will obtain a monthly listing of approved Trust-wide strategies, policies, procedures and guidelines at TMC or Trust Board (as appropriate), assign a document number for new policies, procedures and guidelines (the Performance Team will assign a number to strategic documents), and update the document database with new / revised strategy, policy, procedure and guideline details (including version control).
- 3.9.2 Final copies of approved Trust-wide policy, procedure and guidelines will be uploaded to the Intranet by the Policy Management Officer and will create a PDF. Strategic documents will be uploaded by the Performance Team.
- 3.9.3 Clinical Illustration department is the custodian for maintaining the archiving of Trust-wide strategies, policies, procedures and guidelines.
- 3.9.4 Any strategy that is 6 months past its review date will be automatically referred to the next TMC for consideration for removal.

3.10 De-ratification/Removal of Strategies, Policies, Procedures and Guidelines

Where a document is de-ratified the same 2 stage process as approval (Section 3.4.1) is followed the Author must complete a de-ratification and seek authorisation by the responsible Chief Officer; this information is then provided to Trust Policy Group and Trust Management Committee, and the decision recorded on the Policy database. Where the document is superseded the replacement document details must be recorded and [Attachment 10](#) must be completed and submitted to the relevant Chief Officer/Group.

4.0 Equipment required

Not applicable

5.0 Training

As per Policy above

6.0 References

As per Policy above

A guide to the Trust's Strategy, Enabling Strategies and Delivery Plans

1. Introduction

This document serves as a guide to the structure of the Trust's strategic documents and provides specific guidance for those writing enabling strategies and delivery plans as to their content and format.

The Trust has one overarching strategy, supported by 8 enabling strategies, broadly aligned to the committees of the board. Underpinning these are a set of delivery plans covering discreet areas of the Trust. This is summarised in Table 1 below.

Type of Document	Number of	Purpose
Trust Strategy	1	To set out the Trust's Strategy, Strategic Objectives and other key enduring themes and values
Enabling Strategies <i>(covers previous topic/area strategies, Enabling Strategies/ Strategic Delivery)</i>	8 <ul style="list-style-type: none"> • People engagement & OD, • Quality & Safety, • Patient engagement*, • Finance & performance • Innovation & Research • Estates* • Digital & IT* • Trust Charity 	To set out the strategic approach and actions within each of these areas including the high level aims to be achieved over the life of the Enabling strategy and philosophy of delivery.
Delivery Plans <i>(covers previous Implementation Plans, Delivery Frameworks)</i>	As agreed* e.g. Under People: <ul style="list-style-type: none"> • Attraction and Retention • Engagement • Leadership and OD • Wellbeing • Employee Relations • Education * tbc by relevant Committee of the Board	To set out the detailed objectives/deliverables and detailed philosophy of delivery together with a credible action plan to be monitored through the *relevant board committee.

Table 1: Strategic Document Structure

2. Structure of Documents

The Trust Strategy and Enabling Strategies will be formatted by the Trusts clinical illustration department. The guidance below is intended to support the writing of documents by articulating the headings to be used and detail to cover within them.

2.1. Trust Strategy

Our Vision and Values

The vision is the end point for which the organisation is trying to reach – it is our guiding aspiration and underpins the Trusts strategy (which in turn details the areas and issues that need to be addressed in order to fulfil the Trusts vision). The values are the qualities that are important and define how the Trust needs to behave in order to achieve the vision; values may be expressed as beliefs, traits, characteristics or rules.

Our Strategic Context

The strategic context of the organisation covers a description for the reader of the organisation and the population it serves. It is useful to include information around the services on offer, how these are provided, the activity the Trust undertakes and the people it employs.

The strategic context should also cover the partnerships between the hospital and other stakeholders, e.g. commissioners, other providers etc.

Finally the strategic context should articulate the drivers that are guiding this strategy, e.g. the NHS Long Term Plan.

Strategic Analysis

The strategic analysis, as the name suggests, is an analysis of where we sit or compares to a given benchmark, e.g. other similar organisations, national targets etc. This analysis is usually split between the external environment, i.e. outside of the organisation and internal, i.e. within the organisation.

The external analysis should analyse the external landscape against the factors in the PESTLE tool – i.e. political, economic, societal, technological, legal and environmental. For each, it is useful to examine what the factors or drivers are against each domain and how that may impact on the Trust.

The internal analysis should focus on a SWOT analysis of the Trust – i.e. the strengths, weaknesses, opportunities and threats of the Trust. In considering each, it is useful to expand upon how strengths can be utilised, weaknesses can be overcome, opportunities can be pursued and threats can be mitigated.

Strategic Objectives

The strategic objectives are then a small list (typically no more than five) of targets to support the Trust in achieving its vision. Objectives should be SMART in their nature, i.e. specific, measurable, achievable, realistic and time based. For each objective, it is useful to set out the aspiration for the objective, where we are now, why this objective matters to us, what success looks like and how we are going to achieve this success.

Implementing the Strategy

Finally, the strategy should summarise how the strategy is being implemented into action. This will include how progress will be monitored and how the strategy will be reviewed. It is likely that this will vary depending on whether this is the Trust strategy (which will be the focus on the Trust Board) or enabling strategies (where the focus will most likely be from committees of the Trust Board).

2.2. Enabling Strategies

The format of the enabling strategies should replicate (in the most part) that of the Trust Strategy – the main difference being that it is specific to the area in question, for example quality and safety. Enabling strategies should clearly reference the Trust Strategy and support the delivery of the strategic objective (relevant to the enabling strategy in question) in the Trusts corporate strategy.

Our Strategic Context

The strategic context of an enabling strategy should articulate the environment specific to the domain in question, e.g. quality and safety as well as the relative standing of the organisation within this environment. Similar to the Trust strategy, it should articulate the drivers that are guiding this strategy, e.g. the NHS Long Term Plan. The key difference being that this is at a theme level rather than corporate level. As an example, the reduction of sepsis related deaths may be one of the national priorities within the patient safety agenda.

Strategic Analysis

The strategic analysis, as the name suggests, is an analysis of where we sit or compares to a given benchmark, e.g. other similar organisations, national targets etc. For an enabling strategy, this analysis is similar to at a Trust strategy level however the PESTLE and SWOT analysis will be focused on the theme in question, for example political factors affecting the quality and patient safety theme specifically. Like with the Trust strategy, this is usually split between the external environment, i.e. outside of the organisation and internal, i.e. within the organisation.

The external analysis should analyse the external landscape against the factors in the PESTLE tool – i.e. political, economic, societal, technological, legal and environmental. For each, it is useful to examine what the factors or drivers are against each domain and how that may impact on the Trust.

The internal analysis should focus on a SWOT analysis of the Trust – i.e. the strengths, weaknesses, opportunities and threats of the Trust. In considering each, it is useful to expand upon how strengths can be utilised, weaknesses can be overcome, opportunities can be pursued and threats can be mitigated.

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Implementing the Strategy

Finally, the strategy should summarise how the strategy is being implemented into action. This will include how progress will be monitored and how the strategy will be reviewed. It is likely that this will vary depending on whether this is the Trust strategy (which will be the focus on the Trust Board) or enabling strategies (where the focus will most likely be from committees of the Trust Board).

3. Delivery Plans

Whereas the Trust strategy is based at a corporate level and enabling strategies cover a theme of work, e.g. patient safety, a delivery plan is specific to a single area of work. For example, you could have a dementia plan that falls under the patient experience enabling strategy or a CIP delivery plan falling under the finance and performance enabling strategy.

Delivery plans are much shorter in their nature to enabling strategies and should typically be no longer than 4 pages in length. Broadly, a delivery plan should cover:

Context

Covering the national and local agenda specific to the topic in question and what the drivers are for a delivery plan.

Current Position

How the organisation compares at the moment – where its strength and weaknesses lie and the work undertaken thus far.

Objectives

What is the Trust trying to achieve and what does success look like.

Action Plan

A traditional action plan articulating the action, owner, timescale and update on progress. The actions, as seems obvious, should clearly articulate how they support the achievement of the overall priority.

4. Queries

For any queries on this process or the completion of strategies, please contact either Timothy Shayes, Deputy Director of Planning and Performance or Keith Wilshere, Company Secretary on timothy.shayes@nhs.net or keith.wilshere@nhs.net.

Frameworks at RWT

A framework describes the operationalising of principles of good governance. When applying these principles, it is important that the good governance of Frameworks is included.

- A Framework is a set of complex, interrelated structures, systems, processes, information and data that supports interventions applied in a health care environment.
- A Framework in this context, provides the component principles of what make a good service in health care
- Frameworks are underpinned by the available research.



For example – a professional Framework provides the strategic vision and thought translated into an open and transparent structure and plan which can be replicated.

- It provides challenges, direction and improvements.
- It provides a road map for staff involved.
- It supports good governance and can integrate an organisation's quality, safety and risk agenda.
- It has the ultimate impact on patients' outcomes as a central theme.

Key elements of a framework

- What is the system, process and structure? (Structure; system/process; information/data.)
- How is it monitored and evaluated? (Structure; system/process; information/data.)
- Who or what has what role and function? (Structure; accountability; workforce; capacity.)
- Who or what is responsible for this/these? (Accountability and support.)
- How might this be improved? (Research, learning, continuous evaluation & improvement activity.)

Governance of frameworks

A framework is only as good and as useful as the process and system for governing it. Therefore, each Framework requires a clear Governance element outlining who/where is responsible for the good Governance of that Framework, how often it is reviewed, and the process for ownership and dissemination.

Frameworks – Structure, process, governance

What is a Trust Framework at RWT?

- It is a description of overall structure and accountability – and describe who and what it is for.
- It should describe and reinforce 'Ward to Board' and whole organisation structure and accountability.
- It should not contain 'new' or novel information.
- It can gather together information from a variety of pre-existing sources e.g., Policy, Strategy, Enabling Strategy, Delivery Plan, Procedures etc.
- It should describe and reinforce Roles and Responsibilities.
- It should describe and reinforce Governance, monitoring and/or arrangements.
- It requires updates as and when there is a significant shift in a major component or element of the Framework e.g. establishment of a new Divisional structure.
- It can be used to describe and reinforce the desired culture, behaviours and desired outcomes.
- It can be used to describe the means by which these are achieved and any milestones established.

What Frameworks have we got?

- Clinical Systems Framework.
- Accountability Framework.
- Risk Framework.

Where can they be found?

On the Intranet under 'Strategies and Frameworks'.

How are they structured?

Frameworks are structured to address the need identified.

They do require a minimal amount of version control as per the Frameworks Version Control Sheet and Template.

They require a responsible Chief Officer and Author/Manager.

They are logged and have oversight by the Company Secretary and Policy Management Officer using the InPhase system.

Process - they require approval from either:

- The Trust Board or a Committee of the Board, or
- The responsible Chief Officer or Executive Directors Meeting.

This will be identified in the Version Control Template.

Governance

- The Governance of a Framework is led by the Chief Officer owner and the structure they have in place to oversee the Governance of the Framework, e.g., the Clinical Systems Framework is led by the CNO and Governed by the Senior Nursing and AHP bodies.
- The Trust Policy Group will note and log Frameworks.
- The Company Secretary (through the Policy Management Officer) will periodically seek assurance of the good governance of the Framework e.g. that they have been reported upon as required, updated as required (at least annually).

TEMPLATE FOR A TRUST POLICY

This template MUST be used for all Trust-wide Policies. (Please remove this highlighted information when submitting the policy)

Policy Number

If creating a new policy a policy number will be assigned by the Policy Administrator

Title of Policy

Policy name must be a simple and clear reflection of the subject
(Bold, 18, centered)

□ 2.5cm left margin, 1.5cm right margin □

Contents**Sections****Page**

ALL SECTIONS IN BLUE ARE GUIDANCE AND MUST BE REMOVED PRIOR TO SUBMITTING POLICY

Text Arial 12, Left Justification
1.5cm top margin, 1.9cm bottom margin
1.27cm header, 1.7cm footer
Insert 'page break' at end of every page

Attachments**Appendices**

All hyperlinks to be inserted

All sections to be numbered and indexed to facilitate rapid access to relevant information

1.0 Policy Statement (Purpose / Objectives of the policy) (*all headings to be bold, Arial 12, sentence case)

State the purpose/objectives of the document including rationale for development. The aims / objectives and where relevant criteria must also be included here in bullet format.

The document must state the expected outcomes resulting from the implementation of the policy / procedure taking into account the purpose stated.

All aspects of this document regarding potential Conflicts of Interest should refer first to the Conflicts of Interest Policy (OP109). In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

2.0 Definitions*

Alphabetically list of the terms used and their meaning within the context of the document to clarify interpretation.

3.0 Accountabilities*

An overview of the individual, departmental and committee responsibilities.

4.0 Policy Detail*

Short and precise directing readers to [Procedure Appendices and supporting attachments](#). Appendices to be included as part of the associated numbered

Policy and Procedural document where appropriate. Please note **Attachments** (forms etc.) **must be numbered** and as they maybe separate documents from the Policy when inputted onto the Intranet. Where possible include a flowchart to provide guidance to staff.

Include details of which Strategy the policy has been developed to support.

5.0 Financial Risk Assessment* (where assessed in the policy does not need to be repeated for the procedure)

1	Does the implementation of this policy require any additional Capital resources	Yes – No
2	Does the implementation revenue resources of this policy require additional	Yes - No
3	Does the implementation of this policy require additional manpower	Yes - No
4	Does the implementation of this policy release any manpower costs through a change in practice	Yes - No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff	Yes - No
	Other comments	

If the response to any of the above is 'Yes' please complete a standard business case report and which is signed by your Divisional Accountant and Directorate Manager for consideration by the Divisional Management Team before progressing to your specialist committee for approval. **Please retain all yes content in the final policy.**

6.0 Equality Impact Assessment* (where assessed in the policy does not need to be repeated for the procedure)

Authors are required to complete an Equality Impact Assessment via the following [link](#) and issues identified from the assessment must be included here with a summary of redress action.

An equality analysis has been carried out and it indicates that:

Tick	Options
	A. There is no impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.
	B. There is some likely impact as identified in the equality analysis. Examples of issues identified, and the proposed actions include: <ul style="list-style-type: none"> • • •

7.0 Maintenance*

Short statement identifying who will ensure the Policy is kept up to date and which committee / working group will recommend any changes / amendments.

8.0 Communication and Training*

Must include methods for targeted (as appropriate) and Trust wide communication of key deliverables within the policy. Training required and how to access this must be explicit. If training is mandatory there must be a cross reference to the Trust mandatory training policy OP 41 and training needs analysis for all staff groups.

9.0 Audit Process*

State the audit of the process outlined within the policy. Identify measuring for monitoring / reporting on the effectiveness / level of compliance with the policy. Also include details of which strategic objective the policy supports delivery of.

Keep relevant, simple and achievable. Where possible tie into existing audit/monitoring processes.

Also include details of which strategic objective the policy supports delivery of [Visions and Values](#).

Criterion	Lead	Monitoring method	Frequency	Committee
At a minimum needs to reflect monitoring that demonstrates compliance with the Policy objective.	Who produces the audit / monitoring report	What is the means of monitoring used e.g. routine / random audit, KPI	How often a report is produced	Which committee / group receives and acts on the report

10.0 References - Legal, professional or national guidelines must underpin policies and be referenced here. Where appropriate cross references must be made to other policies.

All references to appendices and attachments within the body of the document must be highlighted in blue and all hyperlinks inserted.

