University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY FOR THE DEVELOPMENT AND MANAGEMENT OF PROCEDURAL DOCUMENTS

Reference Number: POL-COR/171/ 07	**Version:** 7		**Status:** Final	**Author(s):** Deb Price/ Laura Reekie **Job Title**: Associate Director - Medical Directors Office/ Corporate Governance Officer
Version / Amendment History	Version	Date	Author	Reason
	7.2	September 2020	Deb Price/ Laura Reekie	Significant amendments to definition of documents
	7.3	June 2021	Dr Jothi Srinivasan/ Dr James Crampton/ Laura Reekie	Inclusion of Local Safety Standards for Invasive Procedures (LocSSIPs)
Intended Recipients: All staff with responsibility for generating Procedural Documentation.				
Training and Dissemination: Launched through Intranet.				
To be read in conjunction with: Trust's Records Management Policy, Expansion & Implementation of Developing Scope of Professional Practice Policy				
In consultation with and Date: Clinical Guidelines Group; Clinical Compliance Group,				
EIRA stage one Completed Yes Stage two Completed N/A				
Approving Body			Trust Delivery Group September 2021	
Date Approved			September 2021	
Review Date and Frequency			January 2023 (then every 3 years)	
Contact for Review			Trust Secretary	
Lead Executive Director Signature			Chief Executive	

Contents

TRUST POLICY FOR THE DEVELOPMENT AND MANAGEMENT OF PROCEDURAL DOCUMENTS

1. Introduction

Procedural Documents are necessary to ensure that the Trust's intentions and methodologies are clearly understood by all stakeholders. The management of these is a key element of the controls which enable the Trust to manage those risks which threaten the achievement of its objectives and the strategies that define them.

2. Purpose and Outcomes

The purpose of this Policy is:

- To describe the approach to the development and approval of Procedural Documents;
- To provide a standard outline for the content of Procedural Documents;
- To ensure that there are arrangements for dissemination so that staff are aware of their responsibilities in relation to the Procedural Documents;
- To describe arrangements for ensuring such Procedural Documents are regularly reviewed to reflect current guidance;
- To describe the process for version control to ensure staff have access to – and are operating to - the most current version;
- To ensure arrangements are in place for archiving Procedural Documents in line with records management requirements.

3. Definitions of Procedural Documents

Held on Koha

3.1 A **STRATEGY** is a corporate statement which sets out a plan of action designed to achieve a long term or overall plan. These Procedural Documents tend to be high level and for a period of 3 to 5 years. They will link with Policies to ensure there is clear guidance to ensure effective delivery.

3.2 A **FRAMEWORK** is an overarching document that outlines the interlinked items which support a particular approach to a specific objective.

3.3 A **POLICY** is a high level statement. Each Policy should specify its purpose and may also include a procedure setting out how the Policy will be achieved. A Policy enables management and staff to make correct decisions, deal effectively and comply with legislation, Trust processes and good working practices.

3.4 A **CLINICAL GUIDELINE** is a document to guide diagnosis, management or treatment of a specific condition. Clinical Guidelines are systematically developed recommendations to assist practitioners to make decisions about appropriate health care, including diagnosis, management and treatment for staff with specific diseases and conditions. They are based on the best available evidence for the care and services that are suitable for most staff with a specific condition or need (NICE article [PMG20] Oct 2014) but do not replace the clinician's knowledge, skills or professional judgement.

Clinical Guidelines aim to improve the quality of patient care in order to improve patient outcomes and pursue the most effective use of resources. They may be used in the education and training of health professionals. Any Clinical Guideline may be changed as a result of learning from experience or from changes in knowledge or practice e.g. in response to new or revised NICE Guidance.

3.5 **A LOCAL SAFETY STANDARDS FOR INVASIVE PROCEDURES (LocSSIPs)** is a written SOP that sets out the critical safety and quality steps required for invasive procedures. An invasive procedure is defined as a procedure that has the potential to be associated with a Never Event if safety standards are not set and followed which includes all surgical and interventional procedures performed in operating theatres, outpatient treatment areas, labour ward delivery rooms, and other procedural areas.

In September 2015 NHS England issued the National Safety Standards for Invasive Procedures (NatSSIPs), developed by a multidisciplinary group of clinical practitioners, professional leaders, and human factors experts and lay representatives. The NatSSIP sets out key steps necessary to deliver safe care for patients undergoing invasive procedures and are designed to support organisations delivering NHS-funded care in standardising the processes that underpin patient safety. Individual organisations are required to develop Local Safety Standards for Invasive Procedures (LocSSIPs) that include the key steps outlined in the NatSSIPs and to harmonise practice across the organisation.

LocSSIPs should therefore be considered as part of a larger patient pathway, and should be included in the continuum of care rather than becoming the sole focus of it.

3.6 A **SCOPE NOTE** applies to any significant expansion to the Scope of Professional Practice of an individual, excluding Medical staff, and applies to all registered and non-registered staff at the Trust including both temporary and permanent staff. For the purpose of this policy significant expansion is deemed to be any change that has an impact on an individual's training needs or resources. Please refer to the Expansion & Implementation of Developing Scope of Professional Practice Policy for further details.

Held on Net-I - ***these documents are the responsibility of the individual Business Units***

3.7 A **PROCEDURE or STANDARD OPERATING PROCEDURE (SOP) or GUIDELINE (non-clinical) or FORM** may be incorporated into a Policy as an appendix but really should be a stand-alone document that can be amended without the need for the Policy to be altered. They are the practical way in which a Policy is translated into action. They explicitly outline how to accomplish a task or activity, giving detailed instructions. They often allocate specific roles that specific individuals must undertake. If they are directly linked to a Policy then it needs to be held on Koha as a separate document but linked to its "parent" Policy. However if it has no direct link to any Policy then it will be held in a designated section of the Divisions intranet site.

3.8 **OTHER DOCUMENTS** such as referral forms/ pathways, patient information leaflets will be held in a designated section of the Divisions intranet site.

4. Managing the Development and Management of Procedural Documents

4.1 Style and Format

All Procedural Documents should be written in a style that is clear, concise and unambiguous. Titles should be kept simple and accurate to the subject to assist easy identification of the document.

All Procedural Documents need to be concise and not over-long to ensure they can be understood and are able to be easily used.

Strategies and Frameworks may follow a different layout but should still follow the corporate style requirement such as Arial 11 point and clarity.

The standard font is Arial 11 point. Uppercase and underlining should be avoided except in headings. Page numbers must be used.

4.1.1 Clinical Guidelines will be documented in the same format to standardise documentation across all sites.

1. Summary Clinical Guideline

   This must be 1 or a maximum of 2 pages long. The aim is to direct the management of patients within a busy clinical setting. This can take the form of a checklist, algorithm or flow chart where possible.

2. Full Clinical Guideline

   All charts / diagrams will be in portrait format where possible. All guidelines can be printed off for use in the clinical setting; however staff must be aware that printed copies are not document controlled.

4.1.2 LocSSIPs scope and applicability

Includes any procedure where:

a) A cut or hole has been made to gain access to the inside of the body
b) Access to a body cavity (such as the digestive system, airway, or bladder) is gained without cutting into the body, for example endoscopy
c) Electromagnetic radiation is used such as with x-rays, lasers, gamma rays, ultraviolet light for treatment, for example using a laser to treat skin lesions.

This applies to all areas where invasive procedures are performed, including:

a) All surgical and interventional procedures performed in operating theatres, outpatient treatment areas, labour ward delivery rooms, and other procedural areas within an organisation
b) Surgical repair of episiotomy or genital tract trauma associated with vaginal delivery
c) Invasive cardiological procedures such as cardiac catheterisation, angioplasty and stent insertion
d) Endoscopic procedures such as gastroscopy and colonoscopy
e) Interventional radiological procedures
f) Thoracic interventions such as bronchoscopy and the insertion of chest drains
g) Biopsies and other invasive tissue sampling.

This does not apply to procedures that involve the simple penetration of the skin or entry of a body cavity, such as the insertion of an intravenous line or a urinary catheter, or the use of ionising radiation, such as the taking of a plain X-ray.

LocSSIPs should include the seven organisational and eight sequential steps for the patient on the pathway to undergo an invasive procedure.

ORGANISATIONAL	SEQUENTIAL
1. Governance and audit 2. Documentation of invasive procedures 3. Workforce 4. Scheduling and list management 5. Handovers and information transfer 6. Induction 7. Multidisciplinary Training	8. Procedural verification and site marking 9. Safety briefing 10. Sign in 11. Time out 12. Prosthesis verification 13. Prevention of retained foreign objects 14. Sign out 15. Debriefing

Please see Appendices A to G for template and content guidance.

4.2 Glossary

Acronyms and technical language, where necessary must be explained and included in a glossary.

4.3 Justification

The identification of need for each Procedural Document must link with the business of the Trust and could arise for a number of reasons, for example:

- National initiatives and local priorities
- Legislation
- New Regulations
- National guidance
- The outcome of Audit assessment
- The results of a risk assessment process
- Findings of investigation into an incident, complaint or litigation.

4.4 Approval of Procedural Documents

The approval pathways for Procedural Documents are detailed in Appendices B to G.

4.5 Review of a Procedural Document

At the time of approval, all Procedural Documents should have a clearly defined review date. This may be brought forward if earlier review is required, for example because of an identified risk or change in national Policy. Strategies and Frameworks

are typically reviewed every 3 to 5 years, all Policies, LocSSIPs and Clinical Guidelines must be reviewed at least every 3 years. . As good practice Procedures, SOP, Guidelines (non-clinical) or Forms at least annually.

4.6 Dissemination and Training

The author is responsible for the development of an Implementation Plan. This could include raising awareness via presentations at Trust meetings, Intranet news, Taking Pride articles, e-mail communication, newsletters or training.

4.7 Stakeholders

The involvement of key stakeholders within the Trust is integral to this process and all Procedural Documents being developed or reviewed should be able to evidence their process for engaging stakeholders.

4.8 Equality Impact Risk Assessment (EIRA)

No Procedural Document will be approved by the Trust without evidence of stage one EIRA. If a full EIRA (stage 2) is indicated this must be completed alongside the draft Policy development.

4.9 Version Control

All Procedural Documents must have the version number, date of issue and the review date clearly marked on the front cover and as a footnote.

This is based on the following system
1.0 Initial document
1.1 All Lead Director approval changes
2.0 Fully revised document

4.10 Register / Library of Procedural Documents

It is the responsibility of the Library and Knowledge Service to ensure that the Procedural Documents detailed in sections 3.1 – 3.6, once approved, will be converted to PDF format and published on Koha.

