University Hospitals of Leicester NHS
NHS Trust

Policy for Developing and Approving Clinical and Non-Clinical Policies and Other Guidance[1] Documents

([1] known as 'Policy for Policies')

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Guidelines, Procedures, Standard Operating Procedures, Protocols and any other document that provides guidance to staff.

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Review dates and details of Changes made during the review

This is a significant rewrite to reflect that this Policy is to be approved by the Trust Board and there are separate approval routes depending on whether the policy or guideline is clinical or non-clinical.

Key Words

Policy for Policies

Standard Operating Procedures

SOP

Developing and Approving Policies

Policy and Guidelines Policy

P&G Policy

PAGL

Writing policies

Writing guidelines

1 INTRODUCTION AND OVERVIEW

1.1 Organisations need formal written documents (policies, guidelines, procedures) which communicate standard organisational ways of working. These help to clarify strategic and operational requirements and bring consistency to day-to-day practice. In addition, they can improve the quality of work and increase the successful achievement of objectives.

1.2 A common format and approval process for such documents helps to ensure that policies, guidelines or procedures in use are current and reflect an organisational approach.

1.3 It is the responsibility of the Trust to ensure that all policies, guidelines or procedural documents (clinical and non-clinical) are appropriately evidence-based, rigorously developed, formally approved, effectively implemented and disseminated and routinely monitored and reviewed.

2 POLICY SCOPE- WHO THIS POLICY APPLIES TO AND ANY SPECIFIC EXCLUSIONS

2.1 This Policy applies to all members of staff working within UHL who are involved in any aspect of Policy and Guideline development and use.

2.2 This policy applies to all policies and guidance documents (P&Gs) used in the Trust, as defined in Section 3 and includes those P&Gs that apply to single departments or CMGs as well as those with wider implications within the Trust.

2.3 The policy does not apply to the development and approval of strategy documents. These should be reviewed and approved by the appropriate Trust committee.

3 DEFINITIONS AND ABBREVIATIONS- IN ALPHABETICAL ORDER

3.1 **Approval Body** is the body authorised to approve certain categories of P&Gs. For Category A documents this is the Trust Board. For Categories B and E this is the Clinical Policy and Guideline Committee (for Clinical documents) and the Non-Clinical Policy and Guideline Committee (for non-clinical documents). For Categories C and D this is the CMG Board, as determined by the appropriate Clinical Director, with responsibility for approving P&Gs (eg quality and Safety Board)

Category	Final approval body
A	Trust Board
B (clinical)	Clinical Policy and Guideline Committee
B (non-clinical)	Non-Clinical Policy and Guideline Committee
C	CMG Board with responsibility approving P&Gs (eg Quality and Safety)
D	
E (clinical)	Clinical Policy and Guideline Committee
E (non-Clinical)	Non-Clinical Policy and Guideline Committee

3.2 Associated Documents

3.3 Associated documents are other UHL policies or guidelines that are separate from but have relevance to the P&G in question.

3.4 Document Categories

The scope of P&G-documents will vary with some just being applicable to one department or CMG or a specific staff group whilst others will apply to every member of staff in the Trust.

Definitions of Categories used within UHL are as follows:

Category A– are those documents which must be approved by the Trust Board. They will fall into two types; either the Trust Board will have reserved to itself the power to approve such documents or otherwise an external body will require that the Trust Board must approve the document.

Category B – are those P&Gs that are to be used by staff in more than one CMG or Corporate Directorate, but which do not require explicit Trust Board approval.

Category C – are those P&Gs that are to be used entirely within one CMG or one Corporate Directorate, but which do not require explicit Trust Board approval.

Category D – are those P&Gs that are to be used across both the Women's and Children CMG and the Children's Emergency Department, but which do not require explicit Trust Board approval.