Part A - Document Control

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and Policy version: New documents / first version = v0.0 Each amendment or addition to be given next number sequence 0.1 Draft, 0.2 Draft etc. Once approved it will be benchmarked a whole number e.g. v1 or next in sequence	Policy Title	Status: Draft or final		Author: title Chief Officer Sponsor: title
Version / Amendment History	Version	Date	Author	Reason
				Brief reference/ description as to why an amendment has been made
Intended Recipients: State who the policy is aimed at – staff groups etc.				
Consultation Group / Role Titles and Date: State which groups you have consulted with and when. Give names in full followed by abbreviations.				
Name and date of Trust level group where reviewed		See approval flowchart at attachment 7		
Name and date of final approval committee		See approval flowchart at attachment 7		
Date of Policy issue				
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)		State year and frequency e.g. 2008 every 3 years		
Training and Dissemination: How will you communicate the policy, cascade the information and address training?				
To be read in conjunction with: State the name / s of any other relevant policies / procedures.				
Initial Equality Impact Assessment (all policies): Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator8904				

Monitoring arrangements and Committee	Briefly state the monitoring report and key committee receiving the report.
Document summary/key issues covered.	Please provide a brief summary of the document to direct staff attention as to its main purpose and content.
Key words for intranet searching purposes	

<Name of Domain> Enabling Strategy

This template should be read in conjunction with the 'A guide to the Trust's Strategy, Enabling Strategies and Delivery Plans' document. This template should only be completed if you are authoring an 'enabling strategy' for one of the following areas of work:

- *People engagement & OD,*
- *Quality & Safety,*
- *Patient engagement,*
- *Finance & performance*
- *Innovation & Research*
- *Estates*
- *Digital & IT*
- *Trust Charity*

The following serves as a template for use. Once completed, it should be emailed to timothy.shayes@nhs.net and/or r.crossey@nhs.net to ensure consistency of approach.

Where we are now:

Should include:

- *Description of environment within which you are working, e.g. quality environment, and*
- *The national and local agenda relative to the domain in question and drivers of this strategy, e.g. ambitions within the NHS Long Term Plan*
- *An analysis of where the Trust sits/compares to a given benchmark, e.g. other similar organisations, national targets etc.*
- *PESTLE analysis (for an analysis of external factors) and SWOT analysis (for the internal factors)*

Where we want to get to:

Should include:

- *A small list of SMART objectives that support the achievement of the relevant Trusts' Strategic Objectives:*

Care	Excel in the delivery of Care	
Colleagues	Support our Colleagues	
Collaboration	Effective Collaboration	
Communities	Improve the health and wellbeing of our Communities	

- with a description of:
 - What, by when and how success will be achieved and the quantitative factors to be measured.

How we will get there:

Should include:

- High level approach to achieving goals, e.g. collaboration, consolidation, revised pathways or workforce, etc.

What we will do:

Should include:

- Minimum of a two-year action plan, detailing who will be doing what, and when, and (if known) what budget is allocated to the activity.

How we will know we have succeeded:

- A log of risks and mitigations related to delivery of the strategy
- Governance of the strategy including how progress will be monitored and when and where progress will be updated
- When it will be reviewed.

<Name of Topic> Delivery Plan

This template should be read in conjunction with the 'A guide to the Trust's Strategy, Enabling Strategies and Delivery Plans' document. This template should be completed if you are authoring a 'delivery plan' for a topic that supports one of the following committee areas of work:

- *People engagement & OD,*
- *Quality & Safety,*
- *Patient engagement,*
- *Finance & performance*
- *Innovation & Research*
- *Estates*
- *Digital & IT*
- *Trust Charity*

The following serves as a template for use. Once completed, it should be emailed to timothy.shayes@nhs.net to ensure consistency of approach.

Context

Should include:

- *Description of environment within which you are working, e.g. quality environment, and*
- *Why the delivery plan is being written and what it is that we are hoping will be achieved*

Current Position

Should include:

- *A description of the current performance of the service in question and relative strengths and weaknesses*

Objectives

Should include:

- *What the Trust is hoping to achieve and what success looks like*

Action Plan

Should include:

<i>Ref</i>	<i>Objective</i>	<i>Action</i>	<i>Owner</i>	<i>Deadline</i>	<i>Update on Progress</i>
001					
002					
003					
004					

Part A - Document Control

To be completed when submitted to the appropriate committee for consideration/approval

Delivery Plan version: New documents / first version = v0.0 Each amendment or addition to be given next number sequence 0.1 Draft, 0.2 Draft etc. Once approved it will be benchmarked a whole number e.g. v1 or next in sequence	Title	Status: Draft or final		Author: title Chief Officer Sponsor: title
Version / Amendment History	Version	Date	Author	Reason
				Brief reference/ description as to why an amendment has been made
Intended Recipients: State who the delivery plan is aimed at – staff groups etc.				
Consultation Group / Role Titles and Date: State which groups you have consulted with and when. Give names in full followed by abbreviations.				
Name and date of Trust level group where reviewed		See approval flowchart at attachment 7		
Name and date of final approval committee		See approval flowchart at attachment 7		
Date of Policy issue				
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)		State year and frequency e.g. 2008 every 3 years		
Training and Dissemination: How will you communicate the strategy, cascade the information and address training?				
To be read in conjunction with: State the name / s of any other relevant policies / procedures.				
Initial Equality Impact Assessment (all policies): Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator8904				
Monitoring arrangements and Committee		Briefly state the monitoring report and key committee receiving the report.		
Document summary/key issues covered. Please provide a brief summary of the document to direct staff attention as to its main purpose and content.				
Key words for intranet searching purposes				
High Risk Policy? Definition: <ul style="list-style-type: none"> Contains information in the public domain 		Yes / No (delete as appropriate) If Yes include the following sentence and relevant information in the Intended Recipients section above –		

<p>that may present additional risk to the public e.g. contains detailed images of means of strangulation.</p> <ul style="list-style-type: none">• References to individually identifiable cases.• References to commercially sensitive or confidential systems. <p>If a policy is considered to be high risk it will be the responsibility of the author and director sponsor to ensure it is redacted to the requestee.</p>	<p>In the event that this is policy is made available to the public the following information should be redacted:</p>
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Part B

Ratification Assurance Statement

Name of document:

Name of author:

Job Title:

I, _____ the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date:

Name of Person Ratifying this document (Chief Officer or Nominee):

Job Title:

Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Delivery Plan number and version	Delivery Plan Title	
Reviewing Group		Date reviewed:
Implementation lead: Print name and contact details		
Implementation Issue to be considered (add additional issues where necessary)	Action Summary	Action lead / s (Timescale for completion)
Strategy; Consider (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.		
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form		
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record MUST be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed		
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?		
Financial cost implementation Consider Business case development		
Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation		

TEMPLATE FOR A TRUST FRAMEWORK

This template MUST be used for all Trust-wide Frameworks. (Please remove this highlighted information when submitting the Framework)

Title of Framework

Framework name must be a simple and clear reflection of the subject (Bold, 18, centered)

□ 2.5cm left margin, 1.5cm right margin □

Contents

Item

Page

ALL SECTIONS IN BLUE ARE GUIDANCE AND MUST BE REMOVED PRIOR TO SUBMITTING FRAMEWORK

*Text Arial 12, Left Justification
1.5cm top margin, 1.9cm bottom margin
1.27cm header, 1.7cm footer
Insert 'page break' at end of every page*

Attachments

Appendices

All hyperlinks to be inserted

All sections to be numbered and indexed to facilitate rapid access to relevant information

1.0 Framework Statement/Introduction (Purpose / Objectives of the framework)

*(*all headings to be bold, Arial 12, sentence case)*

Notes/Guidance

- What is the system, process and structure? (Structure, system/process, information/data)*
- How is it monitored and evaluated? (Structure, system/process, information/data)*
- Who or what has what role and function? (Structure, accountability, workforce, capacity)*
- Who or what is responsible for this/these? (Accountability, support)*
- How might this be improved? (Research, learning, continuous evaluation & improvement activity)*

State the purpose/objectives of the document including rationale for development. The aims / objectives and where relevant criteria must also be included here in bullet format.

The document must state the expected outcomes resulting from the implementation of the Framework taking into account the purpose stated.

All aspects of this document regarding potential Conflicts of Interest should refer first to the Conflicts of Interest Policy (OP109). In adhering to this Framework, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and

overriding Policy.

2.0 Strategic and External Context and Background

3.0 Framework Detail*

Short and precise directing readers to [Procedure Appendices and supporting attachments](#). Appendices to be included as part of the associated numbered Framework document where appropriate. Please note Attachments (forms etc.) must be numbered and as they may be separate documents from the Framework when inputted onto the Intranet. Where possible include a flowchart to provide guidance to staff.

- *It can gather together information from a variety of pre-existing sources e.g. Policy, Strategy, Enabling Strategy, Delivery Plan, Procedures etc.*
- *Include details of which Strategy the Framework has been developed to support.*
- **Accountabilities / Roles and Responsibilities**
An overview of the individual, departmental and committee responsibilities.
- *It should describe and reinforce Roles and Responsibilities.*
- *The Governance of a Framework is led by the Chief Officer owner and the structure they have in place to oversee the Governance of the Framework e.g. the Clinical Systems Framework is led by the CNO and Governed by the Senior Nursing and AHP bodies.*
- **References - Legal, professional or national guidelines** –detail must underpin frameworks and be referenced here. Where appropriate cross references must be made to other policies.
- *All references to appendices and attachments within the body of the document must be highlighted in blue and all hyperlinks inserted.*

4.0 Communication*

Must include methods for targeted (as appropriate) and Trust wide communication of key deliverables within the framework. Training required and how to access this must be explicit. If training is mandatory there must be a cross reference to the Trust mandatory training policy OP41 and training needs analysis for all staff groups.

All Frameworks are to be considered publishable in the public domain.

- **Implementation Plan** –details should include the implementation and monitoring of the framework

Part A - Document Control

To be completed when submitted to the appropriate committee for consideration/approval

Framework number and version: <i>New documents / first version = v0.0 Each amendment or addition to be given next number sequence 0.1 Draft, 0.2 Draft etc. Once approved it will be benchmarked a whole number e.g. v1 or next in sequence</i>	Framework Title	Status: <i>Draft or final</i>		Author: <i>title</i> Chief Officer Sponsor: <i>title</i>
Version / Amendment History	Version	Date	Author	Reason
				<i>Brief reference/ description as to why an amendment has been made</i>
Intended Recipients: <i>State who the framework is aimed at – staff groups etc.</i>				
Consultation Group / Role Titles and Date: <i>State which groups you have consulted with and when. Give names in full followed by abbreviations.</i>				
Name and date of Trust level group where reviewed	<i>See approval flowchart at attachment 7</i>			
Name and date of final approval committee	<i>See approval flowchart at attachment 7</i>			
Date of Framework issue				
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	<i>State year and frequency e.g. 2008 every 3 years</i>			
Training and Dissemination: <i>How will you communicate the framework, cascade the information and address training?</i>				
To be read in conjunction with: <i>State the name / s of any other relevant procedural documents such as policies / procedures.</i>				
Monitoring arrangements and Committee	<i>Briefly state the monitoring report and key committee receiving the report.</i>			
Key words for intranet searching purposes				

(Delete if not necessary)

Disclaimer:

Our recommendations are based on current national guidelines and relevant evidence-base. This guideline helps inform clinicians clinical judgement. However, clinicians will consider the trade-off between the benefits and harms of an intervention before making a clinical decision.

OP01 Attachment 6

ALL SECTIONS IN BLUE ARE FOR GUIDANCE PURPOSES AND MUST BE REMOVED PRIOR TO SUBMITTING

TEMPLATE FOR TRUST-WIDE AND LOCAL PROCEDURE/GUIDELINES
(Please remove this highlighted information when using the template)

Title of Procedure/Guidelines Number

If creating a new Trust-wide procedure/guidelines a number will be assigned by the Policy Management Officer/if a new local procedure or guideline number will be assigned by Central Governance

Title of Procedure/Guidelines

Use this template for trust procedure/guidelines as the use is identical – and must be used for those that apply Trust-wide.

(Bold, 18, centered)

□ 2.5cm left margin, 1.5cm right margin □

Text Arial 12, Left Justification

1.5cm top margin, 1.9cm bottom margin

1.27cm header, 1.7cm footer

Insert 'page break' at end of every page

All sections to be numbered and indexed to facilitate rapid access to relevant information

IMPORTANT: For a procedure attached to or within a Trust policy, sections 1 to 6 only are needed using the same document control sheet as the host policy. For standalone or local procedures not linked to a Trust policy sections 1 to 9 must be completed along with the document control template above.

1.0 Procedure Statement (Purpose / Objectives of the Procedure) (*all headings to be bold, Arial 12, sentence case)

State the purpose of the document including rationale for development. The aims / objectives and where relevant NHSLA criteria must also be included here in bullet format.

The document must state the expected outcomes resulting from the implementation of the policy / procedure taking into account the purpose stated.

All aspects of this document regarding potential Conflicts of Interest must refer first to the Conflicts of Interest Policy (OP109). In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

2.0 Accountabilities*

An overview of the individual, departmental and committee responsibilities.

3.0 Procedure/Guidelines Detail / Actions*

Short and precise directing readers to **Procedure Appendices and supporting attachments**. Appendices to be included as part of the associated numbered Procedural document where appropriate. Please note **Attachments** (forms etc.) **must be numbered** and as they maybe separate documents from the Procedure

(Delete if not necessary)

Disclaimer:

Our recommendations are based on current national guidelines and relevant evidence-base. This guideline helps inform clinicians clinical judgement. However, clinicians will consider the trade-off between the benefits and harms of an intervention before making a clinical decision.

when inputted onto the Intranet. Where possible include a flowchart to provide guidance to staff.

Equipment required – identify equipment necessary including safety checks, training or competency requirements etc.

4.0 Equipment Required*

Identify what equipment is needed, where located, any prerequisites to use.

5.0 Training*

Must include methods for targeted (as appropriate) and Trust wide communication of key deliverables within the document. Training required and how to access this must be explicit. If training is mandatory there must be a cross reference to the Trust Mandatory Training Policy OP41 and training needs analysis for all staff groups.

6.0 Financial Risk Assessment (where assessed in the policy does not need to be repeated for the procedure)

1	Does the implementation of this document require any additional Capital resources	Yes – No
2	Does the implementation of this document require additional revenue resources	Yes – No
3	Does the implementation of this document require additional manpower	Yes – No
4	Does the implementation of this document release any manpower costs through a change in practice	Yes – No
5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff.	Yes – No
	Other comments	

If the response to any of the above is 'Yes' please complete a standard business case report and which is signed by your Divisional Accountant and Directorate Manager for consideration by the Divisional Management Team before progressing to your specialist committee for approval. **Please retain all yes content in the final policy.**

7.0 Equality Impact Assessment (where assessed in a Trust policy or other local document does not need to be repeated for the procedure – simply refer to main assessment outcomes)

Authors are required to complete an Equal Impact Assessment via the following [link](#) and issues identified from the assessment must be included here with a summary of redress action.

An equality analysis has been carried out and it indicates that:

Tick	Options
	A. There is no impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.

(Delete if not necessary)

Disclaimer:

Our recommendations are based on current national guidelines and relevant evidence-base. This guideline helps inform clinicians clinical judgement. However, clinicians will consider the trade-off between the benefits and harms of an intervention before making a clinical decision.

	<p>B. There is some likely impact as identified in the equality analysis. Examples of issues identified, and the proposed actions include:</p> <ul style="list-style-type: none"> • • •
--	--

8.0 Maintenance

Short statement identifying who will ensure the document is kept up to date and group/department/specialist lead will recommend any changes / amendments.

9.0 Communication and Training

Must include methods for targeted and general communication of key actions/responsibilities within the document. State the initial and refresher training required and how to access this (must be explicit). If training is mandatory there must be a cross reference to the Trust Mandatory Training Policy OP41 and training needs analysis for all staff groups.

10.0 Audit Process

State any audit/monitoring of the document. Identify measuring for monitoring / reporting on the effectiveness / level of compliance with the policy.

Keep relevant, simple and achievable. Where possible tie into existing audit/monitoring processes

Criterion	Lead	Monitoring method	Frequency	Evaluation
At a minimum needs to reflect monitoring that demonstrates compliance with the document objective/ statement.	Who produces the audit / monitoring report	What is the means of monitoring used e.g. routine / random audit, KPI	How often a report is produced	Which forum / group e.g. team meeting, appraisal etc. receives and acts on the results

11.0 References - Legal, professional or national guidelines must underpin policies and be referenced here. Where appropriate cross references must be made to other policies.

All references to appendices and attachments within the body of the must be highlighted in blue to enable hyperlinks to be incorporated.

(Delete if not necessary)

Disclaimer:

Our recommendations are based on current national guidelines and relevant evidence-base. This guideline helps inform clinicians clinical judgement. However, clinicians will consider the trade-off between the benefits and harms of an intervention before making a clinical decision.