Maintaining the library of Procedural Documents is the responsibility of the Library and Knowledge Service, within the requirements of the Trust's Records Management Policy.

It is the responsibility of the author for Procedural Documents detailed in sections 3.7 – 3.8 to send to the Digital Communications Team who will upload to the stipulated section of Net-i. It is not the responsibility of the Digital Communications Team to maintain an audit trail or version control.

4.11 Archiving Arrangements

Formal archiving of the Procedural Documents detailed in sections 3.1 – 3.6 is the responsibility of the Library and Knowledge Service. Archiving will be undertaken within the requirements of the Trust's Records Management Policy.

The documents detailed in sections 3.7 – 3.8 have no review date and there is no formal governance procedure in place regarding uploading or archiving. The Digital

Communications Team upload whatever documents are sent to them; it is the responsibility of the Divisional area/ Business Unit that is requesting the upload to ensure that there is a robust process in place and back copies of documents should be kept where appropriate.

4.12 Freedom of Information (FOI)

Trust Policies and Clinical Guidelines must be made available on the internet as part of the Freedom of Information Publication Scheme. As the Policies will be uploaded onto Koha, the library management system, they will be automatically available both internally and externally, whilst ensuring version control is managed.

4.13 Patient Safety

A National Patient Safety Alert around ligatures and ligature point risk assessment tools and policies was issued to the Trust. As part of the alert, the Trust is required to ensure that the content of local publication procedures uploaded to public facing websites does not risk the safety of patients or the public. Prior to approval, all authors have a responsibility to ensure this has been considered.

4.14 Restoration and Recovery

Where changes in practices occur as a result of the restoration and recovery phase, the relevant Lead should review the associated policies and amend in accordance with the normal procedure.

5. Monitoring Compliance and Effectiveness

The key requirements of this Policy will be monitored in a composite report presented on the Trusts Monitoring Report Template:

Monitoring Requirement	To demonstrate that, the Trust is monitoring compliance with the process for the development of organisation-wide Procedural Documents, in relation to the ratification process and control of Procedural Documents, including archiving arrangements.
Monitoring Method:	The Trust Delivery Group will receive a monthly report on out of date policies.
Monitoring Report presented to:	Trust Delivery Group and Audit Committee
Frequency of report	Monthly for Trust Delivery Group

6. Key Responsibilities / Duties

6.1 Trust Board

Trust Board has overall responsibility for approving Strategies, Frameworks and Policies which are of major strategic significance or are required by legislation.

Policies requiring approval by the Trust Board may be approved by a Board Committee subject to appropriate delegated authority being granted through the Terms of Reference and Scheme of Delegation.

A full list of these policies can be obtained from the Trust Secretary.

6.2 Trust Delivery Group (TDG)

TDG will review, then approve, all policies that cannot be approved by the Lead Director due to the level of change in the Policy. TDG will be responsible for monitoring that the Policy documents are kept up to date and have been disseminated and implemented as required.

6.3 Lead Executive Director

Each Procedural Document detailed in sections 3.1 – 3.3 will have an appointed **Lead Executive Director**. The **Lead Executive Director** will be responsible for:-

- Engaging relevant stakeholders in the development of the Procedural Document
- Ensuring appropriate arrangements are in place for managing any resource implications, including dissemination and training
- Ensuring the most current version is in use and obsolete versions have been withdrawn from circulation.

Lead Executive Directors have authority to approve policies where it is appropriate; these will then be passed to TDG for ratification.

6.4 Trust Secretary

The Trust Secretary is the lead person for corporate governance within the Trust. They are responsible for working with the Library and Knowledge Service to ensure that all new Procedural Documents:

- Meet the agreed format and criteria
- Meet the required approval process

6.5 Library and Knowledge Service

All Policies detailed in section 3.3, once approved, will be submitted to the Library and Knowledge Service Manager who will issue new policies with their own unique identifier.

6.6 Specialist Groups / Committees

Specialist Groups / Committees are responsible for reviewing the documents detailed in sections 3.4 – 3.6 as part of the consultation process. The duties of the Specialist Groups / Committee will be defined by their Terms of Reference and will include ensuring that the Trust has Policies and Procedures in place to meet national and clinical requirement.

6.7 Divisions

The Divisions are responsible for reviewing the documents details in sections 3.7 – 3.8.

6.8 Staff

All staff need to be aware of the Trusts Procedural Documents and how they impact on their work. All approved new Procedural Documents are communicated through the staff briefing and via the intranet with staff having an individual responsibility to seek out this information.

7. References

Information Governance Standards

CQC Standards

Equality Impact and Risk Assessment (EIRA)

Retention and Destruction Schedule

APPENDIX A

CONTENT GUIDANCE FOR PROCEDURAL DOCUMENTS

All sections to be numbered and indexed to facilitate rapid access to relevant information. Font is Arial 11, with headings to be in bold and underlined:

1. Introduction
Overview of the background and importance of the subject of the document.

2. Purpose and Outcomes
Purpose of the document including rationale for development plus expected outcomes.

3. Key Responsibilities / Duties
An overview of the individual, departmental and committee responsibilities.

4. Definitions Used
List of the terms used and their meaning within the context of the document to clarify interpretation.

5. Monitoring Compliance and Effectiveness
Identify how the key requirements will be monitored including how you are going to identify deficiencies and develop and produce action plans to implement changes accordingly.

6. References
This should refer to procedures, manuals, external publications, regulations, law etc. And indicate where these can be obtained from (web site details).

7. Appendices
These must be numbered and added to the top right hand corner of the page Procedures and forms are part of the appendices.

APPENDIX B

STRATEGY DOCUMENT TEMPLATE

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

EXCEPTIONAL Care Together

Our XXX Strategy (Working Draft) 20XX to 20XX

Purpose

Context and Background

Our 5 year strategic objectives

Strategic aim

[description]

HOW we will do this:

-
-

WHAT we will do:

-
-

Outcome: How we will measure success and impact:

We will measure this through:

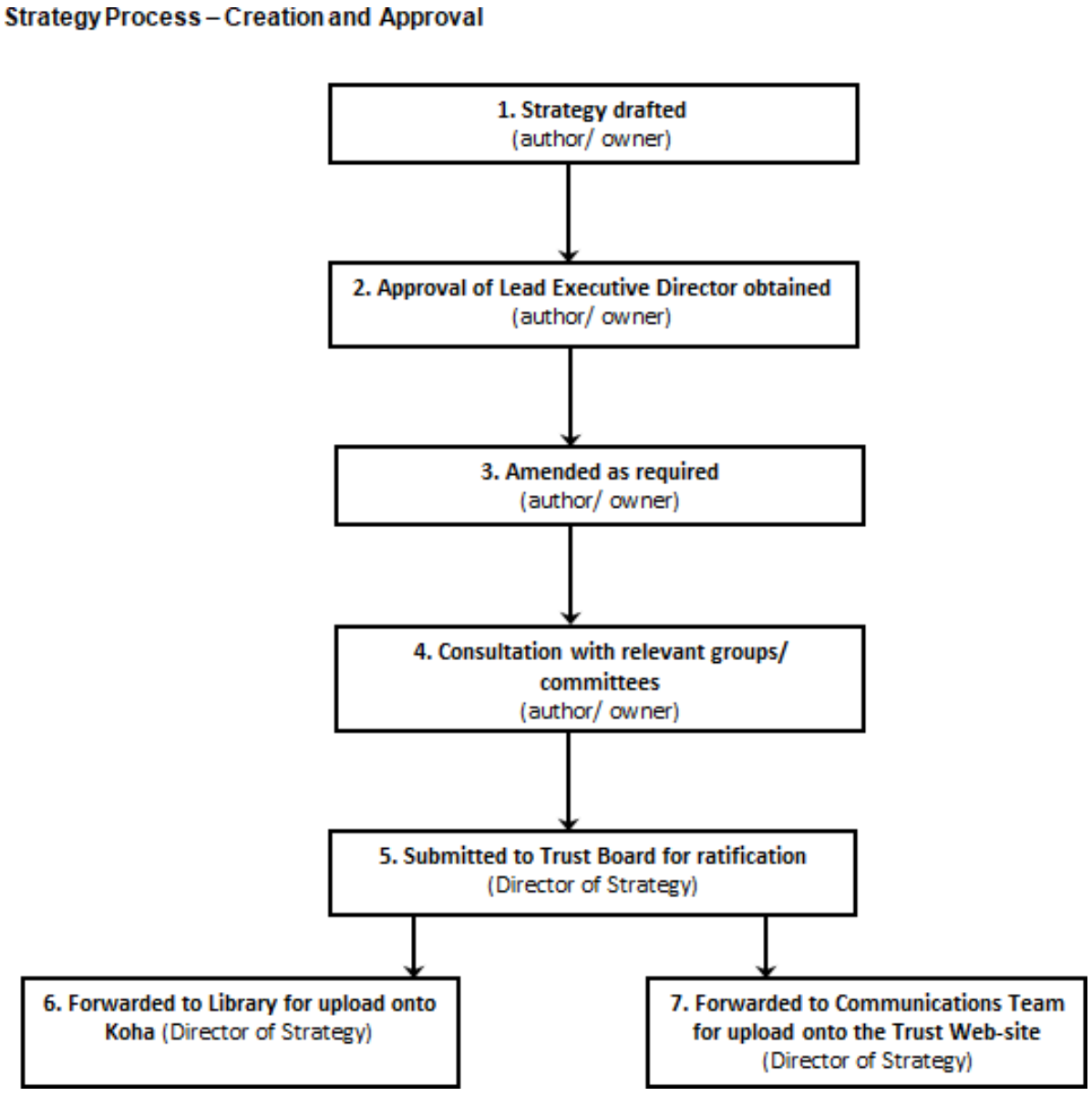
-

Appendix

Our Priorities	PRIDE Ambition/Performance measures	20/21	21/22	22/23	23/24	24/25

APPENDIX B1

STRATEGY PROCESS – CREATION AND APPROVAL



APPROVAL OF STRATEGIES

Strategies will be presented to the Trust Board for approval.