Category E – External P&Gs – are those P&Gs which have been developed by UHL alongside external organisations and where PGC have authorised a deviation from Trust format at the request of the Trust lead for the document, but which do not require explicit Trust Board approval**.**

3.5 Guideline

A **guideline** is a statement by which to determine a course of action. By definition, following a guideline is never mandatory. Reasons for deviation from the guideline are possible but must be fully justifiable and agreement from senior management must be sought in all cases of any doubt. Guidelines are mainly used in the clinical setting where they provide a clear indication of the best choices for the management of a patient's clinical condition. Guidelines may relate to an overarching policy but can be stand- alone. Where more specific clinical detail is required this may be contained within a supporting procedural document.

A **Clinical guideline** is a Guideline which includes the provision of advice on clinical matters.

A **Non-Clinical guideline** is a Guideline which does not include the provision of advice on clinical matters.

3.6 Policy

A statement of the Trust's agreed position and governing principles relating to particular issues or situations

An overarching statement of what is required by the Trust and describes the scope of that statement and associated roles and responsibilities. The procedural methods of how this will be achieved, may be contained within the policy document, often as an appendix.

A **Clinical policy** is a policy which includes the provision of advice on clinical matters.

A **Non-Clinical** policy is a policy which does not include the provision of advice on clinical matters.

3.7 Procedures, Protocols, Standard Operating Procedures

Policies and Guidelines will often have at least one or two of the above, which support

implementation of the Policy of Guideline.

All of these documents should have an overarching Policy or Guideline which they sit under and which will determine whether they are to be viewed as being clinical or non-clinical in nature.

a) **Procedures**

A set of actions which is the official or accepted way of doing something. Reasons for the deviation should be recorded.

Procedures define the practical steps to be taken to achieve compliance with a policy and / or guideline. Procedures can be clinical (e.g. inserting a nasogastric tube, administering an intravenous drug, etc) or non-clinical (e.g. applying for a car parking pass).

b) **Protocol**

A detailed plan of how to carry out an action (clinical or non-clinical) and predominantly used in research.

c) **Standard Operating Procedure (SOP)**

Prescribed or established methods to be routinely followed in respect of designated procedures or in designated situations. Standard Operating Procedures are a nationally recognised term in Pathology and Pharmacy and should not be confused with the term 'Procedures' as defined above.

A LocSSIP (Local Safety Standards for Invasive Procesures) is a SOP which involves piercing the skin or gaining access to a body cavity without cutting into the body(eg bronchoscopy) or using electromagnetic radiation (eg laser eye treaments).

Very often SOPs are written to minimise health and safety risks. Senior management agreement must be obtained for any proposed deviation.

*A **Clinical Procedure, Protocol, or Standard Operating Procedure** is one which includes the provision of advice on clinical matters.*

*A **Non-Clinical Procedure, Protocol, Standard Operating Procedure** is one which does not include the provision of advice on clinical matters.*

3.8 Supporting References

Supporting references will be the list of external evidence used to underpin the P&G document e.g. national policies and guidelines, published research, journal articles, internal audit reports.

4. ROLES – WHO IS RESPONSIBLE FOR WHAT

4.1 Board Director Responsibility

4.1.1 The Chief Executive shall consider how each Category A policy or guideline shall be disseminated and whether this is to be by the Chief Executive Bulletin.

4.1.2 The Director of Corporate and Legal Affairs has executive responsibility for this policy and is the person charged with notifying the Trust Board of any developments in this area. The Director of Corporate and Legal Affairs has responsibility for the appointment of the Chair and Vice-Chair of the Non-Clinical Policy and Guideline Committee (NCPGC).

4.1.3 The Chief Nurse has responsibility for ensuring that the Policy and Guideline Library (PAGL) is adequately maintained and that management reports about the state of PAGL and all Guidance documents covered by this policy are produced as required.

4.1.4 The Medical Director and Chief Nurse, between them, have responsibility for the appointment of the Chair and Vice-Chair of the Clinical Policy and Guideline Committee (CPGC).

4.2 Corporate and Clinical Directors

4.2.1 Directors, whether Clinical or Corporate, are responsible for identifying the need for guidance documents that support the services for which they have responsibility which will include appointing a Trust Lead for each guidance document. In addition they must ensure that any such documents are developed in line with this policy, appropriately stored, disseminated, reviewed and archived, and that the guidance within the document does not conflict with any other guidance document within the Trust.