Part A - Document Control

For Trust-wide Procedures and Guidelines - To be completed when submitted to the appropriate committee for consideration/approval (Please remove this highlighted information when using the template)

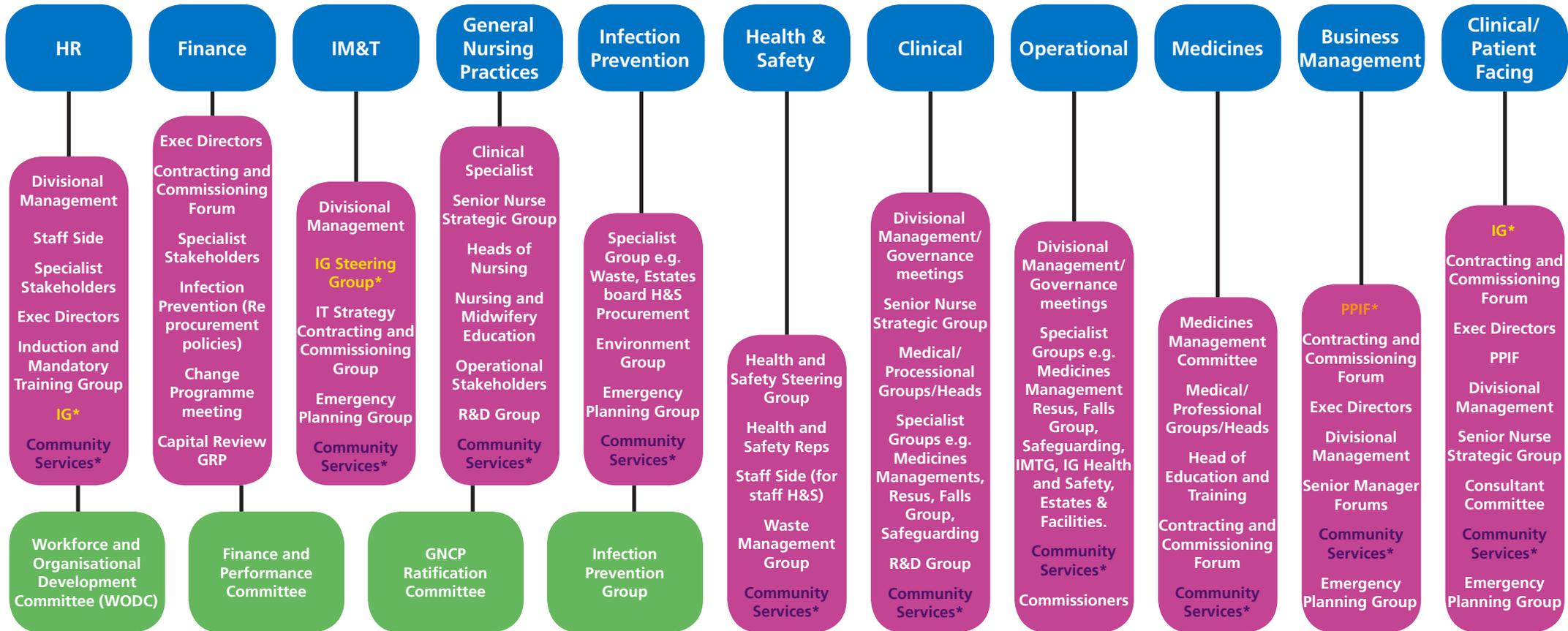
These templates MUST be used for all local i.e. Divisional/Directorate/Department Procedure documents developed or review after May 2017. (Please remove this highlighted information when using the template)

Procedure/ Guidelines number and version	Title of Procedure/Guidelines New documents / first version = v0.0 Each amendment or addition to be given next number sequence 0.1 Draft, 0.2 Draft etc. Once approved it will be benchmarked a whole number e.g. v1 or next in sequence	Status: Draft or final		Author: title For Trust-wide Procedures and Guidelines Chief Officer Sponsor: title For local procedures and guidelines Lead Sponsor (either clinical/ managerial lead)
Version / Amendment History	Version	Date	Author	Reason
				Brief reference/ description as to why an amendment has been made
Intended Recipients: State who the procedure/practice/Guideline is aimed at – staff groups etc.				
Consultation Group / Role Titles and Date: State which groups you have consulted with and when. Give names in full followed by abbreviations.				
Name and date of group where reviewed				
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)				
Date of Procedure/Guidelines issue				
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)		State year and frequency e.g. 2019 every 3 years		

Training and Dissemination: How will you communicate the document, cascade the information and address training?	
To be read in conjunction with: State the name / s of any other relevant policies / procedures.	
Initial Equality Impact Assessment: Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Management Officer 85887 for Trust- wide documents or your line manager or Divisional Management office for Local documents.	
Contact for Review	This must match the author of the procedure/guideline if different please state the contact by job title.
Monitoring arrangements	Briefly state the monitoring report and key committee receiving the report.
Document summary/key issues covered. Please provide a brief summary of the document to direct staff attention as to its main purpose and content.	
Key words for intranet searching purposes	

Consultation Flowchart Trust-wide

Strategy / Policy / Procedure / Guidelines



- Type of Strategy / Policy / Procedure / Guideline.
- Consultation.
- Trust Level group / Committee review policy prior to submitting for approval to Policy Group.
- Approval of Strategy / Policy / Procedure / Guideline.
- ✳ Always consider the need for patient engagement.
- ✳ Documents relating to exchange or use of person identifiable information consult with IG steering group.
- ✳ Always consider consultation with and impact on Community Services / satellite sites e.g. Cannock.

All Trust-wide Policies, Procedures and Guidelines to be approved by the Policy Group and the Trust Management Committee

All Strategies to be approved by the Trust Board as well as Policy Group and the Trust Management Committee.

Trust Policy Group /Trust Management Committee Report

Meeting Date:	Date of the TPG/TMC Meeting the paper/report is for.
Title:	Of the Trust-wide procedural document. This is the title that will be used on the Agenda and referred to in the minutes.
Purpose of the Report:	Why is the report or paper being presented to TPG/TMC? i.e. Full scheduled review or for approval following significant updates prior to next scheduled full review
Action required:	TPG/TMC can either: Make a decision; Approve; Receive for assurance; Received and noted. If the item has already been approved by a body with delegated powers of approval then the item would be received and noted.
Assure	<ul style="list-style-type: none"> Items in the paper/report summary that provide assurance to the Board or that the Committee reported to consider as evidence of assurance. This may include items previous Advised or Alerted where the mitigations/actions have changed the level of concern/risk.
Advise	<ul style="list-style-type: none"> Items in the paper/report summary that provide areas of actual and/or potential concern now or in the future where the risk is not determined or low.
Alert	<ul style="list-style-type: none"> Items of immediate and pressing concern including areas of known or anticipated high risk. This may include items previous reported in the Alert section where the risk and/or nature has changed.
Author + Contact Details:	Tel 01902 Email @nhs.net
CQC Domains	(delete as appropriate) Identify which of the 5 Domains this item contributes toward: Safe: Effective: Caring: Responsive: Well-led.
Trust Strategic Objectives	(delete those that do not apply to your Trust-wide procedural document) <ol style="list-style-type: none"> Excel in the delivery of Care – We will deliver exceptional care by putting patients at the heart of everything we do, embedding a culture of learning and continuous improvement. Support our Colleagues – We will be inclusive employers of choice in the Black Country that attract, engage and retain the best colleagues reflecting the diversity of our populations. Improve the health of our Communities – We will positively contribute to the health and wellbeing of the communities we serve. Effective Collaboration – We will provide sustainable healthcare services that maximise efficiency by effective collaboration with our partners.
Counter Fraud Checklist (with the exception of clinical policies)	Refer to the completed counter fraud checklist.
Financial Implications:	Does the Policy/Procedure commit the Trust to any additional (or new) expenditure (capital or revenue)? (This could include changes to equipment, items used etc) If yes, then has a relevant Financial Risk Assessment been undertaken, and/or Business Case approved? (This needs to include references if yes)
Equality and Diversity Impact	Refer to the completed EA proforma
ICT and Health Records implications	<ol style="list-style-type: none"> Does the policy/procedural document include significant or major changes that include IT systems or applications? Yes / No (delete as appropriate) Does the policy/procedural document imply or include any IT related capital investment in systems and/or hardware? Yes / No (delete as appropriate) Does the Policy/procedural document include procurement of, or

	<p>relationship with external/third party IT providers (hardware, software, systems)?</p> <p>Yes / No (delete as appropriate)</p> <p>4. Does the Policy/procedural document comply with, or impact upon Cyber Security policy OP12?</p> <p>Yes / No (delete as appropriate)</p> <p>5. Does the policy/procedural document include any changes, or impact to the patient's Health Record?</p> <p>Yes / No (delete as appropriate)</p>
Publishing Requirements:	<p>The Trust is expected to publish all documents unless there is a good reason why. Policies, procedures et al, will be published on the Trust's public website unless there is a good reason not to. The main reasons for not publishing:</p> <ul style="list-style-type: none"> • Commercially confidential data or personal information. • Patient or public safety risk <p>The answer to the next question is expected to be yes. However, if you indicate no, you will need to explain why.</p> <p>Can this document be published on the Trust's public page:</p> <p>Yes / No</p> <p>If no, please indicate why in simple terms.</p>
Risks:	Consider reputation of the organisation, financial, clinical or corporate risks that need to be highlighted
Risk register reference:	(if on local or trust risk register, Trust Risk Register (TRR) or Board Assurance Framework (BAF))
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	<p>1. Is this document relatively mature?</p> <p>2. Has there been any potential legislative or major procedural changes since the document underwent its last full review?</p> <p>3. Based on the responses to the above two questions please identify below the review frequency that should be applied to this document:</p> <p>_____ Year(s) review period (1 year being the shortest period of time and 4 years being the maximum review period that can be applied)</p>
High Risk Policy? Definition:	Yes / No (delete as appropriate)
<ul style="list-style-type: none"> • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. <p>If a policy is considered to be high risk it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee.</p>	<p>If Yes include the following sentence and relevant information in the Intended Recipients section above – In the event that this is policy is made available to the public the following information should be redacted:</p>
Other formal bodies involved:	e.g. Capital Group, CCG et al. Also state if linked approval given.

Report Details	
Title:	As per front sheet title
Item/paragraph 1.0	<p>Detail (Include details regarding updates that have been made to document as part of the review process – these can be bullet pointed)</p> <p>Or include details regarding why this document is required and has been produced.</p> <p>1-2 pages max.</p>

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version	Policy Title	
Reviewing Group		Date reviewed:
Implementation lead: Print name and contact details		
Implementation Issue to be considered (add additional issues where necessary)	Action Summary	Action lead / s (Timescale for completion)
Strategy; Consider (if appropriate) <ol style="list-style-type: none"> 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide. 		
Training; Consider <ol style="list-style-type: none"> 1. Mandatory training approval process 2. Completion of mandatory training form 		
Development of Forms, leaflets etc; Consider <ol style="list-style-type: none"> 1. Any forms developed for use and retention within the clinical record MUST be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed 		
Strategy / Policy / Procedure communication; Consider <ol style="list-style-type: none"> 1. Key communication messages from the policy / procedure, who to and how? 		
Financial cost implementation Consider Business case development		
Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation		

Ratification Assurance Statement

Name of document:

Name of author:

Job Title:

I, _____ the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines (OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Management Officer for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date:

Name of Person Ratifying this document (Chief Officer or Nominee):

Job Title:

Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to:
The Policy Management Officer

Non Clinical Strategy/Policy/Procedure/Guideline review Counter Fraud Considerations	Author response
Information	
Does the content/area of the policy involve potential fraudulent abuse by employees, sub contractors of third parties <i>(Appendix A provides an example of those policies that may be required to have preventative counter fraud controls in place).</i>	
Have fraud risks been considered at the outset and the policy requirements therefore aim to mitigate or reduce the associated levels of risk through the policy and procedural controls in place?	
If the potential for fraud or bribery is identified;	
a) Is the Trust's zero tolerance policy reiterated?	
b) Is there clear reference to the Trust's anti fraud and anti bribery policy to provide routes of reporting concerns and escalation and reference to the sanctions that could be applied?	
Does the policy make reference to the how it will be monitored for effectiveness?	
Does the policy state the consequences of failing to comply? •Disciplinary action •Civil action •Criminal prosecution •Action by relevant regulatory body	

Appendix A: Common types of policies, procedures and guidelines that can be fraud-proofed (not exhaustive)

Policy title/ area of coverage	
Accounts Receivable	Mobile computing and remote access
Asset register/Capital charge monitoring	Patients' property
Authorised signatories	Patient-identifiable information
Budgetary control procedures	Patients' travelling expenses
Cash/payment receiving and handling	Payments to primary care contractors
Car parking charges	Petty cash
Charitable funds	Pre-/post-employment checks
Code of Conduct	Private practice/fee paying-work
Confidentiality	Procurement
Controlled stationery	Recruitment
DBS/Disclosures	Relocation expenses
Declaration of interests	Secondary employment
Disciplinary	Sickness absence
Finance monthly closure	Sponsorship
Freedom of Information	Staff travel and expenses
Holiday/special leave	Standards of Business Conduct
Hospitality	SFIs/Standing Orders
Information governance	Suspension
Information security	Temporary workers
Interpreters	Tenders
Invoicing	Timesheets
Lease car scheme	Training
Lone workers	Value Added Tax
Losses and compensation	Whistleblowing

**REQUEST FOR REMOVAL/DE-
RATIFICATION OF
STRATEGY/POLICY/PROCEDURE/
GUIDELINES**

Checklist please complete all fields	
Title of document.	
Version of document.	
Name and title of person requesting removal of document.	
Will removal create a risk to the Trust or a specific staff group?	
Why is a removal requested?	
Approval for removal obtained from Chief Officer sponsor.	Chief Officer name: Date
Names of Groups and Committees consulted on removal.	
Does removal need to be communicated to any specific groups, staff or directorates if so please state.	

OP 01 Attachment 11

Divisional Standard Operating Procedure (SOP) for the Development and Control of Local Procedures and Guidelines

1.0 Procedure Statement

- 1.1** This procedure sets out the process to be used for the development and review of local procedures and guidelines. Documents are considered local where they do not overlap with an existing Trust-wide Strategy/Policy/Procedure or Guideline and their application relates solely and specifically to the activities of a local area, service or staff group. If it applies to more than one Directorate within the same Division then it remains a local procedure. If it applies to more than one Directorate across different Divisions, then it becomes a Trust wide procedure.
- 1.2** Local procedures and guidelines must not conflict with Trust-wide strategy, policy, procedures or guidelines and where appropriate, must reference the Trust-wide document which it relates to, or it is related to.

2.0 Accountabilities/Responsibilities

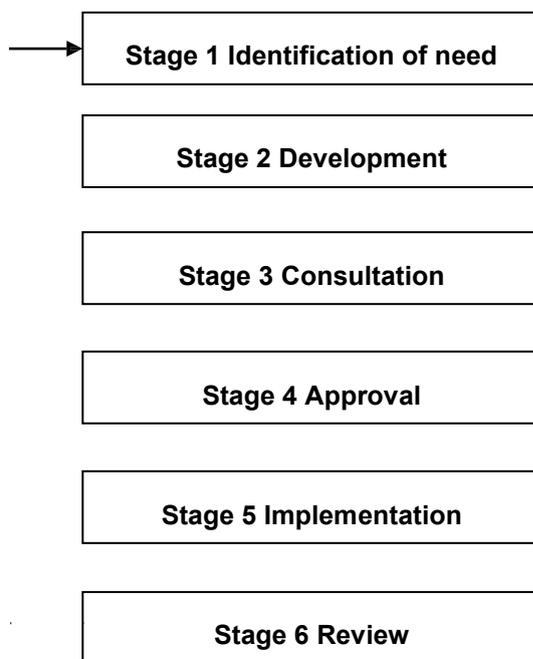
- 2.1** **The author** is responsible for the development of a local procedural document or guidelines. They will ensure that new and amended documents are developed, approved and maintained in accordance with SOP. The author must ensure appropriate consultation has been undertaken for all new and revised documents. The author is responsible for identifying implementation actions in liaison with the manager responsible for the area in which the local document applies. The author is responsible for updating all agreed changes throughout the process and providing a final approved copy of the document to the Directorate management team for file, and ultimately to the Intranet management team for publication.
- 2.2** **Directorate Management** is responsible for initial and final sign off (at Directorate Governance meetings) and for notification to the Division of any new or revised local procedures or guidelines. In such notification, the Directorate must check for adequate consultation, clarity of the document and ensuring that the document does not impact or contravene any Trust level policy. The Directorate must retain a final copy of the final document and ensure it is located on the Directorates local intranet page and is accessible by all staff. The Directorate has the responsibility to ensure their staff are made aware of new or revised local policies and procedures. The Directorate is responsible for monitoring staff engagement in newly devised or updated procedures. Communication mechanisms can be determined by each Directorate at a local level.