APPENDIX C

FRAMEWORK DOCUMENT TEMPLATE

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

xxxx Framework

20xx-20xx

Introduction

In this framework, we set out our **Why?** our **How?** and our **What?**

1. OUR WHY?

2. Our HOW?

3. Our WHAT?

Priorities for the next three years -

20xx -20xx

-

20xx -20xx

-

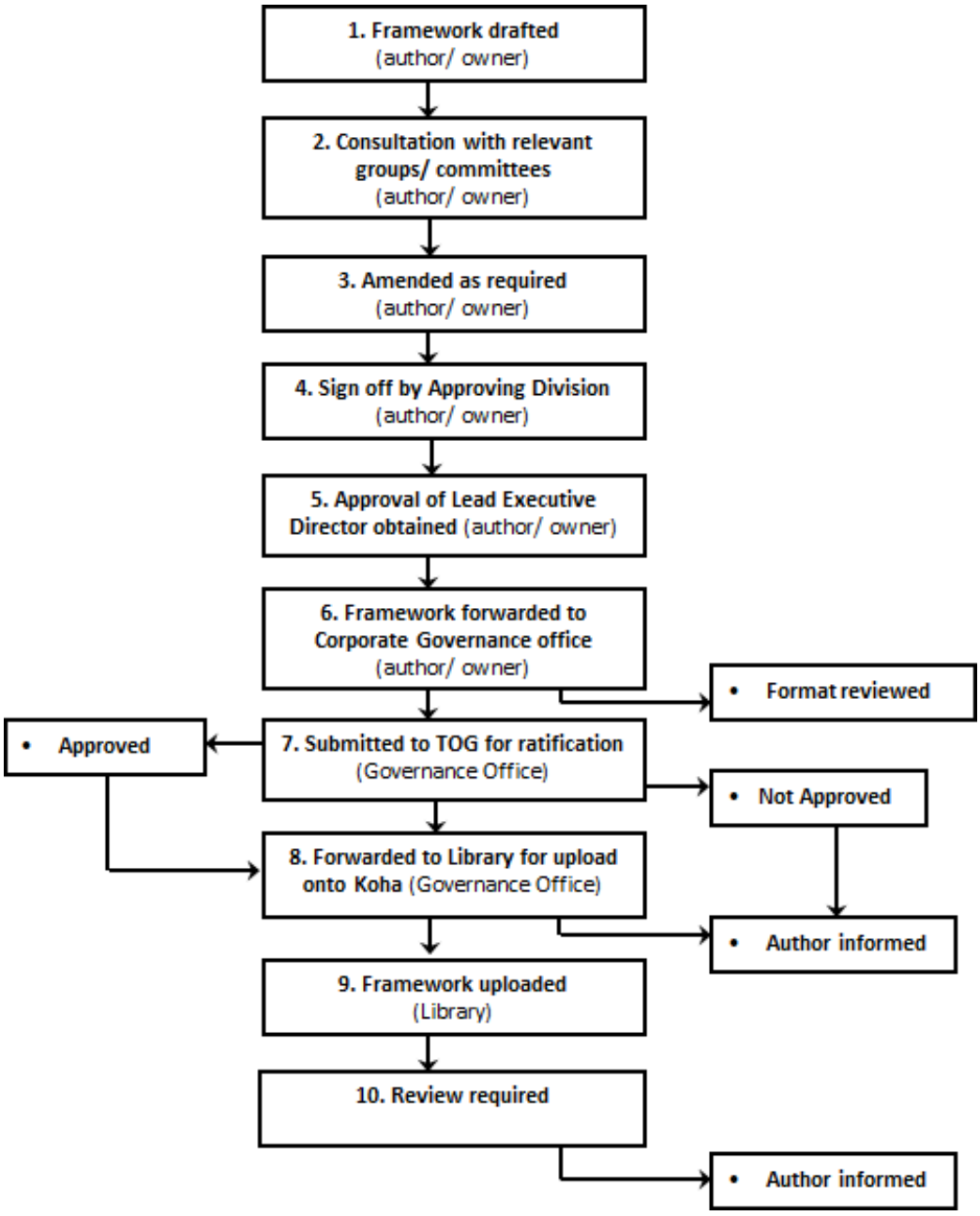
20xx -20xx

-

Appendices:

APPENDIX C1

FRAMEWORK PROCESS – CREATION AND APPROVAL



APPROVAL OF FRAMEWORKS

The Group with expert subject knowledge (e.g. Patient Experience Group for the Patient and Experience Framework) is responsible for developing and approving specialist content; then recommending final approval of new Procedural Documents.

APPENDIX D

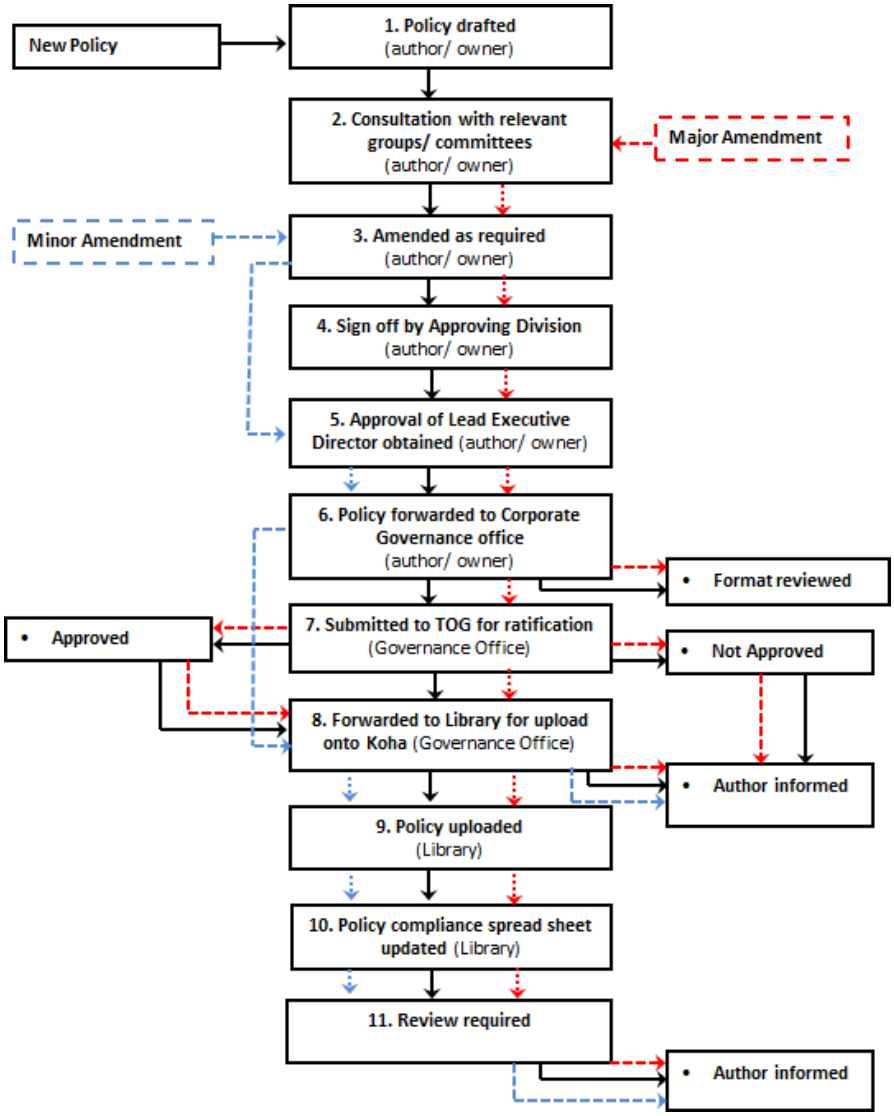
POLICY DOCUMENT TEMPLATE

TRUST POLICY FOR ……..

Reference Number From Library and Knowledge Service Manager	**Version:**		**Status**	**Author:** **Job 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				
Training and Dissemination: How will you implement the policy, cascade the information and address training				
To be read in conjunction with: State the name(s) of any other relevant policies: / procedure				
In consultation with and Date: State which groups you have consulted with and when. Give names in full followed by abbreviations e.g. Medical Advisory Committee (MAC)				
EIRA stage One Completed Yes / No *Delete as appropriate* stage Two Completed Yes / No *Delete as appropriate*				
Approving Body and Date Approved			Date and Full Name of Approving Body followed by abbreviations	
Date of Issue			Month and Year	
Review Date and Frequency			Year and Frequency e.g. 2008 every 3 years	
Contact for Review			This should match the author of the policy if different please state who the contact is by Job Title	
Executive Lead Signature				

APPENDIX D1

POLICY PROCESS – CREATION AND APPROVAL



Approval of Policies

The Group with expert subject knowledge (e.g. Health and Safety Group for Health and Safety Policies) is responsible for developing and approving specialist content; then recommending final approval. Where there is a new Policy or significant changes made to an existing Policy, following approval of the Policy by the relevant committee with expert subject knowledge, the Lead Executive Director for the Policy will approve the Policy and then submit to the TDG for final sign off.

Where there are no or minor changes the approval will be by the Lead Executive Director.

Policies will not be presented in full at the TDG meeting, but as a list of policies for approval / ratification. The Policies requiring approval will be circulated to the TDG members via email prior to the meeting so that the Executive Team have the ability to review/comment on each Policy electronically.

APPENDIX E

CLINICAL GUIDELINES TEMPLATE

TRUST CLINICAL GUIDELINE FOR ……..

<table>
<tr><td>Reference Number

From Library andKnowledge Service Manager</td><td colspan="2">Version:</td><td>Status

Draft or Final</td><td>Author:
Job Title:</td></tr>
<tr><td rowspan="3">Version / Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td colspan="2">Reason</td></tr>
<tr><td></td><td></td><td></td><td colspan="2">Brief reference / description as to why an amendment has been made</td></tr>
<tr><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td colspan="6">Intended Recipients: State who the Clinical Guideline is aimed at – staff groups etc.</td></tr>
<tr><td colspan="6">Training and Dissemination: How will you implement the Clinical Guideline, cascade the information and address training</td></tr>
<tr><td colspan="6">Linked Documents: State the name(s) of any other relevant documents</td></tr>
<tr><td colspan="6">Keywords:</td></tr>
<tr><td colspan="3">Business Unit Sign Off</td><td colspan="3">Group:
Date:</td></tr>
<tr><td colspan="3">Divisional Sign Off</td><td colspan="3">Group:
Date:</td></tr>
<tr><td colspan="6">EIRA Stage One Completed Yes / No Delete as appropriate
Stage Two Completed Yes / No Delete as appropriate</td></tr>
<tr><td colspan="3">Date of Approval</td><td colspan="3">Month and Year</td></tr>
<tr><td colspan="3">Review Date and Frequency</td><td colspan="3">Year and Frequency e.g. 2008 every 3 years</td></tr>
<tr><td colspan="3">Contact for Review</td><td colspan="3">This should match the author if different please state who the contact is by Job Title</td></tr>
<tr><td colspan="3">Lead Executive Director Signature</td><td colspan="3"></td></tr>
</table>

APPENDIX E1

Full Clinical Guideline

Reference no.:

1. Introduction

[Cover succinct introduction to the guideline and why it is required.]