4.2.2 Directors, whether Corporate or Clinical, are responsible for ensuring that processes are in place for the approval and management of P&Gs solely applicable to their area (ie Categories C and D) fulfil the requirements of this policy.

4.2.3 Directors, whether Corporate or Clinical, are responsible for ensuring that processes are in place for appropriate dissemination of P&Gs in their area (ie Categories C and D) whether by direct contact with staff or via CMG meetings or via the Chief Executive's Bulletin.

‘

4.3 Trust Lead (otherwise described as ‘author’ or ‘Nominated Writer’) for a policy of guidance document

A Trust Lead has responsibility for

4.3.1 Ensuring the development, contents (including the maintenance of any hyperlinks used within the guidance), consultation, approval, storage, dissemination and archiving of their guidance documents. Where the document is stored and archived within PAGL then PAGL team upload and archive the document.

4.3.2 Ensuring that there is appropriate representation of subject ‘experts’ in the development stage including any requirement to involve a Non-Executive Director or Trust committee.

4.3.3 Ensuring robust evidence and national guidance documents such as NICE are used to inform the P&G recommendations where applicable. Where national guidance or the evidence-base relied upon changes during the lifetime of a document, the Trust Lead is to consider whether an early review of the P&G is required

4.3.4 Making sure any policies covering new roles and procedures are in line with service needs and other policies.

4.3.5 Ensuring the consultation is appropriate and involves all necessary staff groups and specialties.

4.3.6 Implementing the P&G including identification and actioning of any training, financial or other implementation issues including appropriate monitoring and audit.

4.3.7 Ensuring dissemination of approved guidance to all necessary staff groups in line with the appropriate processes in place within the CMG or Corporate area.

4.3.8 Identifying appropriate timescales and leading on the review of the P&G ensuring that this is undertaken in line with the review date of the P+G.

4.3.9 Ensuring the document content and layout meet the standards as detailed in this policy.

4.3.10 Ensuring the timely submission of both the draft guidance document and required governance proformas to the approval body (see Appendices 6 and 7).

4.3.11 Following submission to the appropriate Approval Body for its consideration, to ensure that any required action is undertaken within two months of consideration of the guidance of the Approval Body.

4.4 UHL Staff Managers

4.4.1 All UHL managers shall have responsibility for disseminating relevant polices to those staff for whom they have line-management responsibility whether by direct contact, discussion at Team Meetings or otherwise, in line with the appropriate processes in place within the CMG or Corporate area.

4.5 UHL Staff Members

4.5.1 All members of staff are responsible for complying with guidance which applies to them.

4.5.2 All UHL staff are responsible for informing relevant managers and clinical leads if there are any implementation or compliance issues with policies or guidance and for participating in the monitoring of compliance as applicable.

4.6 UHL Non-Clinical Policy and Guideline Committee (NCPGC)

4.6.1 The NCPGC reports directly to the Patient Safety Committee

4.6.2 The NCPGC is responsible for reviewing all non-clinical category A; B and E policies and guidelines (as defined in section 3.4) and either approving them for adoption, (with or without further amendments), or, in the case of Category A documents, recommending them onward for approval and adoption by the Trust Board where appropriate.

4.6.3 The NCPGC is responsible for receiving details of all non-clinical Category C and D policies and guidelines approved by the CMGs and uploaded to PAGL, for noting.

4.6.4 The NCPGC is responsible for approving all Policy and Guideline Libraries (whether clinical or non-clinical).

4.6.5 The NCPGC is responsible for considering whether any Category B or E non-clinical P&G merits dissemination to Staff via the Chief Executive's Bulletin.

4.6.6 The NCPGC is responsible for considering and approving any requests to:

(a) extend the review date of individual non-clinical category A, B and E policies and guidelines, and/or

(b) remove individual category B and E non-clinical policies and guidelines from PAGL

4.7 UHL Clinical Policy and Guideline Committee (CPGC)

4.7.1 The CPGC reports directly to the Patient Safety Committee.

4.7.2 The CPGC is responsible for reviewing all clinical category A; B and E policies and guidelines (as defined in section 3.4) and either approving them for adoption, (with or without further amendments), or, in the case of Category A documents, recommending them onward for approval and adoption by the Trust Board where appropriate.