- 2.3 The Central Governance Department is responsible for the maintenance of a local procedural and guideline document database system and for the management of the local procedures and guidelines Governance process, including issuing monthly reports to Directorates to review and manage their procedures and guidelines.
- 2.4 **Intranet management team (IT Web Services)** is responsible for working with author(s) to ensure publication of new or revised local procedures and guidelines on Local Intranet Pages and for ensuring Local Procedures and Guidelines pages for Directorates are kept up to date by working with the Local Lead, Author(s) and Central Governance. IT Web Services is also responsible for ensuring copies of all new and out of date documents are retained and archived by Web Services.

3.0 Procedure Detail / Actions

Staff and managers developing local procedures and guidelines must follow the following procedural framework.

The Procedural Document Development Framework



3.1 Stage 1 Identification of need

Check if such a procedure or guideline or similar procedure or guideline already exist within your or another local department via the intranet department page. If yes, consider its content for consistency, best practice and the need for developing or reviewing the local document. In all cases the proposer must discuss the need for the new or revised procedure with their line manager in the first instance and the manager of the area to which the document will apply (if different).

3.1 Stage 2 - Development

3.1.1 Attachment 12 of the Trust OP01 policy outlines the steps for each stage of the

document development. In addition, authors will need to consider any professional or specialty specific material as well as local intelligence from the area concerned in developing the local document.

3.1.2 The author of the document is responsible for the following.

- Drafting the local procedure or guideline in line with style, format and minimum content as per template in [attachment 6](#) in OP01.
- Collating consultation information supplied by stakeholders.
- If there are new forms or training requirements, liaising with appropriate departments to ensure delivery of these, e.g. Education and Training, Clinical illustration etc.
- Agreeing who will communicate, implementation and monitoring the local procedure or guideline.

3.1.3 There is an increasing number of people/services who have realised that using documents already written and adopted elsewhere makes more sense than either writing your own and/or re-writing what someone else has already done.

The 3 main sources of these documents:

1. National – usually a national organisation or similar e.g. NICE, Royal Colleges.
2. Regional – usually West Midlands or Black Country network based e.g. West Midlands Cancer Network.
3. Local – usually agreed with commissioners at the ICB or with other providers.

As with existing practice regarding local documents, in each case we will require some form of evidence of the good governance of these by the producers. In each case this is likely to be something like:

1. Publication on NICE or Royal College web site.
2. A minute from a meeting providing evidence of a process and approval e.g. WMCA Minute, web site publication.
3. A minute/note/action point from an appropriate local governance meeting providing evidence of a local process and approval e.g. ED Governance Group.

In each case a copy will be required in a pdf file of the documentation in an appropriate form and where a review date has been determined, log this on In-phase.

Where links are provided to external web sites to source a document, we need to ensure staff can access them e.g. access is not restricted by a log-in/registration and/or pay-wall.

3.2 Stage 3 – Consultation

3.2.1 The author is responsible for distribution of the document for consultation and will take guidance from management and colleagues to identify key stakeholders.

3.2.2 The author must consider the impact of the document affecting patients and visitors to the service, finance, the work environment, staff, external stakeholders etc., and ensure adequate input and consultation.

3.2.3 Where local procedures and guidelines impact on or are affected by Trust-wide strategies, policies, procedures and guidelines authors must consult with those corporate services or document leads.

3.2.4 Local procedures and guidelines applicable for specific professional groups of staff must have the input of the lead professional at local level e.g., Matron, Clinical Director etc.

3.3 Stage 4 – Approval

- 3.3.1 Local procedures and guidelines **must** be approved at the Directorate Governance meeting with Directorate management and appropriate leads or specialist involvement.
- 3.3.2 This also serves to inform the Directorate management team on local practices in place.
- 3.3.3 This approval process applies to creation of new, revision and de-ratification and removal of local procedures and guidelines.
- 3.3.4** The author must update all agreed changes to the document providing a final version to the Directorate before forwarding for publication.

3.4 Stage 5 Implementation

- 3.4.1 The author is responsible for identifying all implementation actions along with the manager responsible for the area concerned. The manager of the area is ultimately accountable for the application and implantation outcomes of the local document.
- 3.4.2 Implementation of the local procedure or guideline must address the need for communication of the document to all affected staff, availability of local resources and any training, guidance or instruction.
- 3.4.3 Where appropriate it may be prudent to inform patients, visitors or other stakeholders of the existence or key components of the document.

3.5 Stage 6 Review

- 3.5.1 All local procedures and guidelines must have a review date that does not exceed 3 years. The review date is determined by the author in liaison with the responsible manager of the area. The Procedure may be reviewed earlier than determined, if guidance or practice changes or risk are raised that require urgent remedial attention.
- 3.5.2 When reviewing a document, the author must review the evidence base to determine whether the standards have changed.
- 3.5.3 The reviewed document must go through the same approval process as the new procedure.

3.6 Publication Management

- 3.6.1 The Directorate Management Team must establish a responsible lead to maintain a record (including local numerical order for version control) of local procedural documents and guidelines in existence and to liaise with Central Governance and the database.
- 3.6.2 If a recognised document management system is being used (see section 4.17 OP01), [Attachment 13](#) must be completed and a copy sent to the Policy Administrator to be kept on a Register.
- 3.6.3 Final copies of approved local procedures or guidelines will be forwarded by the author/Local Leads as follows:

3.6.4

- Nursing/Midwifery/AHP Local Clinical Practices/Procedures/Guidelines – email Nursing Education at rwh-tr.nursingahpclinicalprocedures@nhs.net;
- Medical and other Local Clinical Practices/Procedures/Guidelines email the Central Governance Department at rwh-tr.rwhgovernancelocalprocedures@nhs.net OR arsha.sharma@nhs.net.

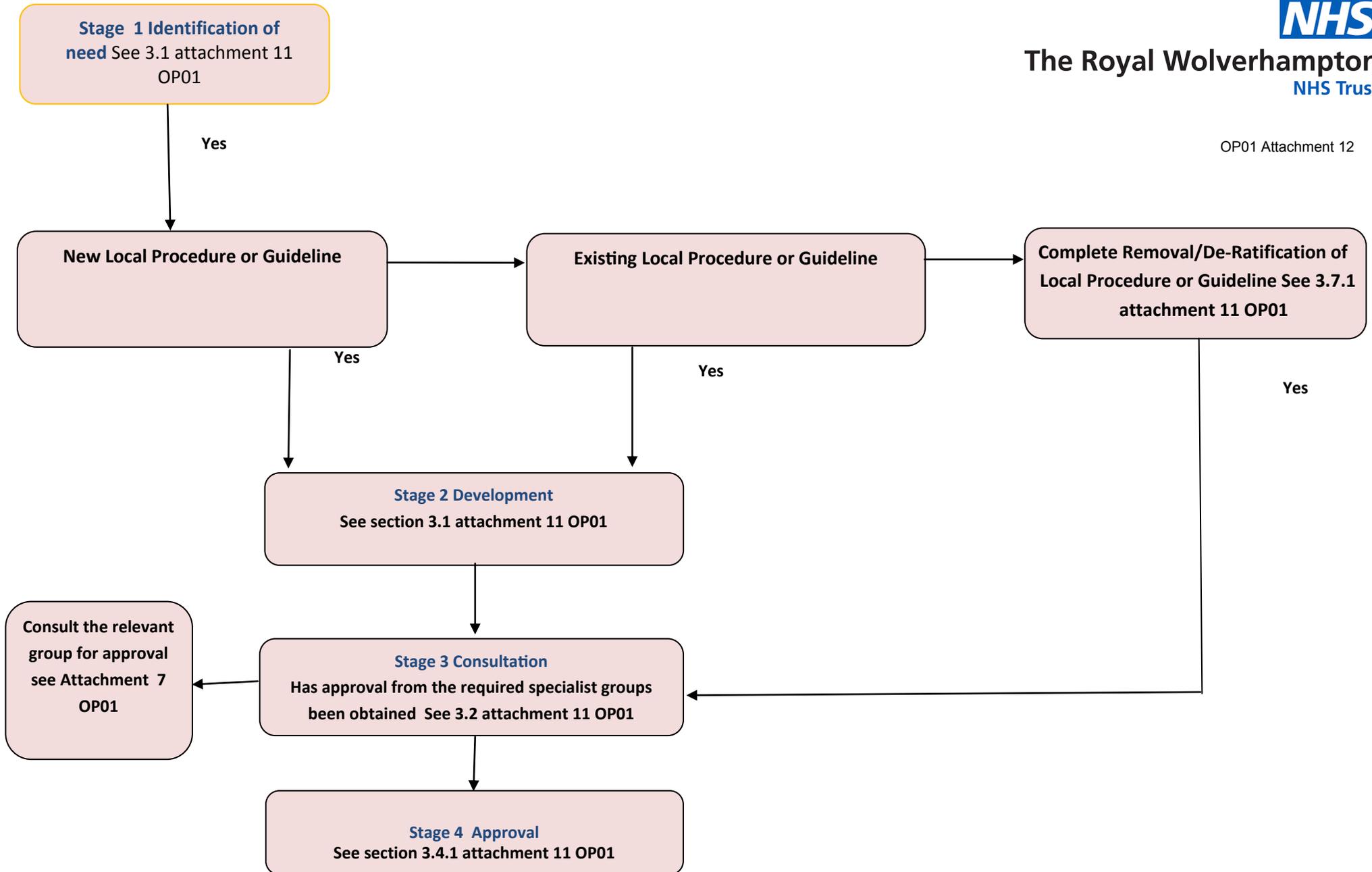
3.6.5 If a recognised document system mentioned in section 3.6.2 above is not being used, the administrators above will assign a document number for new local procedures and guidelines, and update the document database.

3.6.6 The final approved document will be forwarded by the above-named administrators to the Intranet Management Team to create a PDF and publish on the Intranet.

3.6.7 The Intranet Management Team will inform the above Administrators following publication of the documents on the Intranet. The database held by the Central Governance Department will record as a minimum the name of the document, document number, version number, date for review and local contact/author.

3.7 De-ratification/Removal of Local Procedures and Guidelines from use:

3.7.7 Where a document is de-ratified, the same process as for approval (Section 3.3.1, 3.3.2) must be followed (i.e. approved for de-ratification at Directorate level) and the decision recorded on the database. Where the document is superseded the replacement document details must be recorded on the database and an archive record kept by the Directorate.



Self Assessment Declaration for Document Management Systems for Local Procedures/Guidelines

Checklist please complete all fields	
Title of document management system including prefixes used (if any)	
Version of document management system	
Name and title of local contact/manager of document management system	
Date document management system introduced	
Review date of document management system (e.g contract renewal)	
Name of group with local approval responsibility/oversight	
Details of formal governance and approval system – who/where is Governance Assurance forwarded to e.g Directorate Specialist Group Lead/Head/Manager	
Details of any audit undertaken e.g criteria, date, reported to.	

Attachment 14 - Policy, Procedure, Local Procedure and Guideline Risk Assessment for extensions

Purpose, function, process

The Royal Wolverhampton NHS Trust has to assess the risk of extending and continuing using a policy, procedure et al, on a risk assessed basis – i.e., is the risk of maintaining the document beyond its due review date greater than not having any document available. In most cases, documents that remain fit for purpose can be maintained in use without presenting further, additional or unacceptable levels of increased risk. This does not remove the requirement to undertake a full review, it does not re-set the review period for the document and is not an acceptable replacement for a full and proper review. In all cases, only one extension application is acceptable. Multiple requests and extensions are not acceptable and will be refused and subject to further review with the Responsible Director.

In every case where an extension is requested, the responsible Director, with reference to key information from:

- Criteria 1 – Local Procedures and Clinical Guidelines Lead / Policy Management Officer, Intranet, Service Area Leads.
- Criteria 2 – Governance Team re SI/CQC.
- Criteria 3 – Local Procedures and Clinical Guidelines Lead / Policy Management Officer and nominated Author.
- Criteria 4 – Library search, Governance Team, Service Area Leads.
- Criteria 5 – Local Procedures and Clinical Guidelines Lead / Policy Management Officer, Equality, Diversity & Inclusion Team, Counter-Fraud service.
- Criteria 6 – Responsible Directors / Divisional lead Risk Assessment.

is expected to review the risk profile, complete this form and provide it as evidence to the Policy Management Officer, where it will be considered for Chairs action by the Group Company Secretary.

Warning! In the course of introducing this risk-based approach, documents have been presented as risk assessed for extension where there has been legislative change and/or national guidance change, making it no longer fit for purpose! Please ensure that the criteria are properly considered and applied – Criteria 4 below.

Action

Approved by Trust Management Committee, on behalf of the Executive Team. Attachment to OP01

Keith Wilshere, Group Company Secretary, 14.2.23

Review Pro-forma

Ref Number	Policy et al Name	Version	Last review date	
Criteria			Y/N	Initials
1	Is it currently 'live' and in use (on TrustNet, Locally Governed)?			
2	Are there any known related risks from Serious Incidents and/or CQC visits?			
3	Is there a realistic prospect of the scheduled review taking place within the next month?			
4	Has the legal or legislative, regulatory, national instruction or guidance context changed since the Policy was last reviewed/updated?			
5	Is the Equality Impact Assessment in place and in good order (Stage 1 minimum), has any required Counter-Fraud Assessment been completed?			
6	On a risk assessment basis is the responsible Director/Divisional lead prepared to extend the lifetime of the Policy in its current form? – and if so, for how long?			
Date	Director Sponsor (for Trust-wide documents) / Divisional Lead (for local documents)	Extended for	Extended to	



Title	BCPS Document Control
Unique identifier	PAT/SOP/003
Version	2.2
Date issued	March 2021
Review frequency	Biennial
Authorisation	Quality Manager

The electronic copy of this document is the only version that is maintained. Printed copies must not be relied upon to contain the latest updates and amendments.

All processes and procedures described herein are mandatory within the Black Country Pathology Services.

Policy No OP01/ Version 9.0 / TMC Approval January 2022 / Appendix 1

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This is a controlled document; all authorised copies must contain this part of the footer in red. Do not photocopy



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1 INTRODUCTION

1.1 Scope and purpose

This document outlines the control of documents required by the quality management system of the Black Country Pathology Service (BCPS) to ensure that unintended use of any obsolete documents is prevented. Key documents of the quality management system include:

- a quality manual [PAT/SOP/001]
- a quality policy [PAT/SOP/002]
- documented procedures and records required by ISO15189 [PAT/INFO/1]
- documents including the records required for the effective planning, operation and control of its processes
- external documentation such as Royal College of Pathology guidance, IBMS guidance, reference books, standards and regulation.

All controlled documentation must be managed through the software application Q-pulse, which maintains the master inventory of documents and provides an audit trail for document revision and retention of both active and archived versions. Documents which are available as hard copies only, must have a 'document record' created in Q-pulse (stating the location of the hardcopy) to ensure an effective document control system is in place. Examples include external documents such as reference books, relevant regulations and standards.

Controlled documents are those that may vary based on changes in versions or time. Examples include procedures, COSHH and risk assessments, forms, charts, instructions, notices, agreements and biological reference ranges. All of which require regular review and approval for use.

All departmental procedures and investigations must be outlined within a standard operating procedure (SOP). A SOP is a document that provides clear and concise information, policies and guidelines, methodologies or procedures that have been agreed and approved. This document outlines the requirements of a process. Staff must follow and adhere to the relevant SOP(s) when carrying out an activity. SOPs endeavour to cover all aspects of the intended scope, however every eventuality may not be covered, and in these instances staff must seek advice and guidance from a senior member of staff immediately.