2. Aim and Purpose

[What does this document aim to achieve?]

3. Definitions, Keywords

[Any definitions that give the reader a better understanding of the subject matter. Include acronyms or abbreviations in a glossary, as necessary.] Add keywords you think would help to find the document more easily.

4. Main Body of Guidelines – [feel free to change title here to suit the guidance]

[Lay out the guidance you would like to be followed here.]

5. References (including any links to NICE Guidance etc.)

6. Appendices

APPENDIX E2

Summary Clinical Guideline

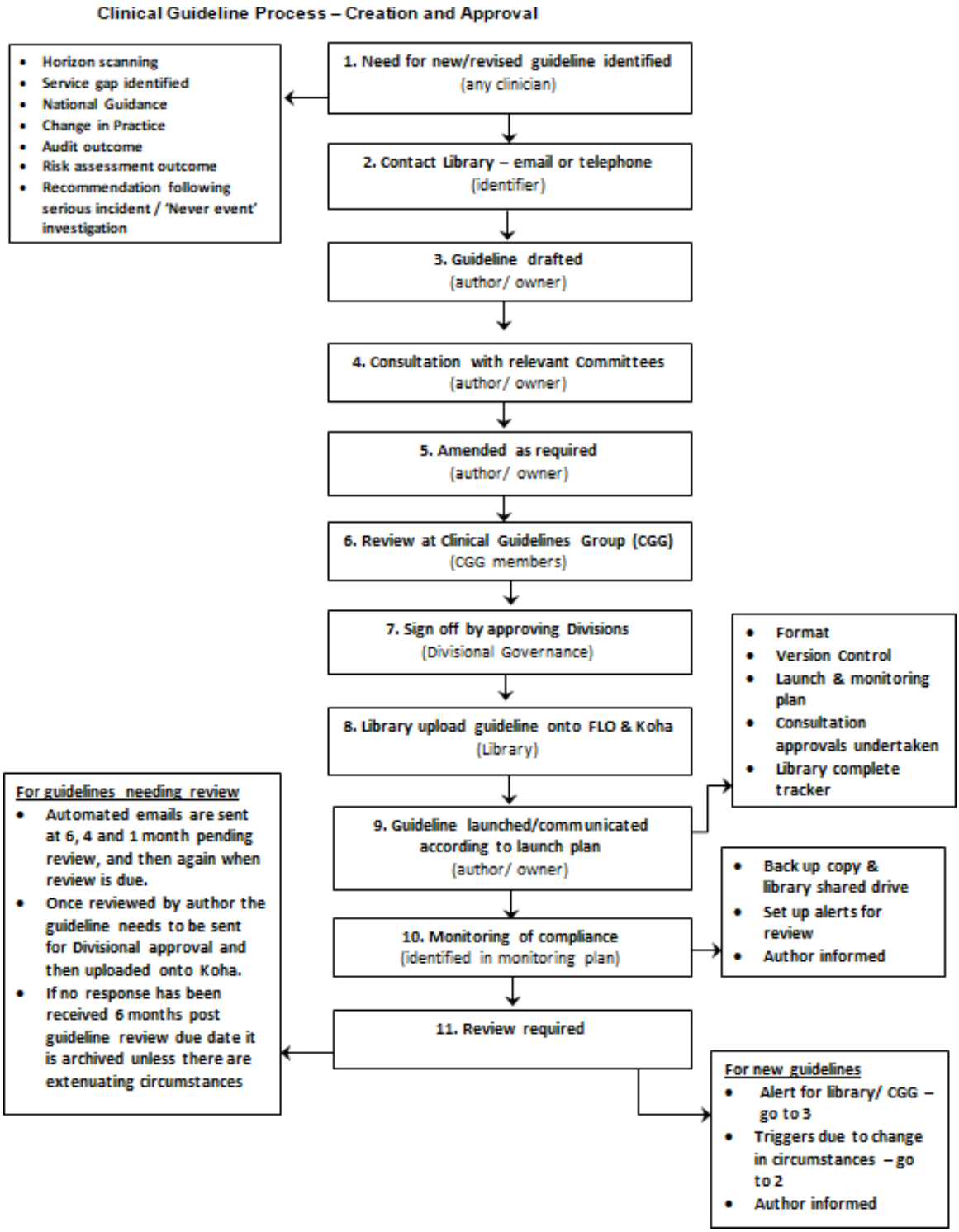
Reference No:

Summary guideline

[For summary guideline – include flow chart / algorithm / checklist here / care bundle detail.]

[Please ensure body text is Arial pt 11.]

APPENDIX E3


Clinical Guideline Process – Creation and Approval
Horizon scanning
Service gap identified
National Guidance
Change in Practice
Audit outcome
Risk assessment outcome
Recommendation following serious incident / 'Never event' investigation
1. Need for new/revised guideline identified (any clinician)
2. Contact Library – email or telephone (identifier)
3. Guideline drafted (author/ owner)
4. Consultation with relevant Committees (author/ owner)
5. Amended as required (author/ owner)
6. Review at Clinical Guidelines Group (CGG) (CGG members)
7. Sign off by approving Divisions (Divisional Governance)
8. Library upload guideline onto FLO & Koha (Library)
Format
Version Control
Launch & monitoring plan
Consultation approvals undertaken
Library complete tracker
9. Guideline launched/communicated according to launch plan (author/ owner)
Back up copy & library shared drive
Set up alerts for review
Author informed
10. Monitoring of compliance (identified in monitoring plan)
11. Review required
For guidelines needing review
Automated emails are sent at 6, 4 and 1 month pending review, and then again when review is due.
Once reviewed by author the guideline needs to be sent for Divisional approval and then uploaded onto Koha.
If no response has been received 6 months post guideline review due date it is archived unless there are extenuating circumstances
For new guidelines
Alert for library/ CGG – go to 3
Triggers due to change in circumstances – go to 2
Author informed

Approval of Clinical Guidelines

Clinical Guidelines will be submitted to the relevant Divisional Clinical Governance Group (CGG), Specialist Forum or equivalent for approval. Authors should be aware that they need to check that there is no duplication of current Clinical Guidelines. Once approved, these can be added to the relevant section on the database by the Clinical Guidelines Group.

All clinical guidelines that mention antibiotics also require approval by the Antimicrobial Stewardship Group uhdb.antimicrobialstewardship2@nhs.net.

Clinical Guidelines will require approval by specialties as required by the CGG and the relevant Division. The approved guidelines are reviewed by the CGG before uploading onto the Trust intranet and appropriate databases.

When new guidance is approved and added to the database any previous versions will be removed and archived by the Library and Knowledge Service.

Evidence of consultation and approval should be provided in electronic, as opposed to paper, format.

University Hospitals of Derby and Burton
NHS Foundation Trust

INSERT TITLE

<table>
<tr><td>Reference Number</td><td colspan="2">Version:

V1</td><td>Status

Draft</td><td>Authors:</td></tr>
<tr><td rowspan="2">Version / Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td>Reason</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Intended Recipients: This LocSSIP is aimed at</td></tr>
<tr><td colspan="5">Training and Dissemination:</td></tr>
<tr><td colspan="5">To be read in conjunction with:</td></tr>
<tr><td colspan="5">In consultation with and Date:</td></tr>
<tr><td colspan="3">Approving Body and Date Approved</td><td colspan="2">Date and Full Name of Approving Body followed by abbreviations</td></tr>
<tr><td colspan="3">Date of Issue</td><td colspan="2">Month and Year</td></tr>
<tr><td colspan="3">Review Date and Frequency</td><td colspan="2">Year and Frequency e.g. 2008 every 3 years</td></tr>
</table>

Local Safety Standards for Invasive Procedures (LocSSIPs) based on the National Safety Standards for Invasive Procedures (NatSSIPs)

Table of Contents

LocSSIPs TEMPLATE

In September 2015, NHS England published a set of National Safety Standards for Invasive Procedures (NatSSIPs) to be modified for local use to produce Local Safety Standards for Invasive Procedures (LocSSIPs). LocSSIPs should be developed by procedural teams with the support of managers rather than simply being handed down by local managers to procedural teams. Different LocSSIPs can apply to different procedural areas within an organisation. Our LocSSIPs supports and tailors the NatSSIPs to our needs and vision and are the standards we expect here at The University Hospitals of Derby and Burton.

"Invasive procedure"

NatSSIPs proposes to address those procedures that have the potential to be associated with a Never Event if safety standards are not set and followed, to include:

- All surgical and interventional procedures performed in operating theatres, outpatient treatment areas, labour ward delivery rooms, and other procedural areas within an organisation.
- Surgical repair of episiotomy or genital tract trauma associated with vaginal delivery.
- Invasive cardiological procedures such as cardiac catheterisation, angioplasty and stent insertion.
- Endoscopic procedures such as gastroscopy and colonoscopy.
- Interventional radiological procedures.
- Thoracic interventions such as bronchoscopy and the insertion of chest drains.
- Biopsies and other invasive tissue sampling.

Does the procedure have a potential to create 'Never event'? Does the procedure require consent? If the answer is yes, then the procedure would be brought under the remit of LocSSIPs.

Aims:

- To reduce 'Never Events' and reduce patient safety incidents.
- Improve delivery of safe care during invasive procedures.
- Improve education and training.

Outcomes:

- Safe, standardized and supportive approach.
- Consistent local standards across all the specialties where invasive procedures are performed.
- Develop generic checklists building on the WHO surgical safety checklist.
- Incorporate the NatSSIPs elements, which include organisational standards and sequential steps.