4.7.3 The CPGC is responsible for receiving details of all clinical Category C policies and guidelines approved by the CMGs and uploaded to PAGL, for noting.

4.7.4 The CPGC is responsible for recommending Clinical Policy and Guideline Libraries to the NCPGC as suitable for adoption as a Trust Policy and Guideline Library.

4.7.5 The CPGC is responsible for considering whether any Category B or E clinical P&G merits dissemination to Staff via the Chief Executive's Bulletin.

4.7.6 The CPGC is responsible for considering and approving any requests to:

(c) extend the review date of individual clinical category A, B and E policies and guidelines, and/or
(d) remove individual category B and E clinical policies and guidelines from PAGL

4.8 The Head of Corporate Governance

4.8.1 The Head of Corporate Governance shall be responsible for ensuring that there is a robust process for checking the approval of Category A, B and E P&Gs and for checking that any extensions of Review Dates for Category A, B, and E P&Gs have been approved by the appropriate Approval Body and shall ensure that the supporting documentation is retained for audit purposes.

4.9 The Head of Quality Assurance

4.9.1 The Head of Quality Assurance shall be responsible for ensuring that there is a robust process for checking the approval of Category C and D P&Gs and for checking that and extensions of Review Dates have been approved by the appropriate Approval Body and shall ensure that the supporting documentation is retained for audit purposes.

5. DELIVERING/IMPLEMENTING THE POLICY – WHAT TO DO AND HOW TO DO IT

5.1 Developing Policies and Guidance Documents

Prior to commencing work on developing a new P&G, permission to do so must be obtained from the relevant Approval Body by the Trust Lead for the document, who will indicate whether a similar P&G is already under development, or is planned, and whether any related or overlapping P&G already exists.

In order to confirm the above, one of the following should be contacted:

a) CMG Quality and Safety Board (if one is in place and is applicable to the P&G being developed).
b) The Corporate and Committee Services Office or the PAGL Team.
c) Appendix 6 should be used to confirm that all aspects of P&G development have been appropriately considered. This checklist is used by the CPGC and NCPCG to appraise submitted Trust-wide P&Gs and should be used by appropriate committees approving Category C and D P&Gs.

5.2 Format of Policies and Guidance Documents

5.2.1 Format

The UHL policy and guidance templates are given in Appendices 2-5 and must be used depending whether the document is a policy, Category B guideline or Category C or D guideline respectively. Where the document is a LocSSIP then appendix 5 must be used. Following these templates will ensure that all P&G requirements are met. Where the P+G is proposed as a Category E it must still contain the Front page and compliance monitoring table. Where the document is a LocSSIP then, notwithstanding paragraph 5.22 – 5.3 below the required format is as set out in appendix 5.

5.2.2 P&G Front/Back Page

All Policy documents must have the following on their front page (see Appendix 2 for Trust Policy Template):

a) University Hospitals of Leicester NHS Trust logo
b) Clear Title which succinctly and accurately reflects the content
c) Name of approving committee or group
d) Date of Original Approval
e) Trust Reference Number
f) Version Number
g) Previous version reference
h) Trust Lead
i) Board Director Lead
j) Date of latest Approval
k) Next review date
l) UHL Standard Footer Format – as used in this document

For guidelines some of this information will be elsewhere within the document (see Appendices 3 and 4 for Trust guideline templates.

5.2.3 P&G Footers

The following information must be included in the footer of all policies and guidelines:

Insert title of document

Page x of y

Version No [x] Approved by: [insert approving committee] on [insert date] Trust ref: [xx]Next Review: [insert date]

NB: Paper copies of this document may not be most recent version. The definitive version is held on PAGL

5.2.4 Technical Requirements

The Policy and Guideline templates are available as stand-alone documents from Corporate and Committee Services and from the PAGL team for use by the authors of policy and guidance documents. The technical requirements are:

a) All documents to be in Arial font size 11 or 12pt
b) Margins to be justified
c) Line spacing should be set at 1 or single
d) Paragraph spacing should be set as 6pt after the paragraph
e) Paragraphs should be numbered and sub-numbered for ease of reference, use alphabet bullet points for long lists.
f) The use of bold and / or underline may be used to help headings and / or sections stand out.