Controlled documents must fulfil the following:

- Be clear, concise, uniquely identifiable and accessible
- Validated and approved for their intended use prior to issue. Hand written amendments are not allowed to printed documentation.
 - Amendments made to written text on controlled documents (i.e. forms) then the amendment should be clearly identifiable. A single 'strike through' the original text with the amendment clearly legible next to the correction.
- Be up to date, reviewed within the stated review period and revised as necessary
- Changes (amendments) and their current version status identified and notified to relevant users
- Only current (active) versions available at the point of use and unintended use of obsolete documents is prevented
- Obsolete documents/ versions are identified as such, archived and easily retrievable
- Documents of external origin are identified and controlled.
- Uniquely identified and accessible.

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1.2 Responsibility

The management of controlled documentation is the responsibility of the departmental service leads; namely the appropriate Discipline/ Clinical lead or delegated quality lead (as defined in the Quality Manual). The administrator for the Q-pulse system is the BCPS Quality Manager.

All controlled documentation must be approved prior to implementation by the named approver or another delegated individual. The pathology wide documents (BCPS procedures) are approved by the BCPS senior management team (generally via the BCPS Quality Meeting) or by the Quality Manager as defined in the Q-pulse document record. If approval is obtained via email or meeting, a record of evidence should be attached to the document record for evidence purposes.

All printed copies of a controlled document must be approved and signed by the author or approver. All authorised printed copies must be bound, signed and dated and contain a footer (as described in this document). **Any copies not meeting these criteria are not valid and must be discarded. The validity of any printed copies should always be checked against the electronic version.**

Single printed sheets from controlled documents can be used provided they are signed by the author or approver and dated. They must have footers containing the controlled document number and the version number.

Staff must adhere to The Royal Wolverhampton NHS Trust policies, BCPS and laboratory's procedures at all times. Departures may only be permitted when it can be shown that there are valid technical reasons for doing so and that the quality of the laboratory's tests is not thereby set at risk. Any such departure from stated procedure must first be approved by either a member of the department's Clinical/Technical management team. The justification for the departure, together with the endorsement of the respective member of staff, shall be noted in the relevant records.

It is the responsibility of all laboratory staff to ensure they are familiar with and work to current versions of the quality manual, referenced documentation and standard operating protocols relevant to their job role.

Where it is found that staff have in any way departed from the laboratory's documented policies and procedures (intentional or unintentional), that any such departures may affect the validity of tests being carried out, work shall be stopped immediately. The senior member of staff responsible for the area concerned shall be informed and the matter thoroughly investigated to assess the potential impact of such deviation and if document review is required. Any test items identified as being at risk shall, where appropriate and possible, be repeated. Alternatively, the user of the service will be notified and a repeat sample requested; in these instances the Clinical and Technical lead of the department must be informed immediately and the incidence reported on the Trust incident management system, Datix.

1.3 References and related documents

OP01 Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedures and Guidelines [OP01 Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines \(xrwh.nhs.uk\)](http://xrwh.nhs.uk)

ISO 15189: 2012 Medical laboratories- Requirements for quality and competence [PAT/INFO/1]

Records Management NHS Code of practice 1 & 2 [PAT/EXT/002]

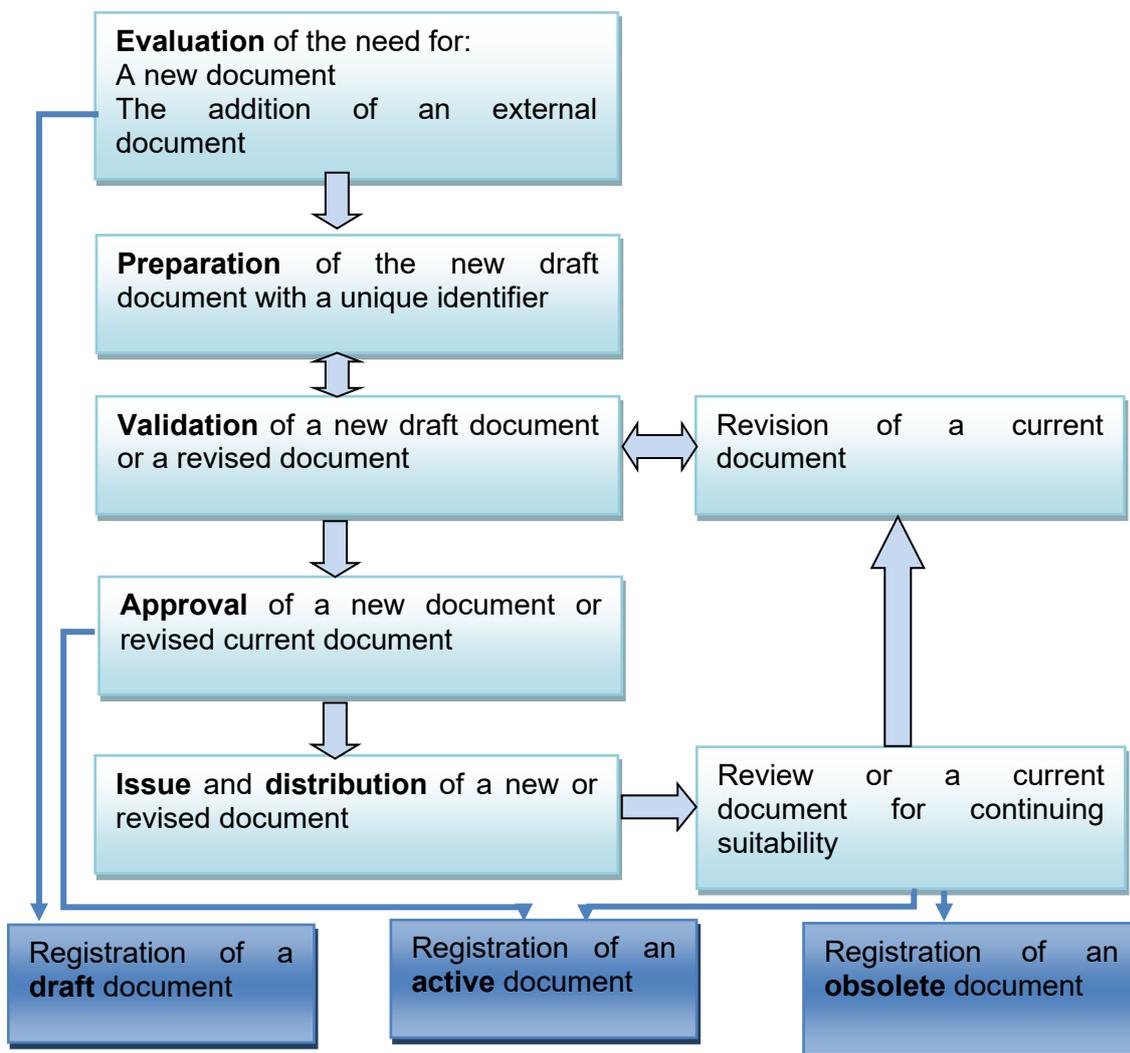
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PAT/SOP/029 Q-pulse guidance

Related Documents include [RWT Quality manual A1.001P.PAT, SWBHT Quality manual 128-85, DGFT Quality manuals- Microbiology QM/00006, Cellular Pathology SOP/CP/M01, Immunology QM/I/0016, Biochemistry QM/002, Haematology QM/00003, Blood Sciences BGS666].

1.4 Documentation

The overall process diagram for the preparation and control of documents is shown below:



2 DOCUMENT CONTROL

2.1 Q-pulse

Controlled documents are managed through the use of the Q-pulse document module. This module records the document unique identifier, title, date of issue, version number, revision status, approval (authorization), distribution and review history. New members of staff will receive instruction on the use of Q-pulse as appropriate to their job via BCPS Induction session run by the

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quality team or delegated individual. All controlled documents must have a different person named as author and approver.

The document module contains three document registers that are used by the BCPS:

- Active register- this register contains only approved current versions of a controlled document and is available to view to all personnel with access to Q-pulse.
- Draft register- this register contains only draft versions of a controlled document, these may be documents currently under review or new un-activated documents. These documents require approval before they are transferred into the active register. Draft documents are available to view to all personnel with access to Q-pulse; however, Q-pulse default settings show users the 'active register' not the draft register.
- Obsolete register- this register contains previous versions of a controlled document which have been superseded or have been made obsolete. The obsolete register is only available to view by personnel with full access permission to the document module.

Q-pulse contains a history for each document, including previous version, author and approver, submission and accepted date.

A routine backup of the Q-pulse system is made automatically by the RWT IT department on a regular basis to an independent drive.

The electronic active version on Q Pulse (the original document) remains the active document for use until the approved draft copy supersedes it.

2.2 Q-pulse access

The Quality Manager is the administrator of Q-pulse. Access to Q-pulse is via a unique login and password control with the user access level customisable depending on the user's role. Q-pulse may be accessed from a number of computers throughout the BCPS. Access is via the Q-pulse main module.

User access levels for Q-pulse are as follows

Level	Permissions	Example job roles
System wide access	Access to all modules	Quality Manager and Deputy Quality Manager
Administration	Full access to the administration module to enable the creation and archiving of users accounts.	Quality Team
Document permissions (static permission)	All members can perform all permissions within this module on ANY record, as these have been granted here as static permissions and not by using Dynamic permissions where users are named	BMS 4 & BMS 3, Quality Leads and BMS2s
Audit permissions (static permission)	All members can perform all permissions within this module on ANY record, as these have been granted here as static permissions and not by using Dynamic permissions where users are named	BMS 4 & BMS 3, Quality Leads and BMS2s.
CAPA permissions (static)	All members can perform all permissions within this module on ANY record, as these have been granted here as static	BMS 4 & BMS 3, Quality Leads and BMS2s

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permission)	permissions and not by using Dynamic permissions where users are named	
Asset permissions (static permission)	All members can perform all permissions within this module on ANY record, as these have been granted here as static permissions and not by using Dynamic permissions where users are named	BMS 4 & BMS 3, Quality Leads and BMS2s
People permissions (static permission)	All members can perform all permissions within this module on ANY record, as these have been granted here as static permissions and not by using Dynamic permissions where users are named	BMS 4 & BMS 3, Quality Leads and BMS2s
Training permissions (static permission)	All members can perform all permissions within this module on ANY record, as these have been granted here as static permissions and not by using Dynamic permissions where users are named	BMS 4 & BMS 3, Quality Leads and BMS2s
Dynamic access	Permission to amend records only if named as the 'raiser', 'author' or 'approver' within that specific record file.	Named individual
Basic access	Allows access to all documents for view, launch pad access and change requests, and suggestions/ actions	All personnel

Table 1 Q-pulse permission levels

3 REVIEW PROCEDURE

All documentation will be subject to a formal review in accordance with table 2. Each controlled document must have a named document author and approver (owner) allocated and recorded in the relevant Q-pulse record.

Document type	Minimum review period	Comments, exceptions
Procedures, protocols and policies	2 years (biennial)	Annual review may be set for key documents and must clearly state if the document requires annual review i.e. quality manual and policy, induction pack, business continuity plan
Forms	5 years	
Notices & instructions	3 years	
Patient information leaflets	2 years	
Action messages	N/A	
Service level agreements	1 year	Unless specified otherwise within agreement
Minutes	N/A	
Audit Templates	5 years	
Training & competency	3 years	Or sooner if associated procedures are changed
Job descriptions	1 year	Review at appraisal

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Change Control		N/A	
MU data		1 year	
External Documents		1 year	Unless review date stated
Health and Safety Documents	COSHH Assessments	2 years (biennial)	Must use RWT template
	Risk Assessments	1 year	Must use RWT template
	SDS	2 years	Unless updated by manufacturer earlier

Table 2 Document review periods

4 EVALUATION

Evaluation is required for the creation of new documents, the addition of external document or the review of an existing document outside the pre-determined review date. Requests for document evaluation can be made by any responsible person, generally the person responsible for overseeing the preparation and control of documentation, including editing and approving documents. Responsible persons may have responsibility for particular activities (e.g. part of a regional group) or be a section lead in a laboratory (e.g. automated section). Change requests however, can be raised by all pathology staff; this can be achieved by raising a change request against the specific document using the 'change request' function in Q-pulse.

Evaluation of the request is carried out by the relevant authorised person (refer to section 1.2). The purpose of evaluating requests is to avoid proliferation of unnecessary documentation. If the need is established then a title and author are decided upon and a target for completion of the document is agreed. Under no circumstances should SOPs be introduced or changed without the prior agreement of the BMS4 or BMS3. Should the document require a revision, the new version must be approved by all allocated approvers for that document before implementation.

The suggested protocol for the version numbers of revisions is

- Use subset numbers for minor revision e.g. 5.1, 5.2 ...etc
- Use whole number steps for major revisions e.g. 5.0, 6.0 ...etc.

Q Pulse up-revises automatically from the last version number, but this can be changed manually if necessary using the above revision number system.

Change requests are recorded in the Q-pulse document record and the author must indicate if change requests are agreed and implemented or document the reason the change request is not implemented.

When a document has been reviewed or amended the older version is archived by Q-pulse and these archived versions remain available for lookup if required.

5 PREPARATION

All new documents require a 'document record' to be created in the draft register on Q-pulse with a unique identifier; this allows the document to be controlled during the creation process.

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The document unique identifier to be used should be created using the appropriate informative filename system adopted by each discipline to label files. The unique document filename system templates are described below:

<p>Department identifier Example: PAT/SOP/000</p>	<p>The abbreviation of the discipline shall be used to identify the document and the associated colour used for the title background colour):</p> <table border="1" data-bbox="400 499 895 884"> <tr><td>Pathology</td><td>PAT</td></tr> <tr><td>Chemistry</td><td>CHE</td></tr> <tr><td>Haematology</td><td>HAE</td></tr> <tr><td>Cellular Pathology</td><td>HIS</td></tr> <tr><td>Cytology</td><td>CYT</td></tr> <tr><td>Immunology</td><td>IMM</td></tr> <tr><td>Microbiology</td><td>MIC</td></tr> <tr><td>Blood Transfusion</td><td>BLT</td></tr> <tr><td>POCT</td><td>POC</td></tr> <tr><td>Sample Reception</td><td>REC</td></tr> <tr><td>IT</td><td>IT</td></tr> </table>	Pathology	PAT	Chemistry	CHE	Haematology	HAE	Cellular Pathology	HIS	Cytology	CYT	Immunology	IMM	Microbiology	MIC	Blood Transfusion	BLT	POCT	POC	Sample Reception	REC	IT	IT
Pathology	PAT																						
Chemistry	CHE																						
Haematology	HAE																						
Cellular Pathology	HIS																						
Cytology	CYT																						
Immunology	IMM																						
Microbiology	MIC																						
Blood Transfusion	BLT																						
POCT	POC																						
Sample Reception	REC																						
IT	IT																						
<p>Categorisation of document Example PAT/SOP/000</p>	<p>AM: Action message EQA: External quality assessment scheme/reports FOR: Forms (AUD: Audit) INFO: Information (External documents, NEWS: Newsletters, PIL: Patient information leaflets) NOT: Notices PER: Personnel (JD: Job description, TC: Training and competency) SLA: Service level agreements SOP: Standard operating procedures MIN: Minutes VAL: Verification, Validation, Change control, Measurement of uncertainty (MU)</p> <p>Categorisations used for health and safety documents are: H&S: Health and safety CA COSHH assessment RA Risk assessment SDS Safety data sheets</p> <p>Minutes of meetings use the acronym of the meeting e.g. governance is GOV</p>																						
<p>Document number Example PAT/SOP/1</p>	<p>Document numbering commences at 1 and increases consecutively as required i.e. 1, 2, 3 etc.</p>																						

All document records must include:

- A title
- A unique identifier on each page
- The current version number
- Page number to total number of pages (e.g. page 1 of 5)
- Authority for use /authorised copy

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- Location of printed copies

The department shall, wherever possible, use methods and procedures that are up-to-date and established as standard. All new methods should be evaluated prior to implementation as per protocol.

Where methods and procedures are used that are not established as standard, or where standard specifications require amplification, such methods and procedures shall be documented to the extent necessary to ensure proper implementation and to ensure consistency of application.

Procedures shall contain all the information necessary to ensure the proper performance of the test. It is strongly recommended that SOPs follow the format adopted in the standard template (attached in document record). A standardised front cover and footer must be used. Most forms and notes are a single page and do not require a front cover. Risk and COSHH assessments must be use the current RWT templates, available on the intranet/ governance department [Templates \(xrwh.nhs.uk\)](http://Templates.xrwh.nhs.uk). SOPs should have clear succinct titles and all printed copies must have a completed, signed and dated front page.