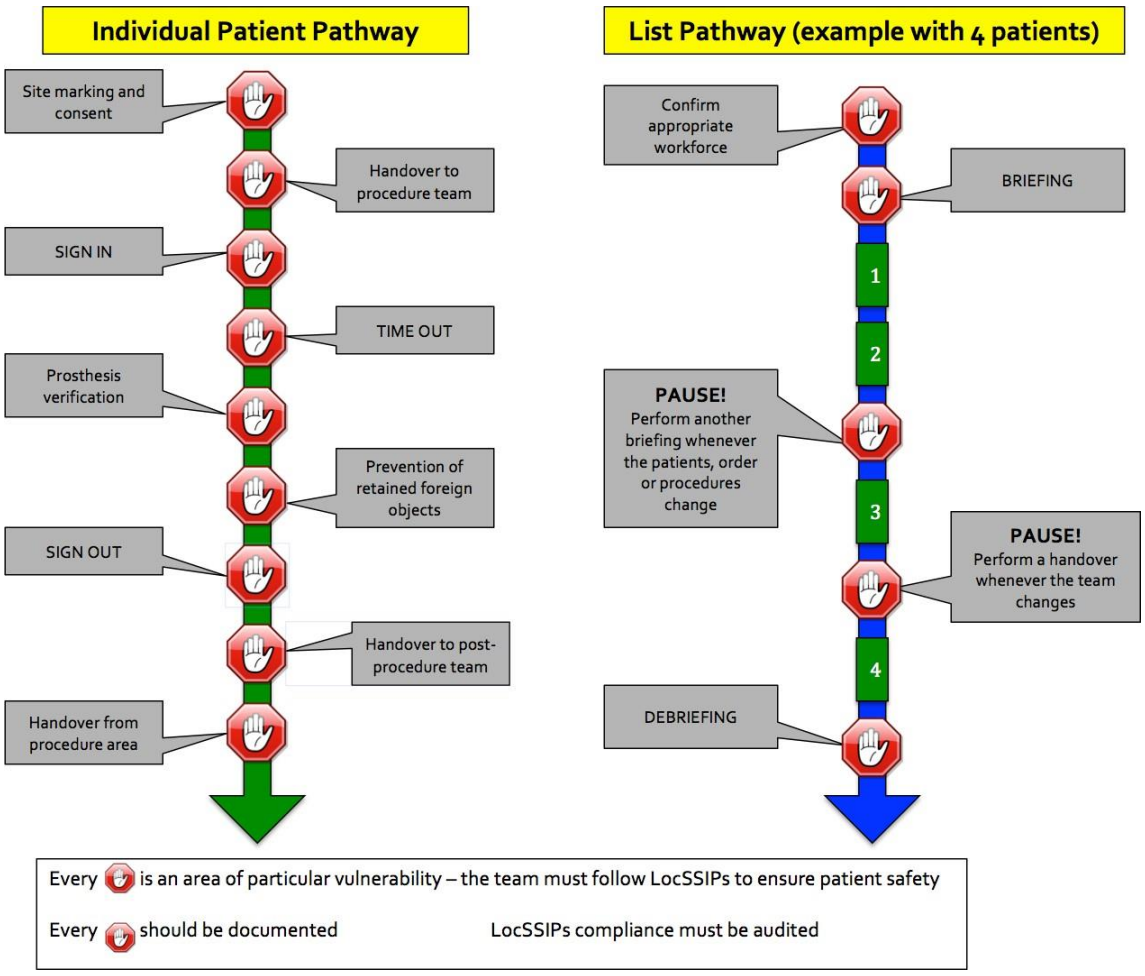
LocSSIPs are locally adapted standards for invasive procedures based on national standards which are adapted for specialty specific procedures or group of procedures. These standards follow the patient through their entire journey from referral, the initial decision to treat through, admission, procedure and discharge.

LocSSIPs therefore be considered a part of a larger patient pathway, and should be included in the continuum of care rather than becoming the sole focus of it.

Review current SOPs to ensure that they are compliant with Trust Safety standards for invasive procedures and national guidelines. Some SOPs may need to be modified to make them LocSSIPs compliant. Others may require full development of LocSSIPs.

Steps in LocSSIPs

ORGANISATIONAL	SEQUENTIAL
1. Governance and audit. 2. Documentation of invasive procedures. 3. Workforce. 4. Scheduling and list management. 5. Handovers and information transfer. 6. Induction. 7. Multidisciplinary Training.	8. Procedural verification and site marking. 9. Safety briefing. 10. Sign in. 11. Time out. 12. Prosthesis verification. 13. Prevention of retained foreign objects. 14. Sign out. 15. Debriefing.



PROCEDURE

Speciality Specific Details

Governance and Audit

- **Compliance of LocSSIPs with NatSSIPs**.
  - Compliance of local practice with LocSSIPs.
  - Evidence of action plans incorporating timescales for addressing non-compliance.
  - Evidence of regular review of LocSSIPs and their adjustment as required.
- All patient safety incidents and near misses should be documented and reported to the organisation's incident reporting system.
- **Management of incidents**: All incidents, including near misses, should be reported via Datix and reporters should expect a response and be involved in the solutions.
- These should be analysed, investigated as appropriate, and learning should be fed back to staff for continuous improvement.
- This should be in accordance with organisational policy, ensuring compliance with the Patient Safety Incident Response Framework and Never Event Framework.
- **Guidelines, standards, policies and protocols**: There should be a process for the development, review, authorisation and dissemination of locally and nationally produced guidelines, standards, policies, protocols and standard operating procedures (SOP)
- **Risk management**: Identifies, assesses and grades risks in and around the services. These risks can cover a wide spectrum including business continuity, staffing, equipment, issues with estates and financial risks

WHO	WHAT	HOW	SAMPLE SIZE	WHEN	REPORTING	REPORTING
… is responsible for monitoring this element? (job title of person or group responsible).	… element of compliance or effectiveness within the procedural document will be monitored?	… will this element be monitored? (method used) Audit in place (title).	Every patient or a sample of patients?	… will this element be monitored? (frequency/how often) Quarterly/half yearly/annual.	Which committee/group will the resultant report and action plan be reported to and monitored by? (report should include any areas of good practice/organisational learning).	How often will the committee/group receive reports and updates?

AUDIT: TO CHECK IF THE STANDARDS FOR EACH CRITERIA ARE MET, IF NOT DESCRIBE ACTIONS TO IMPROVE

All divisions and directorates that carry out invasive procedures will be required to review what we have in place to ensure that they meet the minimum requirements and are appropriate to the procedures in question and if not revise them accordingly. Ensure that all relevant staff are aware of our standards and checklists and are using them in practice.

It is mandatory to audit the compliance of LocSSIPs in each speciality and have a system in place to report them on a quarterly (or monthly) basis.

Documentation

Standardised documentation must be used to ensure the recording of essential information throughout the entire patient pathway during invasive procedures. This involves creating standardised documentation for patients undergoing invasive procedures that promotes the sharing of patient information between individuals and teams and include:

- Pre-procedural assessment.
- Pre-procedural planning.
- Plan for sedation.
- Consent forms.
- Pre-procedure checklist.
- Sedation risks explained and aftercare.
- Team members present.
- Sequential steps LocSSIPs compliance.
- Operation notes.
- Post-procedural care and handover.
- The documentation must be completed, legible, contemporaneous, without abbreviation and jargon, with a standardised terminology.
- The documentation should promote the implementation and audit of, and record compliance with LocSSIPs, to include handovers of care, safety briefing, sign in, time out, checks to ensure correct site surgery, the insertion of the correct prosthesis, prevention of the retention of foreign objects, the sign out at the end of the procedure and debriefing.
- When paper and electronic documentation are both in use, both systems should be aligned such that there is no unnecessary duplication of data entry or inconsistency. The organisation must identify which is the primary information source for later reference.

Workforce

- Establishments and day to day staffing for all professional groups must be adequate to meet the predicted procedural workload.
- The theatre manager, or equivalent individual for each procedural area, should confirm the availability of an appropriate workforce for each operating theatre or invasive procedural area before the start of any list or session.
- Job plans and establishments must take into account the time required to set up, calibrate and perform safety checks on specialist equipment, and for staff to participate in briefing, debriefing and other key safety steps in LocSSIPs
- Should reflect a risk managed mix of substantive and non-substantive staff.
- All professional groups must have clear plans for escalation when clinical demand overwhelms resources and a risk management plan for monitoring the frequency of these events.
- The workforce standards set for out-of-hours work should be the same as the equivalent procedures performed during standard working hours.
- Some clinical specialities may have defined workforce standards published by their professional associations and colleges. It is appropriate to use these workforce standards to inform LocSSIPs.
- All staff must receive continuous professional development (CPD) to keep up to date with changing practice.
- The LocSSIPs must take into account the supervision of students and trainees, including:
    - Doctors in training.
    - Student ODPs.
    - Undergraduate and postgraduate nurses and midwives.
    - Learners in other supporting roles.

Handovers and Information Transfer

- Standard format for handovers should be used. Both written and verbal handovers should be done.
- In case of emergencies where verbal handover has to be done, written documentation can be retrospectively done.
- Areas should specify which team members should be present at each handover. Surgeons or operators must participate in handovers in which the patient's care pathway has deviated from that planned and when patients are handed over to critical care teams after.
- During handovers, only one person should speak at a time, and the conversation during the handover should relate only to the patient. Non-handover activities should cease during the handover. Each team member should be given the opportunity to ask questions and clarify.
- Patient four-point identifiers, allergies, medical history, the planned or completed procedure, medications administered and any other additional relevant information.
- The patient's notes or relevant documentation should be available for use during handover.

Scheduling and List Management

- LocSSIPs must include the unambiguous use of language in all communications relating to the scheduling and listing of procedures.
- The clinical team performing the procedures is responsible for deciding the order of procedures within a list of cases.
- Although the clinical team performing the procedure is primarily responsible for its accurate scheduling, it must when appropriate involve other clinical disciplines such as anaesthesia and radiology to ensure that all healthcare professionals necessary for the safe performance of the procedure are available at the correct time.
- List changes should be avoided if possible.

> *Any list changes made after the deadline for the publication of a final version of the list must be agreed with the procedure team and should be discussed by all members at the Team Brief. Furthermore, all areas of care need to be informed of the changes, admissions and recovery, so that the correct patients are admitted, and patients informed of any additional waiting time as a result of the change.*

List information should include:

- Name, number, date of birth, gender, planned procedure, source of patient e.g., ward or outpatient, urgency, significant co-morbidities, allergies and infection risk.
- Laterality must always be written in full, i.e., 'left' or 'right'. The use of abbreviations should be avoided.
- The order should only change for clinical/ safety reasons and be seen as a risk.
- If the list information is incorrect, a Datix incident form should be completed and steps taken to correct the information as soon as possible.