5.3 Content of Policies and Guidance Documents

5.3.1 Policy Information

Policy documents must contain the following (see Policy template in Appendix 2 for further information unless otherwise stated):

a) Contents Page

b) Details of any changes made

c) Suitable key words that will aid with search in PAGL

d) Introduction and Overview

e) Policy Scope

f) Definitions and Abbreviations – where applicable – if None write 'None'

g) Roles – Who does what

h) Delivering the Policy – what needs to be done including details of any associated documents or associated procedures (which may be appendices to the policy)

i) Educational and training requirements

j) Process for monitoring compliance with clearly stated audit indicators, timescales and lead (see the table as part of the template)

k) Equality Statement including EDI statement (see section 5.6.2 for further information)

l) Supporting references, evidence Base and Related Policies

m) Process for version control, document archiving ad review of the Policy (see section 5.8 for further information).

n) Appendices – where applicable

5.3.2 Guideline documents must contain: (see guideline template in Appendices 3 and 4 for further information unless otherwise stated).

a) Document Header

b) Introduction and details of who the Guideline applies to

c) Standards and Procedures (including flowchart)

d) Education and Training Requirements

e) Details of how compliance will be monitored (see 5.3.5 below)

f) Details of supporting references

g) Keywords

h) Contact and Review Details.

5.3.3. Protocols, Procedures and SOPs must also use the guideline template to ensure standardisation of documents.

5.3.4. It is acceptable in principle for a Trust policy or guideline to contain a hyperlink to a policy or guidance document which has been developed by another NHS body or reputable source. However when doing so it must be clear in the UHL policy or other UHL guidance document which elements of the document that is linked-to have been adopted by UHL and which elements have not been adopted by UHL.

5.3.5 All Policies and other Guidance documents must have the standardised Monitoring Compliance Table and when requesting renewal of a policy or guidance document evidence of adherence to the requirements of the Monitoring Compliance Table is to be submitted to the Approval Body.

5.4 Legal Implications of Policy and Guidelines Documents

Policy and Guideline Leads (both at drafting stage and at review stage) should consider possible legal implications of any practices introduced, authorised, or prohibited. For further advice contact: Head of Legal Services on 0116 502 7079.

5.5 Approval mechanism for Policies and Guidelines

5.5.1 All proposed category A,B and E P&G documents must be submitted by the Trust Lead to the appropriate Policies and Guidelines Committee via the Corporate and Committee Services Team along with the required proforma which appear as Appendix 6 to this policy.

5.5.2 Any P&G submitted for approval, either at CMG (Category C and D) (with the required proforma which appears as Appendix 6 to this policy) or Trust level, must have been through an appropriate review and consultation process beforehand.

5.5.3 All new P&Gs, of whatever category, must be formally approved and given a Trust Reference Number via the Corporate and Committee Services Team for Cat A, B, and E and via the PAGL Team for Cat C and D, before being implemented.

5.6 Process for Submitting Policies and Guidelines to the Approval Body

5.6.1 All submitted P&G documents must be accompanied by a completed:

(a) Governance Pro Forma (See Appendix 6)

5.6.2 Equality Issues

a) When drafting P&Gs, due care should be taken to ensure that they are in line with the Equality Act 2010 and the Public Sector Equality Duty (PSED) covering the nine protected characteristics and socio-economic factors. Due consideration is to be given that, as far as is reasonably possible, all P&Gs meet patient and staff needs and that any adverse impact is mitigated. You can seek support with this from the EDI team at equality@uhl-tr.nhs.uk

b) When drafting a policy an Equality Analysis must be completed.