The content headings of the template should be adapted as necessary to the procedure discussed. Minimum information which shall be incorporated into such methods, where appropriate, should include the following sections:

- Front cover / title page
- Introduction
- Scope and purpose / principle
- Responsibilities
- References / related documents
- Resources required: equipment, reagents (including metrological traceability)
 - Sample collection / reception & rejection / storage / preparation
 - Test procedure
 - Reporting (including calculation procedures)
 - COSHH and risk assessments
 - Health and safety Instructions
 - Footer section: includes unique document identifier, version number, review period, and page number. This should be in colour to identify photocopies.

Reference should be made to external and active internal documents where appropriate. During document review any referenced documents must be checked for version control however it is not expected that referenced documents are reviewed at this point as all controlled documents have a scheduled review date to support pathology's document review plan and help manage resources effectively. For version control checks, any internal documents referenced are checked to establish they are still available on the 'active' register and external documents checked to confirm the BCPS references the latest version.

Controlled documents should use Arial font, size 11, left justified, with the exception of the title page (font size 12) and footer (font size 9); refer to template.

Standardised units should be used where possible. The base unit for volume is Litre (l or L), so use mg/L rather than µg/ml. Use the abbreviations µg and pg for micrograms and picograms (not mcg or pcg (or mmcg)).

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Printed copies of documents are for reference purposes only and must be signed by the author/ approver and dated. The electronic copy must be used as the current version, which is maintained on Q-pulse. Printed copies must have the footer printed in red to identify photocopies. Any copies not meeting these criteria are not valid and must be discarded. Printed copies of documents should be kept to a minimum.

Template document attached (in Q-pulse record) contains a template for front cover, SOP content and footer and a further template document with instructions included regarding automatic contents page links. Forms and notices only require the version controlled footer not first page.

6 SUBMISSION AND APPROVAL

When the draft version of the document is ready for approval the author must submit the document for approval using the electronic submission function within Q-pulse. This records the date of submission and will automatically email the approver stating the specific document requires approval.

The approver must then review the draft document fully and accept the new version if no amendments are required using the accept draft function within Q-pulse. If the approver does not accept the draft version this must be recorded within Q-pulse reject function and the reason for refusal must be provided to enable the author to make the relevant amendments.

Once the draft document has been approved it must be activated using the wizard. The wizard allows the draft version to replace the current active version of the document into the active register and transfers the replaced version into the obsolete register. All controlled documents must be permanently retained.

A document can be approved at a meeting, however, evidence of approval i.e. details of which meeting is was approved so minutes can be checked, must be added to the document record for evidence of approval.

6.1 Transitional phase of BCPS project – document management

During the transition period, BCPS wide SOPs may be approved by the Quality Manager initially until a single QMS across all sites is in place as they may be transitional versions required during the transitional phase of the network consolidation.

Refer to PAT/SOP/029 Q-pulse guidance Appendix 1, for the procedure on how to transfer controlled documents from previous QMS systems across the BCPS (i.e. RWT Q-pulse, DGFT Q-pulse, SWBHT iPassport and WHT iPassport) into BCPS Q-pulse.

7 AVAILABILITY AND DISTRIBUTION

All methods and procedures (standard specifications, in-house methods, etc.) and any other information relevant to the performance of the test procedure shall be readily accessible to staff at all times. All controlled and authorised documentation are available through Q-pulse. Paper copies of this documentation may be available in some departments and where this occurs there must be a robust mechanism in place to ensure these are replaced whenever the authorised version on Q-pulse is updated. It is the responsibility of the person activating the document to ensure all printed copies of

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the document are replaced with the new version. Hardcopies of the new version must be signed and dated by the author/ approver and have a red footer.

To overcome the eventuality of a system failure or network breakdown, which may prevent access to Q-pulse, a signed printed copy of essential documents may be made available. It is essential these copies be kept up-to-date. Examining the page footer easily identifies the version number.

The distribution of new or revised documentation is made through the Q-pulse acknowledgement system. On activating a new or revised document it is essential that the document is distributed to the appropriate staff. Copyholder templates are available to all disciplines which allow pre-defined groups of staff to be notified via Q-pulse; the notification requests the individual to acknowledge the new or revised document which they have been informed about. It is the responsibility of the individual staff member to acknowledge the new version of the document within Q-pulse.

Note: copy holder templates are updated as users are added and removed from Q-pulse by the Quality team, however if staff member move job roles within the BCPS, it is the responsibility of the responsible manager to ensure distribution lists are reviewed and updated accordingly.

One or a combination of the copyholder templates can be used to ensure all appropriate members of staff are informed about new and revised documents. The choice of copyholder templates selected is the responsibility of the individual activating the document.

For key documents such as the pathology wide documents, for example, quality policy and quality manual, it essential all staff within BCPS are included in the distribution list.

It may be inappropriate to use the distribution mechanism in Q-pulse for all staff (such as for RWT transport staff who do not have access to Q-pulse), in which case the person responsible for ensuring all printed copies are replaced with the new version are responsible for ensuring key personal outside pathology are informed. Informing all staff (in this instance Trust transport drivers) may be delegated to the appropriate Manager. Evidence of informing personnel outside of Q-pulse must be recorded and documented evidence attached to the appropriate document record.

All staff have the ability to raise change requests against individual documents within Q-pulse. If staff members identify errors or improvement suggestions they should raise a change control via the wizard (all staff are shown how to raise change controls as part of QMS/basic Q-pulse training). The document author will automatically be notified via email of the request; they can then accept/reject the change request as part of the review process.

8 EXTERNAL PAPER DOCUMENT CONTROL SYSTEM

In some cases external documents are only available as a paper copy, for example equipment manuals, kit inserts, standards and regulations. These may be controlled by a paper document control system provided the following procedure is applied:

- a) External documents shall have a document record created on Q-pulse to record the document title, unique identifier, and date of issue, review date, version number, location of hardcopy and the name of the approver. The version number should match the documents edition number.
- b) External documents should be filed under document type 'external'.
- c) External documents shall be approved for use by authorised personnel prior to issue.

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The documents will be updated as and when new documents become available and as a minimum the complete file will be reviewed every 5 years.

Pathology request forms must be controlled through Q-pulse; however amendments are made by the RWT Medical Illustrations department or the printed stationary supplier who require approval from the BCPS Senior Management team or Discipline Lead. The Quality Manager is authorised to approve request forms on behalf of the BCPS.

9 WEBSITE

The BCPS website is the main facility for users to access relevant information and guidance regarding the BCPS. The website should be regularly maintained to ensure the information contained on the site is current and updates should occur in real-time. Q-pulse must contain a document record for the website to provide a robust mechanism to ensure pages are reviewed at a minimum biennially.

Amendments to the website can be made by personnel issued with a login and password, generally the Clinical Lead, Technical lead, Quality Manager and other designated personnel.

The name of the individual updating the page and the date (month, year) of the update should be indicated on individual web pages as appropriate.

When the amendment has been made, it must be submitted for approval. Approval is performed by the designated person with the appropriate system permissions. Once approved, the new version of the web page shall be published on the website.

10 USE OF LOGO'S

The use of external logos by the BCPS is discouraged, unless written permissions have been obtained from both the logo owner and the BCPS Chief Medical Officer. The only approved logo used by the BCPS is the BCPS logo. In specific circumstances use of Owner Trusts logo may be required; however approval must be obtained from the appropriate Owner Trust and the BCPS Chief Medical Officer.

11 AUDIT

Performance of the document control process will be assessed though the internal audit programme and monitored via KPIs.

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BCPS RISK MANAGEMENT Operating Framework

DRAFT

Version: DRAFT Feb 2020

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1.0 Aim & Objectives

This document specifies the risk management strategy adopted by the Black Country Pathology Services (BCPS) and the Owner Trusts to achieve an effective and integrated approach to governance and risk management. It supports the delivery of high quality services and protects staff, patients and others through an integrated approach to risk management (whether the risk relates to patient care, health and safety, welfare, environmental, information governance, business continuity or finance).

It shall achieve this by:

- Informing staff and the key stakeholders of the principles underpinning the overall risk management arrangements and reporting mechanisms between the BCPS and the Owner Trusts, as agreed in the BCPS Partnership Agreement.
- Defining the systems of risk management and assurance adopted by the BCPS and the Owner Trusts to ensure it operates in accordance with national and legal requirements.
- Outlining a clear and effective communication mechanism between BCPS and the Owner Trusts that enables information sharing and provides effective assurance of risk management.
- Clearly defining the framework of risk management between BCPS and the Owner Trusts to ensure that risks are identified, evaluated, prioritized for action and monitored.
- Defining roles and responsibilities within the BCPS and at the Owner Trusts for risk management to ensure a consistent approach.
- Fostering an open culture that supports the vision of the BCPS Partnership Agreement in the identification of risks and associated learning.
- Promote a culture, environment and structure within BCPS whereby the principles of governance and risk management are applied to improve patient outcomes.

2.0 Scope

The BCPS risk management strategy agreement is made between the BCPS and its Owner Trusts, as stated below:

1. **The Royal Wolverhampton NHS Trust (RWT)**
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
WV10 0QP
2. **The Dudley Group NHS Foundation Trust (DGFT)**
South Block
Russells Hall Hospital
Pensnett Road
Dudley
West Midlands
DY1 2HQ

3. **Walsall Healthcare NHS Trust (WHT)**

Manor Hospital
Moat Road
Walsall
WS2 9HQ

4. **Sandwell and West Birmingham Hospitals NHS Trust (SWBHT)**

Trust Headquarters: Health and Wellbeing Centre
Sandwell General Hospital
Lyndon
West Bromwich
B71 4HJ

The Trust hosting the BCPS on behalf of the pathology network is RWT. The RWT framework for governance and risk management as defined within their Trust policies (Risk Management Assurance Strategy and Risk Management and Patient Safety Reporting Policy OP10) shall underpin this strategy, unless clearly stated otherwise.

3.0 Personnel

It applies to all members of staff, either permanent or temporary working within the BCPS or at one of the Owner Trusts, under a contract for services.

4.0 Definitions

Host Trust	Nominated Trust hosting the BCPS on behalf of all Owner Trusts.
Owner Trusts	Trusts named within the BCPS Partnership Agreement to transform the provision of pathology services within the Black Country, through the establishment of the Black Country Pathology Service (BCPS).
Assurance	Evidence that risks are being effectively managed.
Risk register	A record of risks identified through internal processes that will impact on the delivery of the BCPS objectives/ plans.
Current risk	The risk remaining with the current controls in place.
Mitigated risk	The risk following controls being implemented.
Operational risks	Risks associated with the day-to-day operation of the BCPS and/or Owner Trusts.
Material risk	Defined as a risk with a score of 12 or above

5.0 Strategic Context / Background

All NHS Trusts have a responsibility to ensure that the principles of clinical and other governance domains are embedded throughout the organization.

Clinical governance describes activities, such as risk management, clinical audit and clinical effectiveness that support, maintain and improve the delivery of healthcare services. Moreover, the clinical governance provides a framework and environment within which these activities are to be undertaken. As part of this agenda, the activities described herein, are considered fundamental to the improvement of patient care and the provision of assurance to both the BCPS and the Partner Trusts of the quality of care provided.

The BCPS was established on the 1 October 2018, followed by a period of transition, known as the 'transition period' until the full implementation program is completed as defined in the BCPS Partnership Agreement. Full migration of services to the agreed target model is expected during 2021. During the transition phase there will be incremental changes in the provision of pathology services in the Black Country towards the agreed target model.

Currently, all incidents, complaints and risks raised are managed in accordance with the appropriate Owner Trusts risk management and governance policies and procedures. Data records associated with risk management are managed and retained within the individual Owner Trusts risk management software systems (Datix/ Safeguard). To ensure effective management across all Owner Trusts and BCPS, during the transition phase, key staff members must report in parallel to the appropriate Owner Trusts and the BCPS with all matters regarding risk management.

The formally agreed reporting structure between BCPS and Owner Trusts is detailed below. The strategy intends to define the roles and responsibilities of the BCPS and that of the Owner Trusts in meeting the needs and requirements of the risk and governance agenda. This will include defined communication pathways and the processes by which all parties demonstrate compliance.

6.0 Roles and responsibilities

To support the risk management strategy and framework described herein, key individual roles and responsibilities across the Owner Trusts and BCPS for the delivery of risk management activities are described, these include:

BCPS Strategic Board

Responsible for review and analysis of any material risks that has been escalated by the BCPS, including the monitoring of such risks until mitigated to a risk score below 12.

BCPS Operations Performance Group Chair

Responsible for the management of risks including service failures and their escalation to BCPS Strategic Board as required.

BCPS Clinical Reference Group Chair

Responsible for the monitoring and review of all BCPS risk registers on a monthly basis.

BCPS Clinical Director

The BCPS Clinical Director is accountable to the BCPS Clinical Reference Group for the ensuring BCPS is delivered within the BCPS Partnership Agreement.

BCPS Operations Manager

The BCPS Operations Manager is responsible for developing and monitoring the project plan for the consolidation of pathology services within in the Black Country in accordance with the BCPS Partnership Agreement.

Head of Governance at Owner Trust

The Head of Governance is accountable for supporting the Owner Trust Board members in the risk management activity. RWT, as host of the BCPS shall be responsible for reporting serious incidents and externally reportable incidents associated with the BCPS. The Owner Trusts and the

BCPS have a responsibility to share risk management data appropriate to its service provision to enable effective risk management.

BCPS Quality Manager

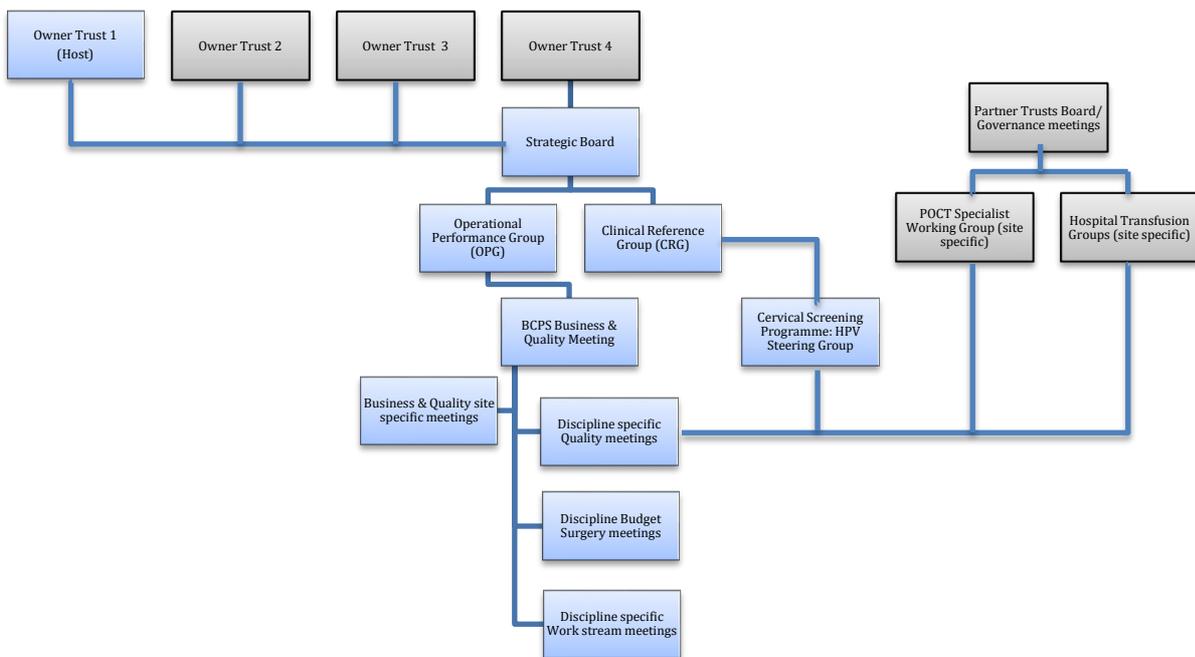
The BCPS Quality Manager has delegated responsibility for risk management activities within the BCPS. They have responsibilities around: incident management, risks, legal claims, clinical audit, NICE, national guidance, external reviews, patient information, and accreditation of services (UKAS), information governance, safety alerts and the BCPS quality management system.

All staff

All BCPS staff members are responsible for governance within their areas of responsibility. They must adhere to policies and process as outlined in this strategy.