> *Organisations must ensure that all relevant personnel are made aware of any late changes to a list. In the absence of electronic list scheduling, the organisation must have clear processes for managing lists and an effective mechanism for version control that ensures that different versions of lists are not available.*

- There is a scheduling standard operating procedure (SOP) and, in some specialities, specific scheduling manuals that must be followed.
- LocSSIPs should include specific safeguards and clear responsibility for ensuring that patients are not deprived of oral nutrition or hydration for unnecessarily long periods due to delays or list changes.
- The procedure list should be clearly displayed in the room in which the procedures are performed, and any other areas that are deemed important for the safe care of the patient. The final version of the list should be available at the safety briefing.

Induction

Mandatory Induction includes:

- Trust induction: Should include most mandatory training requirements before starting in the workplace.
- Local induction: Is mandatory for all new staff working in areas where invasive procedures are carried out.
- A comprehensive induction pack should be given to all new staff members.
- A competency booklet is given to all new staff.
- Induction requires dedicated time, staffing and space to enable delivery without any adverse effects on patient care is given to all new members of staff – Registered and non-registered nurses (4 weeks).
- The induction programme should be planned in advance with named assessors and mentors in place before the start date of the new team member.

Substantive and non-substantive: Staff should be included in local induction

Multidisciplinary Training

Multidisciplinary team training is a minimum standard

- It **must include** multiple professional groups.
- It must be **planned and delivered** on a rolling basis.
- It must include **teaching and understanding** of the local standards LocSSIPs.
- It must be **embedding safety practice.**
- It must include **non-technical skills and human factors.**
- **All MDT** members must receive regular updates and CPD.

UHDB LocSSIPs:

- ❖ **Standardise**
- ❖ **Harmonise**
- ❖ **Educate**

Safer systems – safer culture

Procedural Site Verification and Marking

- Patients must be accompanied by a valid consent form when arriving at the procedural area.
- Procedure site must be marked shortly before the procedure but NOT in the anaesthetic room or the procedure room
- The correct procedure and marking must be verified with the patient, with consent form, with clinical notes and with the operating list.
- Marking must be performed using an indelible marker by the operator or a nominated deputy who will be present during the procedure. The operating surgeon is responsible for marking the patient. This task may be delegated to another doctor; however, this person should be present in theatre during the operation. Marking should be carried out with the active involvement of the patient who should be conscious and alert. The mark must not be ambiguous and should indicate the site to be operated on, ideally with an arrow mark. Patients have the right to refuse marking. This should be clearly documented. The operation does not need to be cancelled if marking is refused.
- In cases the marking is not clear, nor refused by the patient, it should be confirmed thoroughly with the patient and documented and should be discussed in the team brief.
- Planned procedure must be confirmed and the surgical site marking checked at both sign in and time out.
- Marking should be visible throughout the procedure.

Documentation of sign in, time out and sign out should include procedure and surgical site and side.

Team Brief

A safety briefing must be performed at the start of all elective, unscheduled or emergency procedure sessions.

- Any member of the team can lead the team briefing.
- The safety briefing should consider each patient on the procedural list in order from an operator, anaesthetic and practitioner perspective.
- The total time set aside for the procedure or list of procedures should include the time taken to conduct the safety briefing.
- The safety briefing should take place in a discreet location in which patient confidentiality can be maintained.
- The team brief should include
- The senior operator and trainee(s)/assistant(s).
- The senior anaesthetist and trainee(s).
- The anaesthetic assistant.
- Scrub and circulating practitioners or other procedural assistants.
- Any other healthcare professional involved in the procedure
- Each member of the procedural team expected to be involved in the scheduled session must be named and this list made easily visible throughout the session.
- The operator, scrub practitioner and anaesthetist if relevant must be identified for each case listed

Team members should introduce themselves to ensure that their roles and names are known and to encourage people to speak up and silence should be used effectively.

- Diagnosis and treatment.
- Site and side of Procedure.
- Prosthesis.
- Infection risk, e.g., MRSA status.
- Allergies.

- Expected Duration of Procedure and any specific complications.
- Relevant comorbidities or complications.
- Likely need for blood or blood products.
- Patient positioning.
- Likely need for blood or blood products.
- Equipment requirements and availability.

- Every team member should be encouraged to ask questions, seek clarification or raise concerns about patient care.
- A record should be made of the team briefing, and should be displayed in the procedural area for reference during the procedure list.
- If a significant issue about the care of a patient arises during the briefing, a clear and contemporaneous note of this should be made in the patient's records.

Sign-in

- A**ll patients having invasive procedures must undergo sign-in**: This includes all patients under general, regional or local anaesthesia and under sedation.
- **Sign-in should occur prior to sedation or anaesthesia**: Premedication should only be given once the Sign In is done.
- A two-person check: for procedures performed under general, regional or local/ sedation, these should include the anaesthetist and an anaesthetically trained registered practitioner.
- For procedures not involving an anaesthetist, the operator and an assistant should perform the sign-in.
- **Make provision for those who cannot speak English**: Provision must be made for those who cannot speak English or who have special requirements (e.g., disability, impaired hearing or sight etc.) Trust registered interpreters maybe present in the anaesthetic room or a family member. The family member should not act as the interpreter.
- Immediately before the insertion of a regional anaesthetic, the anaesthetist and anaesthetic assistant must simultaneously check the surgical site marking and the site and side of the block (Stop Before You Block).

  This is a separate distinct process to sign in.

- Participation of the patient (and/or parent, guardian, carer or birth partner) in the sign in should be encouraged when possible
- The sign in should not be performed until any omissions, discrepancies or uncertainties identified in the handover from the ward or admission area to the receiving practitioner in the procedure area or anaesthetic room have been fully resolved
- A sign in must be completed and documented on arrival at the procedure area or anaesthetic room.
- **Paperwork required**: Individual Care Plan/ pre-procedure checklist, notes, consent, drug chart or EPMA, allergy and pregnancy status.

The checks performed during the sign in should include:

- Patient name checked against the identity band. Positive Patient Identification with the patient- against the printed ID band, consent form and operating list. This would include name, date of birth and hospital number.
- Consent form checks to include no abbreviations, confirmation of patient understanding, date of consent
- Surgical site marking if applicable.
- Operating list.
- Stent /Prosthesis /Implant including IOL (Individual specialities should specify their own LocSSIPs) for prosthesis /implant. Stent/IOL. These should clearly state the standards, specific forms used for identification and documentation of SPI. The standards should be same across all five sites. These standards should specify the points at which the checks would take place clearly with clear accountability of personnel at each stage. This should be checked against the patient's name, date of birth and hospital number and NHS number.
- Anaesthetic safety checks: machine, monitoring, medications.
- Allergies.
- Aspiration risk.
- Potential airway problems/Arrangements in blood loss
- Pregnancy status.
- Starvation time/ aspiration risk.
- Infection risk.

Time out/STOP moment

- Patient's name and identity band checked against the consent form, procedure to be performed, verification of surgical site
- Any team member who has professional accountability can lead time out. Noise should be kept to a minimum. All team members must be present and the lead should verify all team members are participating.
- ENCOURAGE the PATIENT TO BE INVOLVED if they are awake
- Operator: The anticipated blood loss. Any specific equipment requirements or special investigations. Any critical or unexpected steps. Relevant imaging/ tests available/prostheses & implants/equipment.
- Anaesthetist: Any patient specific concerns. Patient's ASA Physical Status. Monitoring equipment and other specific support, e.g., blood availability.
- Scrub practitioner or operator's assistant: Confirmation of sterility of instruments and equipment. Any equipment issues or concerns.
- Surgical site infection: Antibiotic prophylaxis/ Patient warming/ Glycemic control/ Hair removal if required.
- VTE prophylaxis, allergies, infection, pregnancy status.
- DECLARE TIME OUT 'COMPLETE' and that the procedure can start. Keep a signed record.

Prosthesis Verification

Before the Procedure

- LocSSIPs should define how specific prosthesis requirements are communicated by surgical and other clinical teams to operating theatre and procedural teams.
- Individual specialities should have their protocol for prosthesis/implants/stents/lens verification. Once a specific implant/IOL/prosthesis is identified it should be confirmed with positive patient identification including name, date of birth, NHS number and Hospital number.
- When a prosthesis is non-standard or is not included in an agreed permanent prosthesis stock i.e., a "non-stock" prosthesis, the operator must ensure that the prosthesis requirements are communicated effectively to the procedural team in sufficient time for the prosthesis to be ordered and received
- The operator must use the safety briefing before the start of a procedural list to confirm with the procedural team that the required prostheses.
- The operator must inspect the available prostheses and confirm that the correct prosthesis or range of prostheses.
- A named team member should be responsible for ordering and checking correct implant delivery before the procedure. This information should be available to the rest of the team before the patient is brought in to the procedure area.

During the Procedure

Before removal of the prosthesis from its packaging, the operator should confirm the following prosthesis characteristics with the procedural team, and confirmed with the scrub nurse.