c) If an adverse impact is identified, you must make reasonable changes and implement actions to address the barriers faced by the groups likely to be affected. You can seek support with this from the EDI team at equality@uhl-tr.nhs.uk. The full Equality Analysis must be submitted to the Approval Body

d) All P&G documents should include the following statement to confirm that an Equality Analysis has been carried out:

> The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from bullying, harassment and victimisation and treat all individuals fairly with respect and according to their needs as far as reasonably possible.
>
> **As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.**

e) For further advice on these issues, contact the Head of EDI on 07977 197538

5.6.3 Consultation

a) Consultation should confirm that appropriate elements of the P&G have been considered, and that plans are in place to address any issuesidentified.

b) Consultation should specifically include key stakeholders.

c) Where consultation has been included as part of a meeting, this should be clearly documented in the meeting minutes and must be made available as part of the P&G Document Approval process if requested by the Approval Body.

d) Areas for the Trust Lead to consider for consultation could include but are not limited to those teams as are det out on the Governance Pro Forma which appears at Appendix 6 of this policy.

e) If the P&G has an impact upon patients, carers, service-users or staff or is a major departure from current practice, patient or patient representatives must form part of the consultation process as required by section 242 of the Health and Social Care Act (2001). This would apply where a service provision is changing *from the service-users perspective*. As an example, if a new service is being planned, or if an existing service its opening times, then these would almost certainly fall under the remit of Section 242; but a change of product supplier or contractor *may* not. It is difficult to give generic examples though and each case must be considered on its merits. If appropriate involvement is not undertaken, then Section 242 (commonly known as the "Duty to Involve") provides a legal recourse through which these decisions can be challenged and potentially overturned via a judicial review. While Section 242 has far-reaching implications, it is at heart about embedding good decision-making practice by ensuring that the service-user's point of view is taken into account when planning or changing services.

5.6.4 Administration Process

There are several aspects of P&G implementation that need to be taken into consideration as part of their development. These details must be fully documented in the Governance Proforma which forms part of Appendix 6 (for Categories A and B and E) and Appendix 7 (for Categories C and D) which must be submitted with the policy or guideline for approval to the appropriate Approval Body.

a) Financial Implications

Where there may be financial implications to implementing a policy or guideline, these should be discussed with the relevant managers in the early stages ofdevelopment.

b) Education and Training

Advice should be sought from the relevant Education / Training teams if the policy or guideline is introducing a new area of practice or will require different skills.

Details of education and competency assessment must be provided in those policies and guidelines concerning extended working practices.

Where training needs are identified as part of the implementation plan, a ‘training needs analysis’ should be undertaken, to include details of which staff groups require training, the frequency of training, and who will be responsible for providing the training in accordance with Trust requirements.

c) Dissemination of Policies & Guidelines

The responsibility for dissemination is as set out in the Roles and Responsibility section 4 of this Policy. Details of how a P&G will be disseminated to the relevant staff groups should be stated on the governance proforma (Appendix 6).

Although all P&Gs will be uploaded onto PAGL or other approved library (see paragraph 6.8.4 below) for immediate accessibility, it cannot be assumed that all staff will be aware of the new / revised version. Therefore part of the dissemination plan needs to consider raising awareness and encouraging staff to read the P&G whether directly, team meetings or via the Chief Executive Bulletin. This consideration shall be undertaken by the Lead Director, Lead Author, Approval Body and Line Manager as set out throughout this policy.

5.7 Process for Approving Policies and Guideline Documents

5.7.51 Category A – P&G Documents requiring Trust Board Approval.

Category A P&Gs require Trust Board approval but should be initially submitted to the appropriate UHL Policy & Guideline Committee for review as detailed in section 5.7.2

5.7.2 Category B – P&G Documents for Implementation beyond one CMG or Corporate Directorate

a) Category B P&G Documents will be approved by the appropriate Policy & Guideline Committee (clinical or non-clinical).

b) Where a P&G has significant Trust-wide implications it is expected all relevant CMG Directors, Heads of Operations and Executive Directors will be consulted as a minimum before the document is submitted to the P&G Committee for approval.

c) Following review of the P&G document, the Appropriate UHL P&G Committee may:

   i. Approve in full or

   ii. Approve subject to required changes to be made within 2 months of conditional approval (this may include delegated authority to a committee member to approve the final version). Where amendments are not made within the 2 months referred to then the committee shall have discretion to notify the Trust Lead and Director Lead for that P&G that the P&G in question has not been approved for this reason and will need to be resubmitted to the committee for further consideration following a full consultation process.

   iii. Not approve – any changes to be made and P&G to be resubmitted for future P&G Committee's review within two months of meeting at which the decision was made.