7.0 Current Position

7.1 Assurance Reporting Structure



Meeting title	Interval (minimum)	Chairman
Strategic Board	10 per year	Agreed independent Chair.

BCPS Clinical Reference Group (CRG)	10 per year	Medical Director (RWT)
BCPS Operational Performance Group (OPG)	10 per year	Financial Director (RWT)
BCPS Quality & Business Group	10 per year	BCPS Clinical Director

The BCPS shall provide a risk management summary report to the Owner Trusts each month; trend analysis shall be included in the report on a quarterly basis. The risk management summary reports shall be distributed as stated below.

Site	Contact
RWT	Head of Governance
DGFT	Patient Safety Manager
SWBHT	Head of Patient Safety and Risk
WHT	Director of Governance

7.2 Data sharing

Since 1st October 2018, the BCPS Owner Trusts are Joint Data controllers of the BCPS (refer to the Joint Data Controller Agreement, version 1, September 2018).

8.0 Risk management matrix

All risks will be recorded and evaluated in a five by five risk matrix used by the Host Trust. This is based on scoring the consequence (severity) of the risk by the likelihood of it occurring; consequence x likelihood = risk rating. Owing to the variation in the five by five risk matrices RAG rating between the Owner Trusts (refer to appendix 1), risk rating must be communicated (i.e. likelihood 2 x consequence 2 = risk rating of 4) as opposed to RAG rating. The overall risk rating shall be used as the trigger for escalation.

The BCPS shall use the Host Trusts (RWT) risk categorisation matrix for RAG rating, shown below.

Likelihood	Consequence				
	1 - Insignificant	2 - Minor	3 - Moderate	4 - Major	5 - Catastrophic
5 - Almost Certain	5	10	15	20	25
4 - Likely	4	8	12	16	20
3 - Possible	3	6	9	12	15
2 - Unlikely	2	4	6	8	10
1 - Rare	1	2	3	4	5

8.1 Proposed BCPS risk management system framework

The system framework for risk management used by the BCPS and its Owner Trusts must be adhered to, in order to support the safe delivery of pathology services. Any changes to systems must be approved via the BCPS Clinical Reference Group to the BCPS Strategic Board.

Each Owner Trust shall be required to provide assurances to the BCPS Strategic Board around the effective sharing of risk management data in accordance with this document and any exceptions to this.

8.2 Risk register

Pathology related risks shall be managed in accordance with RWT risk management policies and procedures and shall be maintained centrally by the BCPS on the Host Trusts risk management software system (Datix).

Once a risk is identified, the identifying manager must complete a risk assessment. Requests for registering new risks must be received via a completed new risk notification template (appendix 2) to ensure full disclosure of details relating to the risk identified. The completed new risk notification template must be emailed to rw-h-tr.bcpsquality@nhs.net within the timeframes stated below:

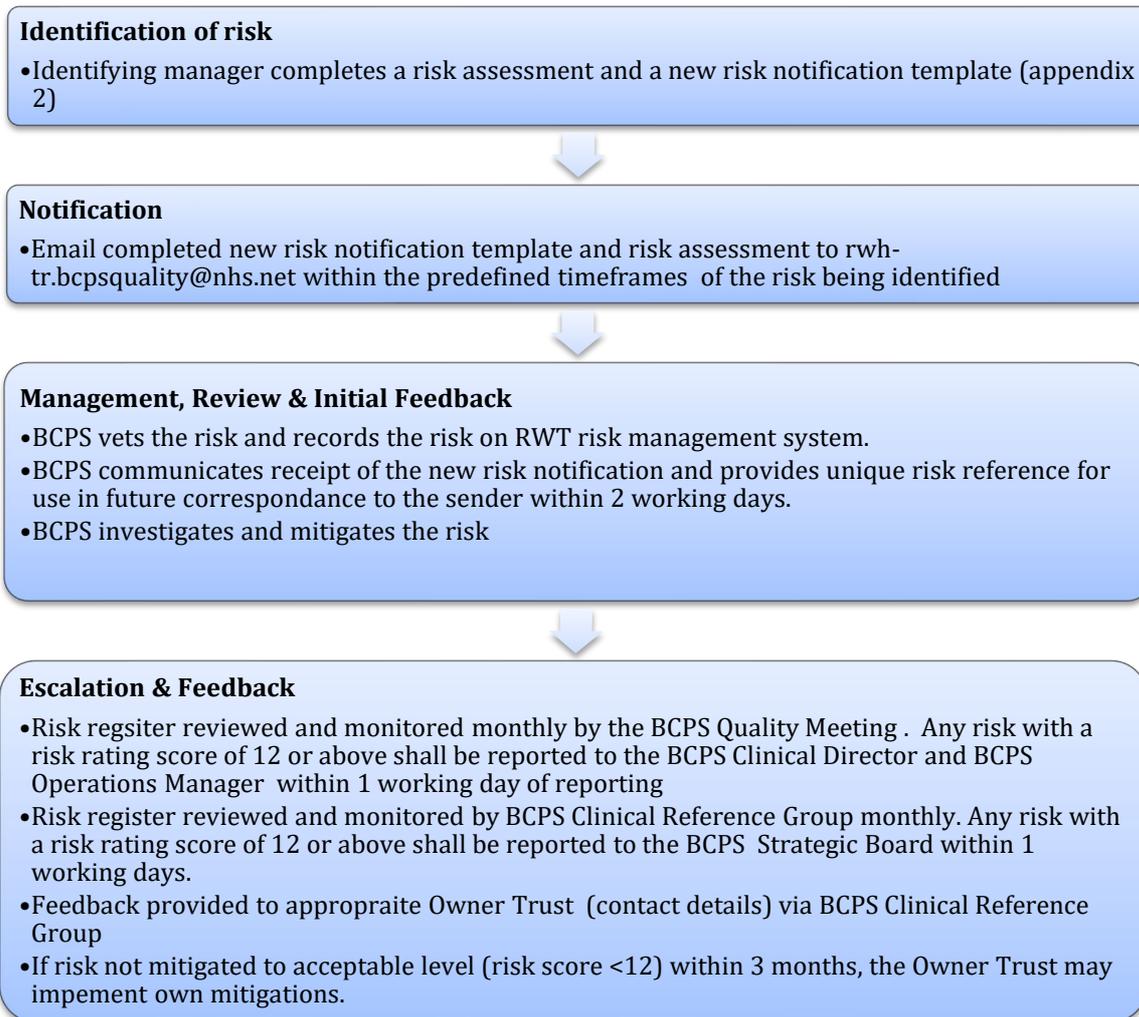
Risk score	Severity level (based on RWT risk matrix)	Notification from identification within
>15	Red	2 hours, max 1 working day
8-12	Amber	3 working days (if SIRI 2 hours, max 1 working day)
1-6	Yellow / Green	5 working days

All risks shall be vetted by the BCPS and recorded on RWT Datix. If there are elements that concern an Owner Trust as well as BCPS, then the risk will be managed by either the appropriate Owner Trust or BCPS, whichever is seen to be the owner of the main issue, with contribution from the other party; records shall be maintained on the appropriate owners risk management system. Examples of risks that may be managed by Owner trusts include risks around Estates which impact pathology services (i.e. water leaks, ineffective physical security measures to pathology laboratories) or IT (i.e. unable to update Trusts electronic pathology requesting system in real-time).

The BCPS risk register shall be jointly reviewed and monitored on a monthly basis by the BCPS Clinical Director at the BCPS Quality meeting and the Clinical Reference Group. The risk register summary shall be reported to the Strategic Board to ensure compliance with risk management process.

Any material risks (defined as a risk with a score of 12 or above) will be reviewed in detail and analysed by the Strategic Board. Should a material risk have a negative impact on the quality of the pathology services under any Service Level Agreement (SLA), then, the BCPS senior management team will have a period of 3 months to implement further mitigation and rectification measures, to be approved at Strategic Board. If 3 months after implementation of mitigation and rectification measures the service is still failing to deliver the required minimum quality, the BCPS

Strategic Board will have the right to give any Owner Trust the right to implement their own mitigation measures to enable the rectification of the service quality issue.



8.3 Incidents

All incidents raised against pathology reported shall be managed on the Host Trusts risk management software system, Datix. BCPS shall take ownership of the incidents and lead on the investigation. BCPS will vet all pathology related incidents with regards to risk categorisation. If there are elements that concern an Owner Trust as well as BCPS, then the incident shall be managed by either the Owner Trust or BCPS, whichever is seen to be the owner of the main issue, with contribution from the other party.

The process for recording and communicating incidents is described below:

8.3.1 Incidents raised on Host Trusts risk management software (Datix)

All incidents reported against pathology within the Host Trust, shall be reported via the Host Trust's Datix incident reporting system whether they originate within or outside Pathology (no change) and be managed by BCPS.

8.3.2 Incidents raised on Owner Trusts risk management software (Datix/ Safeguard)

All incidents raised against pathology reported at Owner Trust sites (DGFT, SWBHT, and WHT) shall be vetted within 2 working days by the Owner Trust Governance Teams (in which the incident was raised) and emailed to the BCPS Quality Team generic email address, rwh-tr.bcpsquality@nhs.net. BCPS shall input the incident onto the Host Trust's Datix system. The reporting Owner Trust shall then mark the incident as an externally reported and close it on their reporting system to reduce the risk of 'double counting/ duplicate external reporting' incidents. BCPS shall be responsible for managing the incident in line with the Host Trusts risk management policies and procedures.

Note. It is recognized that during any incident investigation/fact finding processes contribution from either the Owner Trust or the BCPS may be required to complete the investigation and notification may be outside the 2 working days.

Potential SUIs must be emailed to the BCPS Quality Team generic email address, the RWT Governance SUI inbox, rwh-tr.SUIReporting@nhs.net and telephoned to BCPS Quality Team (01902 307999 ext. 8247) within the same working day the incident is identified as a serious incident. BCPS shall confirm receipt and share unique incident reference number with the notifying Owner Trust.

8.3.3 Incidents raised against Owner Trusts by BCPS

Incidents raised against Owner Trusts by BCPS shall be reported directly onto the Owner Trust reporting systems by pathology disciplines retained on Owner Trusts sites i.e. Biochemistry, Haematology and Blood Transfusion. For pathology disciplines that are based at RWT site and not based at Owner Trust sites (Cellular Pathology (includes Histology), Cytology, Immunology and Microbiology), incidents shall be reported on the RWT Datix incident reporting system. RWT shall report these as external incidents (within RWT Datix these shall be marked as "external" and the Owner Trust/ ward details / locations etc. shall be in the description of the incident). The BCPS shall notify the relevant Owner Trust governance departments of the incident raised and the management of the incident shall transfer to the appropriate Owner Trust.

Site	Contact
RWT	Rwh-tr.bcpsquality@nhs.net
DGFT	dudley.groupincidents@nhs.net
SWBHT	swb-tr.RiskManagement@nhs.net
WHT	wccss.governance@walsallhealthcare.nhs.uk

8.3.4 Incident reporting timeframes

Reciprocal timeframes for reporting incidents for notifying transfer of ownership between the BCPS and the Owner Trust's is shown below:

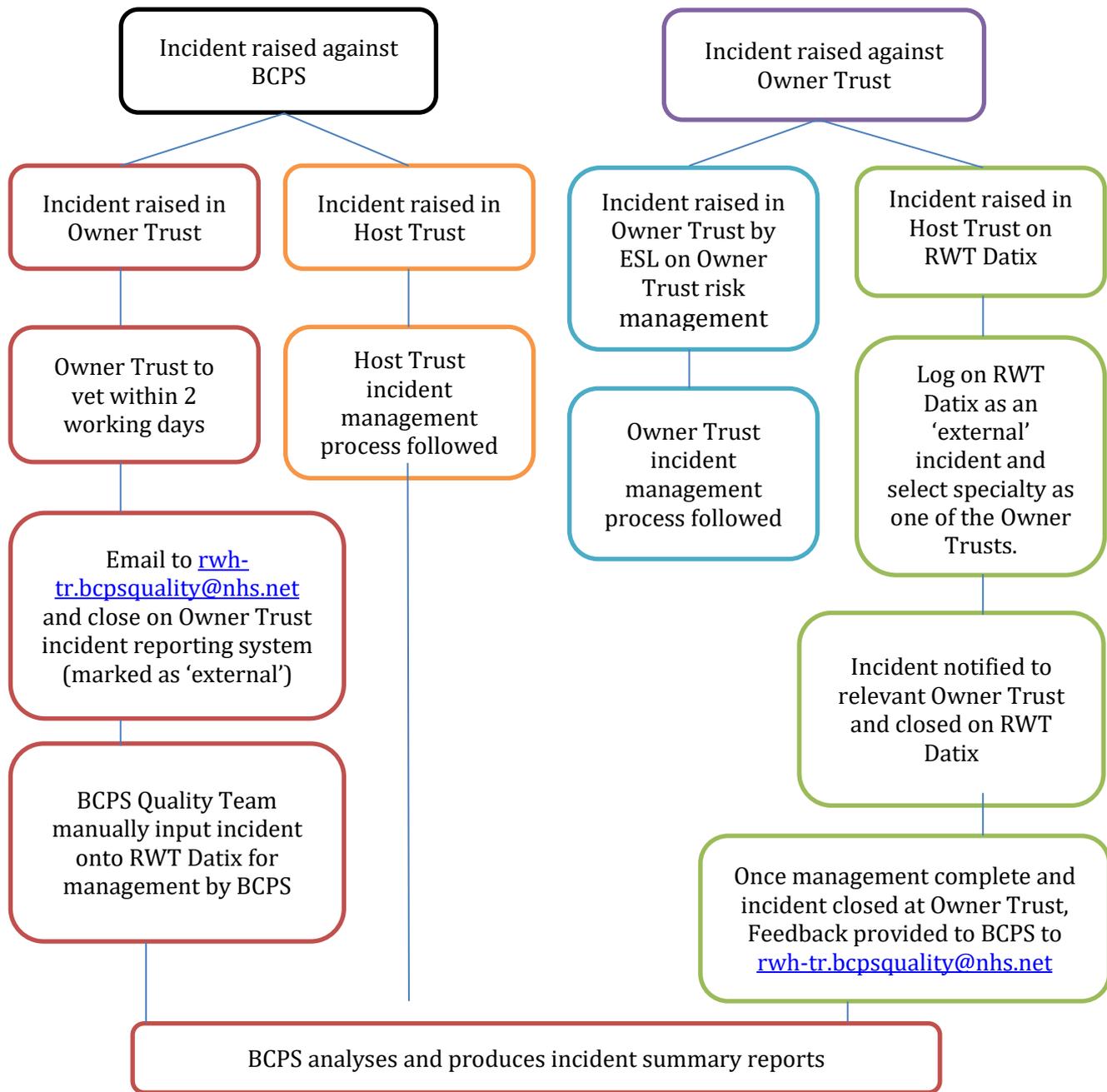
Risk score	Severity level (based on RWT risk matrix)	Notification from identification within
>15	Red	2 hours, max 1 working day
8-12	Amber	2 working days (if SIRI 2 hours, max 1 working day)
1-6	Yellow / Green	2 working days

8.3.5 Serious incidents

For serious incidents (also referred to as Serious Incidents Requiring Investigation (SIRI) or Serious Untoward Incident (SUI), meeting the serious incident criteria in RWT Risk Management Reporting Policy (OP10), the BCPS should be notified within 2 hours and must be notified within 21 working day. Note. that SUIs are not categorized solely by the 12 or above score, many meet this but not all. Some never events have low/no harm but are still classified as SUIs.

RWT as the Host Trust of BCPS, shall report all serious incidents which are owned and managed by the BCPS within 2 working days of the incident being identified as a SUI. This will be reported to the RWT Governance department SUI inbox and reported to commissioners (via the STEIS system). Incidents where the Owner Trust is seen as the main issue holder rather than BCPS, the Owner Trust shall be responsible for externally reporting the incident. It is essential that DGFT, SWBHT and WHT shall record all patient safety incidents, where BCPS are the main owner of the incident, the record should be flagged as 'external' within the Owner Trusts risk management software system to remove the risk of 'double counting' patient safety incidents raised against Owner Trust(s).