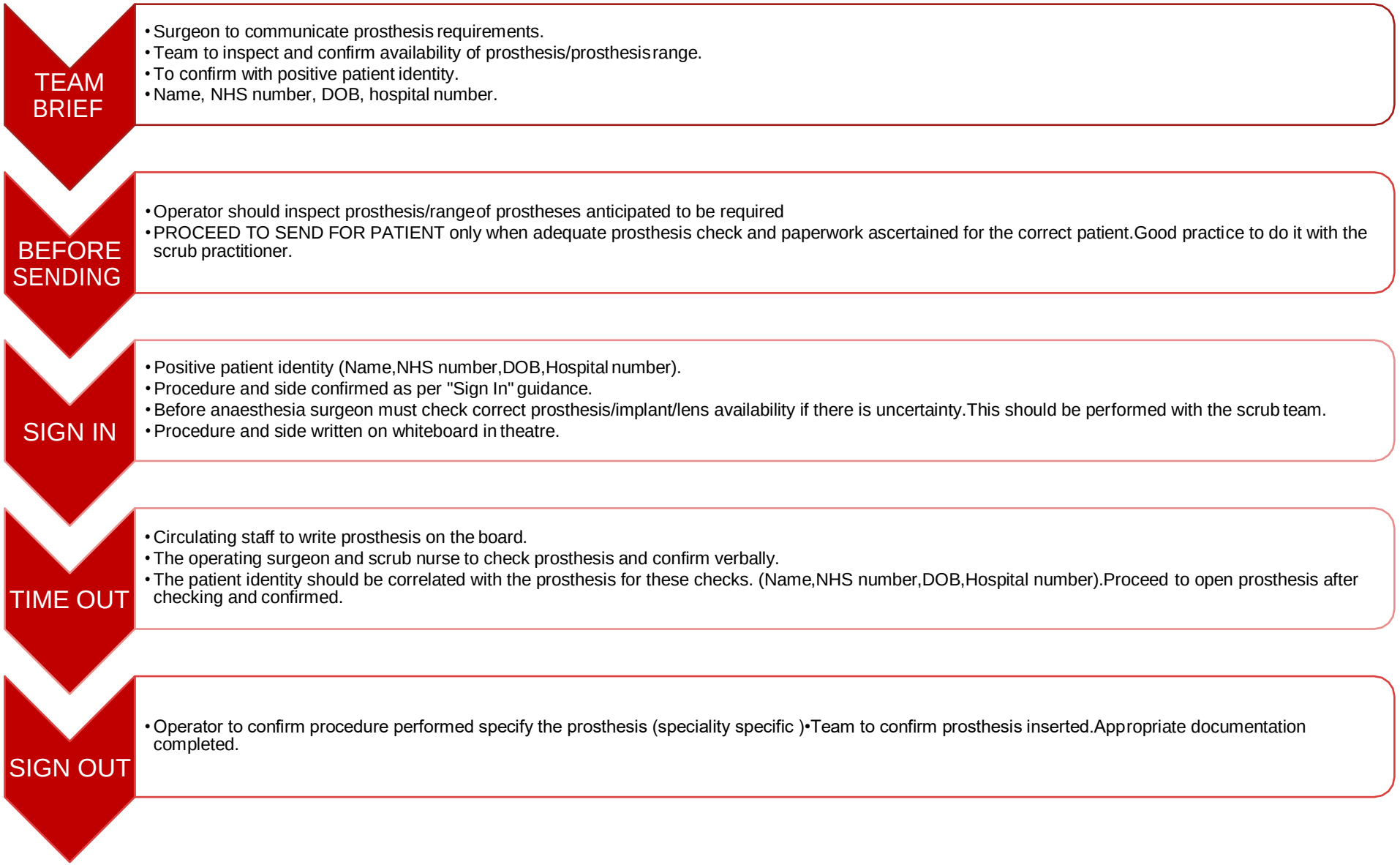
- Type, design, style or material.
- Size.
- Laterality.
- Manufacturer.
- Expiry date.
- Sterility.
- Dioptre for lens implants.
- Compatibility of multi-component prostheses.
- Any other required characteristics.

Once the correct prosthesis has been selected, any prostheses not to be used for that patient should be clearly separated from the correct prosthesis to minimise the risk of confusion

Sign-out or after the Procedure

A record of the SPI (Stent/Prosthesis/implants /IOL) used must be made in the patient's notes and appropriate details should be shared with the patient after the procedure. The following details should be recorded.

- The name of the procedure and the side should be confirmed.
- The team should confirm the specifications of the prosthesis inserted, i.e. by reading aloud the prosthesis label.
- A record of the prosthesis used must be made in the patient's notes.
- When a manufacturer's sticker label is available this should be placed in the notes.
- If a sticker label is **not** available, then ensure the following are recorded: manufacturer; size; style; and serial number.
- Prosthetic details must be added to national registries when required.
- All prosthetic implants must be documented as per departmental procedure in the patients notes and applicable registers, and for re ordering purposes. For standard safe practice, where multiple SPI's are required for the same patient, the same circulating team member should check all SPI's.


TEAM BRIEF
• Surgeon to communicate prosthesis requirements.
• Team to inspect and confirm availability of prosthesis/prosthesis range.
• To confirm with positive patient identity.
• Name, NHS number, DOB, hospital number.
BEFORE SENDING
• Operator should inspect prosthesis/range of prostheses anticipated to be required
• PROCEED TO SEND FOR PATIENT only when adequate prosthesis check and paperwork ascertained for the correct patient.Good practice to do it with the scrub practitioner.
SIGN IN
• Positive patient identity (Name,NHS number,DOB,Hospital number).
• Procedure and side confirmed as per "Sign In" guidance.
• Before anaesthesia surgeon must check correct prosthesis/implant/lens availability if there is uncertainty.This should be performed with the scrub team.
• Procedure and side written on whiteboard in theatre.
TIME OUT
• Circulating staff to write prosthesis on the board.
• The operating surgeon and scrub nurse to check prosthesis and confirm verbally.
• The patient identity should be correlated with the prosthesis for these checks. (Name,NHS number,DOB,Hospital number).Proceed to open prosthesis after checking and confirmed.
SIGN OUT
• Operator to confirm procedure performed specify the prosthesis (speciality specific)•Team to confirm prosthesis inserted.Appropriate documentation completed.

Retained Foreign Objects

- Organisational Responsibilities:
  - Methods and documentation for counting and reconciliation should be standardised in all areas.
  - A list of items that are included in the count should be understood by the team and edited local, with analysis of risks and safety incidents via governance processes.
  - Local induction and handover practice should reinforce a safe count procedure.
- Equipment Management:
  - Instrument sets and equipment should be risk assessed in order to rationalise and maintain an up-to-date list including the number of parts.
  - The integrity of all items must be checked before and after use. **Swabs should never be cut**.
  - All swabs used for invasive procedures must contain radioactive markers.

During the procedure

Who?

The count is completed audibly by two trained and competency assessed staff; one of which must be a registered theatre practitioner (NMC or HCPC). Staff changes should be kept to a minimum and seen as a risk. The final count is confirmed by the surgeon / equivalent other. Any time a discrepancy is suspected, any member of the team can request a count at any time during a procedure

When?

- Baseline (NB. Throat packs inserted by the anaesthetists must be added to the whiteboard and checked ‘removed’)
- Before closure of any cavity, major organs, abdomen
- Before closure of the pericardium/ pleura in thoracic procedures
- Before closure of any first layer of muscle e.g. spinal and joint replacement surgery
- Before wound closure begins
- When skin closure / or equivalent begins
- When skin closure / or equivalent has finished
- Prior to handing over to any other practitioner

How?

A team ‘focus’ without distraction is critical to an accurate count. The start of this is announced to the team, when the scrub practitioner says ‘swab, needles and instrument check’. The end of which the final count is verbally acknowledged by the surgeon / equivalent other.

What?

Any item that enters the surgical field should be accounted for. This includes swabs, needles, sutures and instruments.

All caps, sheaths and bungs are to be removed immediately and discarded in the clinical waste bin.

Failed Reconciliation

Inform the operating surgeon / Equivalent other, repeat the systematic count, theatre and operating site searched, plain x-ray, document, report to theatre co-ordinator, complete incident form, provide patient information- duty of candour.

Intentional Retention of Objects

Retained large swabs procedure must be followed: The information at the WHO ‘sign-out’ recorded/documentation in the electronic care plan and the operating register. This information will also be documented in the medical notes by the surgeon or equivalent other with a clear plan for future care and removal and, clearly handed over to recovery or HDU or ICU.

Sign-out

Sign-out is an essential safety check at the end of the procedure; it occurs before the patient leaves the procedure room. All team members involved with the procedure are to be present and activity stopped while the sign out is completed.

Any **team member** may lead the sign-out, but there should be a designated person responsible for its completion. The team member leading the sign-out confirms that the following steps are completed:

- The **Team Leader** verbally confirms documentation relates to the correct patient and any additions to the original procedure listing and any instructions for recovery.
- Whether the patient needs to be seen before discharge.
- Confirms suitability for direct discharge (if applicable).
- Ensures that all nursing documentation has been completed.
- Any advice regarding medications
- Advice regarding the patients care plan

Any equipment problems should be communicated: In the report form and documented via the relevant Co-ordinator, via IR1 to be completed ASAP

Swab count should be confirmed and IV lines should be flushed and confirmed verbally.

Debrief

Debriefing: Is essential for team communication and to continuously improve safer patient care.

It should involve the whole team: Every member of the procedural team should take part in debriefing. Job plans, scheduling and work patterns should allow and encourage staff to participate in the debrief.

Key areas to consider include:

- **Equipment**
- **Personnel**
- **Environment**

Debriefing enables a team to reflect on what went well; it should be completed at the end of a procedural session.

Usually, the theatre team leader or circulating staff will be in the best position to perform de-briefing.

The team leader/circulating staff should ask the surgical team, the anaesthetic team and the theatre team:

- What went well in the list?
- What could be improved for next time?
- The debrief should be conducted in a confidential manner which enables inclusivity and contribution from all team members.

Staff and team members may feel unable to give feedback which should be recorded to assess how well the debriefs are working.

UHDB LocSSIPs:

- ❖ **Standardise**
- ❖ **Harmonise**
- ❖ **Educate**

Safer systems – safer culture

Sample LocSSIPs Form (Sequential steps)

PATIENT IDENTITY:	**Operator**:
	Assistant:
	Scrub practitioner:
	Level of Supervision: SPR/CONSULTANT
	Procedure Date (DD/MM/YY):
	Grade (FT/CT/SPR/CONSULTANT):
SIGN-IN *(before the procedure)*	
Patient identity confirmed:	YES or NO
Appropriate consent:	YES or NO
Name of the procedure:	LA or Sedation
Are there any contra-indications for performing this procedure?	
PMH:	YES or NO
MEDICATIONS:	YES or NO
ALLERGIES INCLUDING LATEX:	YES or NO
BLOOD TEST/INR/ANTICOAGULANTS:	YES or NO
Are there any concerns for the procedure for this patient?	YES or NO
TIME OUT *(Verbal checks to confirm the role of the team)*	
Procedure confirmed with another member of the team?	YES or NO
Instrument check?	YES or NO
Radiographs?	YES or NO
Any concerns?	YES or NO
If so, have they it been addressed? **Comments:**	YES/NO/Not applicable
SIGN-OUT	
Post-op instructions given?	YES or NO
Any equipment issues?	YES or NO
Histology sample confirmed and documented:	YES or NO
Suture removal in days/weeks:	YES or NO
Follow-up appointment:	YES or NO
OPERATOR SIGNATURE:	
Any further comments?	