5.7.3 Category C and D – Local P&G Documents

Once final draft stage is reached Category C and Category D P&G documents must be submitted for approval to the appropriate CMG or Corporate Directorate Approval Body. Such Approval Body shall also be required to consider a completed version of Appendix 7 of this policy to assist members of the Approval Body with their decision making.

5.7.4 Adoption of Category E – External P&Gs – UHL's Approval Process

a) All guidance documents that have been written by external bodies to the Trust, but which are to be adopted by the Trust, must have a UHL Trust Lead Officer and UHL Board Director Lead identified to confirm their relevance to the organisation. The Lead Officer may have been involved in the development of the external guidance document.

b) The appropriate P&G Committee may raise areas of concern in which case the UHL Trust Lead will be expected to feed these concerns back to the external guidance lead author for consideration at the next P&G review.

5.7.5 Trust P&G Documents Requiring Approval

a) Where there is a policy or other guidance document that needs to be 'fast tracked' due to clinical expediency or legal requirements, the Chair of the appropriate Policy and Guideline Committee has authority to approve category B and E documents and should be contacted via Corporate and Committee Services for Chair's action. This process is also available for category C and D policies and guidelines, and in those cases the authority to approve will sit with the lead Clinical or Executive Director for the document.

b) When sending the policy or guidance for Chair's action, the Trust Lead also needs to provide a completed Appendix 6.

c) Once contacted, the appropriate Policy and Guideline Committee Chair will consider the necessity of fast-tracking and once satisfied, will ensure there is clarification about the development process of the document. The Chair will thereafter seek specific consultation from at least two members of the appropriate Policy and Guideline Committee as a matter of urgency.

d) Following review of the P&G and supporting documentation, in collaboration with other appropriate Policy and Guideline Committee members as applicable, the Chair would then be able to advise whether the policy or guidance document met the agreed criteria for approval. All such approvals must be reported to the next meeting of either CPGC or NCPGC for ratification, depending on whether it is a clinical or non-clinical document.

5.8 Process for P&G Document Registration, Version Control and Archiving

5.8.1 Registration of P&Gs

a) Following approval, category A, B, and E P&Gs need to be sent to the Corporate and Committee Services team for allocation of a Trust reference number before being implemented. The PAGL Team provide Trust reference numbers for category C and D P&Gs.

b) All UHL Category A, B, C, D, and E P&Gs are recorded on the Trust's P&G Register, maintained and kept up to date by Corporate and Committee Services and the PAGL Team.

c) All versions of documents on the same subject will aim to keep the same Trust Reference Number with a different version number used for each update.

d) Previous versions and retired P&Gs will be archived in the Policies and Guidelines Library for governance and audit purposes.

5.8.2 P&G Referencing ('Key-wording')

a) To ensure effective searching, the P&G document should identify relevant keywords which will be support easy identification. These should be listed on the Contents Page.

5.8.3 P&G document control

a) All P&Gs should identify the current version of the document.

b) Where a Trust document on the trust's Intranet or as used in an internal briefing contains a link to a Trust P&G the link must be taken from PAGL and prefixed with the PAGL URL to ensure that the current version is used.