The BCPS shall complete a root cause analysis (RCA) for all serious incidents in which it is seen as the main issue holder; initial RCA shall be completed 48 hours following discovery of the incident, with the full RCA completed by 45 days (in line with RWT policies and procedures). If Owner Trust(s) involvement/ contribution are required to complete the RCA, the Owner Trust shall support the BCPS investigation to ensure the timeframes stated above are met. Reciprocally, where the BCPS is required to be involved in RCA led by an Owner Trust, they also shall support the investigation to ensure the Owner Trusts policies and procedures are met.



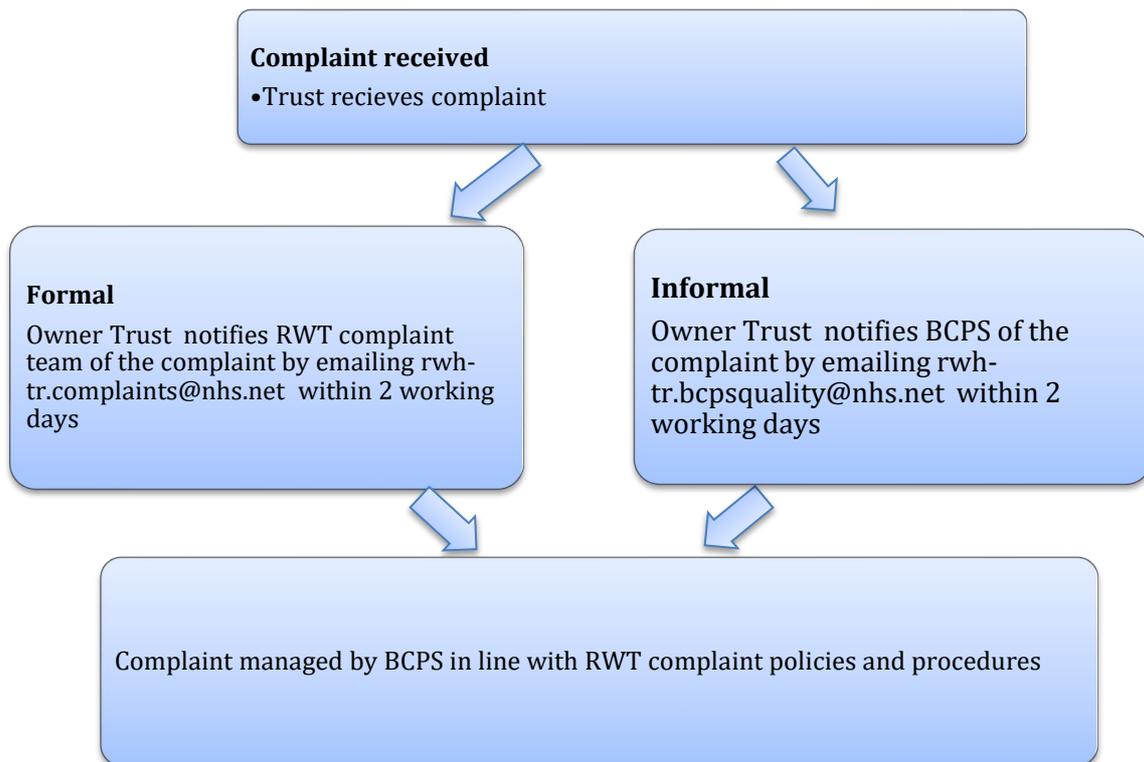
Complaints (PALs, formal complaints)

Complaints regarding pathology services received by Owner Trusts shall be transferred to BCPS for management in line with BCPS Host Trusts (RWT) complaints management policies and procedures. If there are elements that concern an Owner Trust as well as BCPS, then the complaint will be managed by either the Owner Trust or the BCPS, whichever is seen to be the owner of the main issue, with contribution from the other party.

Owner Trust must notify the BCPS of formal complaints by emailing rwh-tr.complaints@nhs.net with the details of the complaint (including copies of any documentation received by the complainant) within 2 working days.

Informal complaints received by Owner Trusts shall be directed to the BCPS for management via rwh-tr.bcpsquality@nhs.net within 2 working days. Informal complaints shall be managed as described in the BCPS quality management system.

The BCPS will take ownership of the complaint and lead on the investigation (or support Owner Trust if they are the owner of the main issue) and respond to the complainant within 45 working days.



8.4 Freedom of information

Freedom of information requests that require input from the BCPS shall be redirected to RWT at rwh-tr.FOI@nhs.net within 2 working days of receipt. The BCPS shall manage all FOI requests in line with RWT FOI policies and in accordance with current legislation and relevant Acts. Information requested from the BCPS by Owner Trusts associated with FOI requests shall be shared with the Owner Trust to enable their response to the FOI request within the target response timeframes stated within the FOI.

8.5 Safety alerts and notices

The Host Trust (RWT) will notify the BCPS of safety alerts and notices received which potentially impact pathology services to rwh-tr.bcpsquality@nhs.net. The BCPS shall co-ordinate management of the safety alert/notice across all disciplines and locations within the BCPS remit, by sharing the alert/notice with the appropriate manager(s) within BCPS for management. All safety alerts and notices shall be managed in line with RWT H&S policies and in accordance with current legislation.



8.6 External visits

The BCPS shall report all external visits to the Trust hosting the BCPS (RWT) in accordance with RWT policies and procedures. The BCPS shall lead on all external visits specific to pathology services. This will include communications with the external agency/regulator to plan the visit, support the visit and manage all findings associated with the visit until successful closure by the external agency. The BCPS shall report directly to the BCPS Clinical Reference Group of any known/ expected future visits and a summary of the outcomes.

The BCPS shall support Owner Trusts with external visits for other areas outside the direct remit of BCPS as required; the external visit shall be managed by the relevant Owner Trust.

Notification

- Owner Trust shall notify BCPS via rwh-tr.bcpsquality@nhs.net of any forthcoming external visits which potentially impact on pathology services



Management

- The BCPS shall log external visits with the Trust hosting BCPS (RWT) in accordance with the Trusts policies and procedures.
- The BCPS shall manage the external visit and all associated findings arising from the visit until successful closure of the visit.



Feedback

- BCPS shall report all external visits and their outcomes to the BCPS Clinical Reference Group on a monthly basis.
- The BCPS Clinical Reference Group shall escalated any significant concerns to the Strategic Board for review.

8.7 Policies, procedures & patient leaflets

Policies, procedures and patient leaflets associated with pathology services shall be submitted to the BCPS Host Trust (RWT) for ratification. Once ratified, the document will be sent to the Owner Trusts for inclusion in their governance.

The BCPS shall support Owner Trusts in the development and review of policies, procedures and patient leaflets associated with pathology services i.e. transfusion services and POCT services.

9 Signatories

The Royal Wolverhampton NHS Trust			
Title	Full name	Signature	Date
Chief Executive	David Loughton		
Caldicott Guardian	Dr Jonathon Odum		
SIRO	Kevin Stringer		
Head of Governance	Maria Arthur		

Sandwell and West Birmingham Hospitals NHS Trust			
Title	Full name	Signature	Date
Chief Executive	Toby Lewis		
Caldicott Guardian	Dr Nigel Trudgill		
SIRO	Kam Dhami		
Head of Risk Management	Refeth Mirza		

The Dudley Group NHS Foundation Trust			
Title	Full name	Signature	Date
Chief Executive	Diane Wake		
Caldicott Guardian	Dr Jeff Neilson		
SIRO	Glen Palethorpe		
Interim Head of Governance	George Gilbert		

Walsall Healthcare NHS Trust			
Title	Full name	Signature	Date
Chief Executive	Richard Beeken		
Caldicott Guardian	Martin Lewis		
SIRO	Daren Fradgley		
Director of Governance	Jenna Davies		

Appendix 1 Risk matrix

RWT

Likelihood	Consequence				
	1 - Insignificant	2 - Minor	3 - Moderate	4 - Major	5 - Catastrophic
5 - Almost Certain	5	10	15	20	25
4 - Likely	4	8	12	16	20
3 - Possible	3	6	9	12	15
2 - Unlikely	2	4	6	8	10
1 - Rare	1	2	3	4	5

WHT

Consequence Score	Likelihood Score				
	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

SWBH

Severity	Likelihood				
	1 Rare	2 Unlikely	3 Probable	4 Likely	5 Almost Certain
5 Catastrophic	Score : 5	Score : 10	Score : 15	Score : 20	Score : 25
4 Major	Score : 4	Score : 8	Score : 12	Score : 16	Score : 20
3 Moderate	Score : 3	Score : 6	Score : 9	Score : 12	Score : 15
2 Minor	Score : 2	Score : 4	Score : 6	Score : 8	Score : 10
1 Insignificant	Score : 1	Score : 2	Score : 3	Score : 4	Score : 5

DGFT

Impact score	Likelihood				
	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

Report Title (PDF)	What is the Risk?		Level of Risk	How are we managing the risk?	Evidence that it is working	Any Evidence that it is not working	What else can we do		Risk after actions	Date Last Reviewed
Datix Field	Description	Initial Level	Current Level	Controls <i>(Assurance Tab – Controls – ‘Controls’ IGNORE ‘gaps in controls’ fields)</i>	Assurance <i>(Assurance Tab – ‘Assurance’)</i>	Gaps in Assurance <i>(Assurance Tab – ‘Gaps in Assurance’)</i>	Actions	Action Lead	Target Level	Review date
Requirements	<p>Description – must identify and describe the risk not incident/issue (individual circumstance). Description should include:</p> <ul style="list-style-type: none"> • The cause – what might trigger the risk/threat • The event – the adverse event • The impact – what will the event result in <p>IF>>>THEN>>>RESULTING IN</p> <p>A date of origin, date of escalation (if applicable) and a proposed date for achieving the Target Level to be added to the Description field.</p> <p>Detailed Risk Assessment to be added as an attached document.</p>	This is the grade of the initial risk identified (before mitigating actions).	<p>This is the grade of the risk at the time of your report and reflects mitigation</p> <p>All risks scoring 12+ must be escalated to the Trust Risk Register via Division.</p>	<p>Controls – barriers to the risk.</p> <p>Controls must be numbered in Datix. Number each control (use brackets).</p> <p>Controls must be dated in Datix Date each control (use brackets)</p> <p>Controls on the <u>cause</u> may reduce the likelihood of the event. Controls on the <u>effect</u> may reduce the impact of the event.</p> <p>Controls must be</p>	<p>Assurance – evidence that the risk is under control.</p> <p>Assurances to be numbered in Datix to align with numbered controls.</p> <p>Assurances must be dated in Datix (use brackets)</p> <p>Assurances must be updated regularly</p>	<p>Where negative assurance indicated, it may require further action to strengthen the control or other controls to be identified</p> <p>Any negative assurance to be numbered in Datix to align with numbered controls.</p> <p>Negative assurance must be</p>	<p>Actions should have a named lead and should be achievable:</p> <ul style="list-style-type: none"> • Specific – clear and unambiguous • Measurable – easy to evaluate • Achievable – within your resources • Realistic – within service constraints • Timely – not out-of-date or inaccurate <p>Actions should</p>		This is the grade that the risk is expected to be managed down to.	This is the date you last updated the risk

				measurable ie there must be an output which informs and provides assurance on the control/ management of the risk.	(monthly, quarterly)to inform live / actual assurance.	dated (use brackets) Negative assurance must be updated regularly	be generated by any gaps in controls or assurance. All actions to be numbered in Datix to align with numbered controls.			
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<i>Likelihood:</i> 1 2 3 4 5	<i>Consequence:</i> 1 2 3 4 5	<i>Severity:</i> (1- 3) green	(4 – 6) yellow	(8 – 12) amber	(15+) ‘Awaiting Divisional Approval’
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Full Name:	Designation:
Signature:	Date:

INPHASE Hosted Customer Solutions Business Continuity and Disaster Recovery Plan

InPhase is committed to the effective protection of its staff, customers and visitors and in the case of an emergency, to effective continuation of services.

1 Policy Statement

1.1 In the event of widespread and/or serious disruption to the life of INPHASE normal business activities the policy is to:

- Protect and minimise risk to customers, prospects, staff and visitors
- Reinstate normal business activities, with a particular emphasis on customer support as soon as possible.

2.0 Background

2.1 INPHASE Software is an organisation housed in one primary site, with satellite sites and home working in Swansea, Manchester, Yorkshire and Buckinghamshire. The main office can accommodate up to a total of 80 people at any one time.

The main site accommodates a small element of the INPHASE IT infrastructure with the majority of IT infrastructure being Microsoft Cloud based for both company and Cloud hosted customers, which is the focus of this specific continuity plan.

2.2 Any severe disruption to the company's Hosted Services presents major operational and logistical challenges:

- Informing the entire company staff and user community of the immediate impact and response
- Implementing contingency plans
- Restoring normality

2.3 Several of InPhase's hosted IT policies are designed to protect occupants and minimise risk before the event. INPHASE partners with a very capable and experienced data centre provider being:

Microsoft Azure

Microsoft has a strong resilience strategy and disaster recover capability for its platform including at least:

100% hardware failover redundancy – every hardware component used by INPHASE solution has a 100% replacement available in the event of hardware failure.

INPHASE always has at least 2 separate physical servers under managed service contract enabling re-instancing for a Customer and re-directing of url within 24 hours.

Location resilience –Microsoft Azure has multiple Data Centres located in Europe that can provide location resilience at an Alternate Data Centre within 24 hours maximum SLA.

Software resilience. INPHASE holds full copies of all required software to install a working solution from bare metal within 4 hours both at the normal Data Centre and the Alternate Data Centre.

Microsoft Azure Data Centres are ISO27001 certified data centres.

3.0 Disaster Recovery Plan

3.1 These day-to-day policies cannot, however, avert the disruption arising from a major disaster such as fire, flood, explosion or epidemic. In these circumstances, the InPhase policy is to reassert control and restore viability for its Customer’s Hosted Solutions by implementing its Disaster Recovery procedure.

3.2 The Procedure is in the form of an easily accessible manual providing management guidance in the immediate aftermath of an emergency, followed by measures to maintain or re-establish business continuity. Copies of the Plan are held by the core staff of the Disaster Recovery Team, at their homes as well as in their respective workplaces.

3.3 Core principals and actions are:

Establish the extent of the impact

Evaluate fastest recovery point options from:

- a) Restore data back-up on failover hardware
- b) Restore data back-up on alternate server at alternate location
- c) Restore INPHASE application and data on alternate server, instigate url re-direct
- d) Re-install INPHASE on alternate server, restore data backup, instigate url re-direct

4.0 Disaster Recovery Team

4.1 Immediately after a Data Centre premises’ evacuation or enforced closure, the Principal or designated deputy may convene a Disaster Recovery Team whose composition shall reflect the scale and nature of the disaster, and the tasks ahead. The core team will consist of key senior management augmented by co-opted divisional staff
Areas of responsibility will include, but not be restricted to, staff and welfare, IT and communications’ continuity, and premises’ restoration.

4.2 In the event of a major incident occurring while the premises are closed, measures are in place to alert the Principal/senior Management Team.

4.3 The Disaster Recovery Team’s location (“Incident Control Centre”) will be incident-dependent, probably within the most appropriate satellite office.

4.4 The Team will be responsible for:

- Assessing the scale, scope and impact of the disaster
- Immediate response actions and short-term plans
- Informing and updating staff, customers, suppliers and the wider business contacts community
- Liaison with incident-critical agencies, organisations, etc.
- Pursuing contingency measures where necessary to minimise disruption e.g. temporary relocation of training courses
- Establishing the business continuity strategy and structure

4.5 Where the disaster has affected a wider area than the Data Centre, including for example INPHASE offices, the Team will coordinate with any “control and command” centre operated by, for example, Buckinghamshire County Council or the emergency services.

5.0 Publicity

5.1 Email and the INPHASE website, www.inphase.com, will be the primary medium for disseminating the latest information and advice for staff and customers. Other media will be used as and when appropriate.

6.0 Conclusion

7.1 Disaster recovery and business continuity are dealing with the unexpected. The measures adopted by InPhase, founded on teamwork; reliable emergency communications; accessible, relevant information and regular risk management assessment should ensure that when a major disruption does arise, the response is both immediate and effective.

Managing Business Continuity at RWT:

"We essentially procure a service from Microsoft in their data centre, in the event of a 'disaster' we would spin up a new server on the Microsoft platform and restore a backup of the data (from the last back up point) which would be the previous day, this would then be an operational service.

The target time we aim for is 4 hours."