APPENDIX F1

LocSSIPs Development

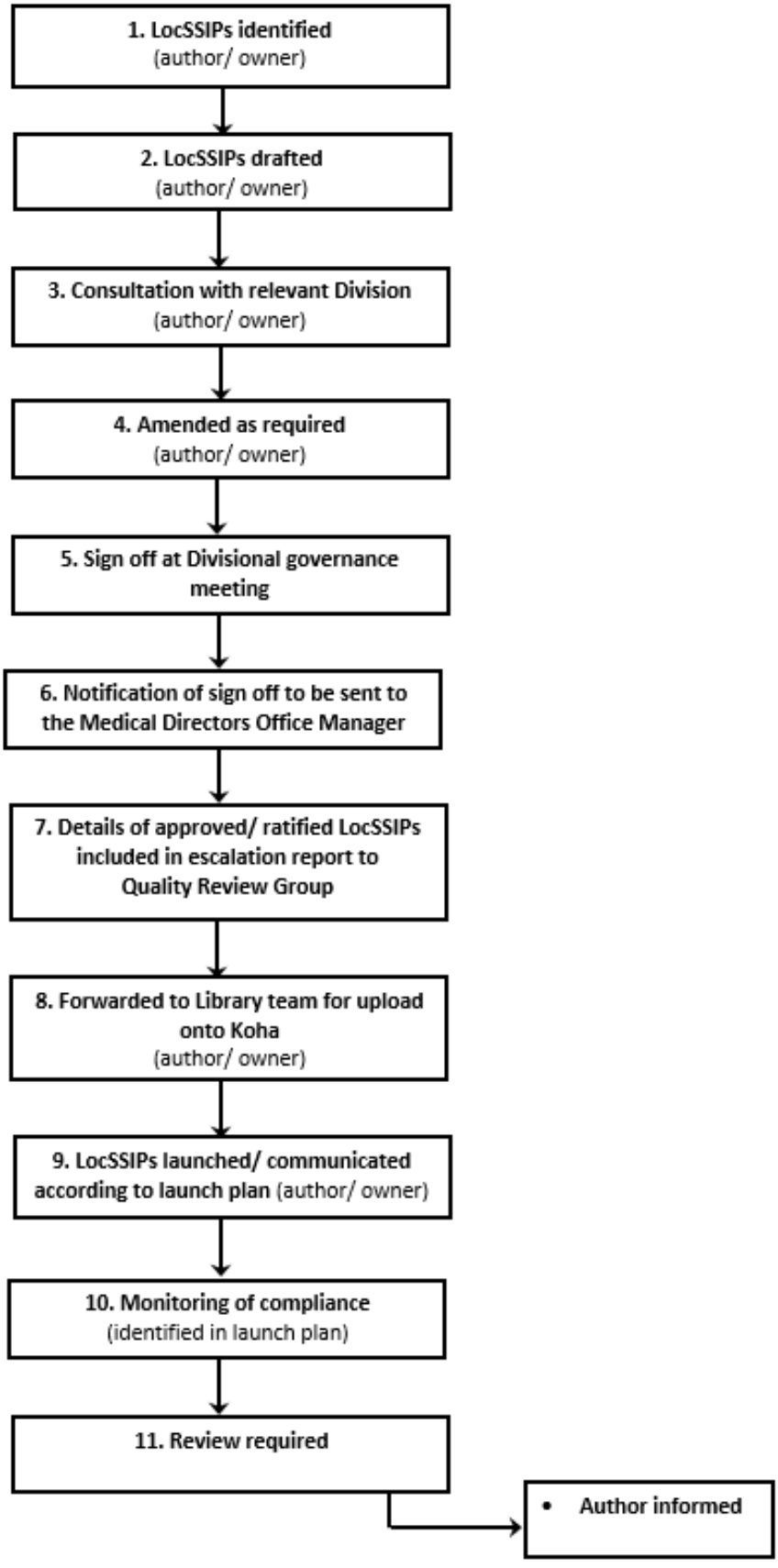
LocSSIPs should be developed by procedural teams (which comprises of the doctors, nurses, Allied health professionals, and members of the procedural teams) with the support of managers using the template provided in Appendix F.

Procedural checklists which form part of the LocSSIPs should be developed by individual procedural teams, ideally written by a team member with expertise and knowledge of the procedure.

Royal College or specialty societies may have their own templates for checklists and these must be used as the basis of a LocSSIPs or documentation when they are available.

If the teams have existing procedural checklists and SOPs these should be checked to ascertain that they are compliant with LocSSIPs standards which is based on the Nat SSIPs document.

LocSSIPS PROCESS – CREATION AND APPROVAL



Approval of LocSSIPS

The LocSSIPs Core Implementation Group is a key advice forum for discussion for the invasive procedures team. The teams which are involved in carrying out invasive procedures are advised to contact the core Group for advice.

The LocSSIPs policy development and update is done by the Trust Clinical Lead for NatSSIPs and LocSSIPs. Quarterly LocSSIPs updates are provided to the Quality Review Group.

The Divisional triumvirate which includes Divisional Medical Directors, Divisional Nursing Directors and Divisional Directors ensure that

- Procedures in their areas of responsibility that require LocSSIPs to be written are systematically identified
- Lead clinicians and or managers are identified for each LocSSIPs
- LocSSIPs are signed off at the relevant Divisional meeting
- LocSSIPs are regularly reviewed to ensure that they remain up to date.
- Regular audits of compliance are carried out and presented to the LocSSIPs core with onward reporting to the Clinical Compliance Group.
- Dissemination of LocSSIPs to relevant team members.

Responsibility of the care of the patient is a shared responsibility of all the staff members of the procedural teams.

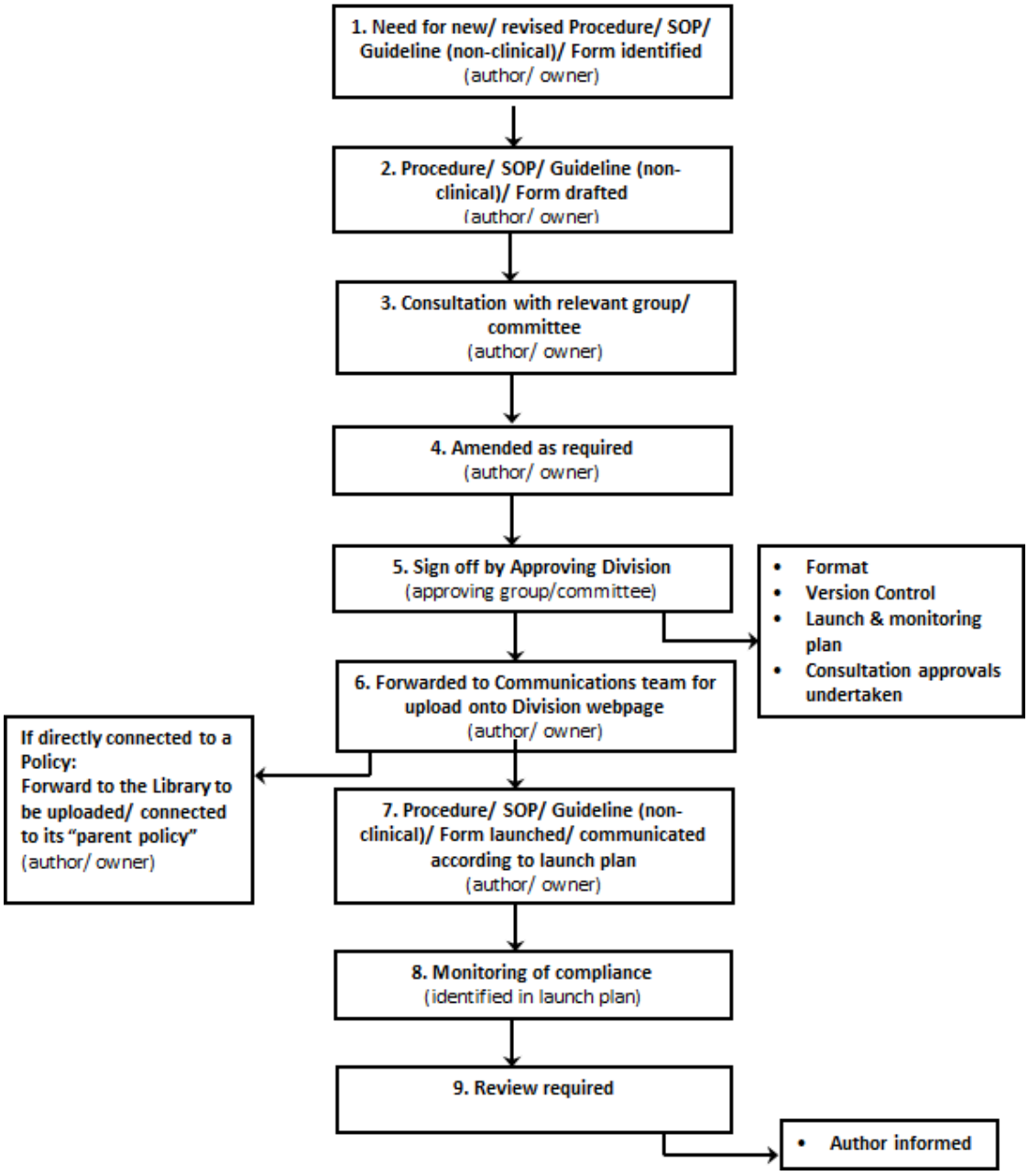
All members have a responsibility to speak up if they have concerns related to the safe delivery of care during an invasive procedure.

All staff involved in the pathway of a patient who is undergoing an invasive procedure:

a) Are responsible for the safe delivery of care to the patient.
b) Must be aware of the Local Safety Standards of Invasive procedure.
c) Must follow the Local Safety Standards accurately for every patient.
d) May be required to participate in the creation, implementation and audit of LocSSIPs.
e) Must participate fully in the agreed safety checks and the steps built into the team LocSSIPs.
f) Must participate in routine and frequent team building and team training.
g) Must ensure that adverse events are documented, through Datix and investigated when appropriate.

APPENDIX G

Procedure/ SOP/ Guideline (non-clinical)/ Form Process – Creation and Approval



Approval of Procedure or SOP or Guideline (Non-Clinical) or Form

Procedures or SOP's or Guidelines (non-clinical) will be submitted to the relevant Divisional Governance Group, Specialist Forum or equivalent for approval. Authors should be aware that they need to check that there is no duplication of current Procedures or SOPs or Guidelines (non-clinical). Once approved (if it has a direct link to a Policy) it can be forwarded to the Library and Knowledge Service Team to be uploaded onto Koha. If there is no direct link to a Policy it should forwarded to the Communications Team to be uploaded to the designated section of each Division's intranet site.