5.8.4 P&G Archiving

All Policies and Guidelines must be archived within PAGL unless expressly agreed otherwise by the appropriate Policy and Guideline Committee in writing. P&Gs will be archived by the PAGL

Team. The only other systems accepted within the Trust where archiving is permitted are eQMS for Pathology SOPs, Q Pulse for Cancer and Clinical Haematology Category C P&Gs and Badger for Neonatal Category P&Gs

5.9 Uploading of Category A, B and E P&Gs

All Category A, B and E Policies and Guidelines must be referred to the PAGL Team for uploading, using the inbox paggs@uhl-tr.nhs.uk

5.10 Uploading of Category C and D P&Gs

a) Following approval by the Approval Body all Category C and D documents must be sent to the PAGL Team together with a copy of the Category C and D approval form (Appendix 7) approving the document. The PAGL Team shall then ensure that the document is uploaded into PAGL and that any previous version is archived and retain all documentation for audit purposes.

b) PAGL automatically archives previous versions of the new document when the new version is uploaded. Where, following agreement in writing from PGC, documents are not stored within PAGL (5.8.4) suitable alternative arrangements must be in place to ensure expired versions of P&Gs are removed from circulation but are accessible if needed for reference (e.g. as part of a claim or investigation). Advice on retention periods can be sought from the Head of Corporate Governance or the Head of Privacy.

c) UHL's previous intranet document management systems may continue to hold previous versions of archived P&G documents. For access to archived documents contact the PAGL Team on ext 14307 or email paggs@uhl-tr.nhs.uk).

5.11 Freedom of Information

Policy authors should note that as part of our legal commitment to maintain a Freedom of Information Act Publication Scheme, Trust-wide policies may be published on the Trust's external public website.

5.12 Policy and Guidelines Review

a) P&G Review Dates

The first review of a new policy or guideline by the Approval Body must take place within 24 months of the date of first approval. Subsequently each appropriate Approval Body should review a policy or guideline no later than five years past the latest approval date.

b) Minor Changes

If minor changes are required to the policy before its formal review date, then these can be presented to the appropriate PGC. The Chairman of the appropriate PGC has discretion to invoke the Minor Approvals Process which does not require the amendment to be placed before a full committee and which, in effect, mirrors the fast-tracking process (see paragraph 5.7.5 above). This process is also available for category C and D policies and guidelines, and in those cases the authority to approve will sit with the lead Clinical or Executive Director for the document.

Minor changes could be an update to a form that is attached to the document as an appendix, job title changes or due to new national guidance which does not materially change the scope or intention of the P&G.

c) Approval of minor changes without full consultation, submission of proforma etc will be at the discretion of the Chairman of the appropriate PGC or the PGC itself where the Chairman has decided that use of the minor amendments process is inappropriate. **All such approvals must be reported to the next meeting of the appropriate PGC for ratification.**

5.13 Submitting Reviewed P&Gs for Approval

The process for submitting fully reviewed and / or updated documents to the appropriate Approval Body is the same as for the development and approval of new documents.

a) Changes made

Upon submission of a reviewed and/or revised P&G, details of changes or additions to the policy must be described within the document. Where only a few changes made, these should be detailed after the contents page. If substantial changes made, a covering letter describing these should accompany the document. Where the P&G has been completely rewritten, this should be explicitly stated after the contents page.

b) No changes made

If a P&G has been reviewed and supporting evidence checked but no changes are needed, there should be a statement to say that the document has been reviewed and is 'fit for purpose' and that the original supporting evidence is still applicable. This should be documented under the Contents page. An accompanying governance proforma is still required even if there have been no changes made.

5.14 Delayed Reviews and Extending the Review Period

a) Where a document has not been submitted to the Approval Body by the Review Date and an extension to that review date is being requested, that request must be referred to the Approval Body with details of
   - rationale for delay
   - anticipated timescales for submission to Approval Body.
   - any associated risks and how they will be managed.

b) The Approval Body will then assess whether the Review Date can be extended or whether the document needs to be removed from circulation

c) Any delayed Category C and D P&Gs must be referred to their approving committee for review in line with the above.

d) The Lead for a document may request up to two extensions of a Review Date for a document, each such extension being limited to a maximum of twelve months. Any further requests for an extension of the Review Date of that document must be made by the Lead Director for that document.

e) The appropriate Policy and Guideline Committee shall have authority to grant extensions of the Review Date for Category A documents.

6. EDUCATION AND TRAINING FOR THIS POLICY

6.1 For further advice or clarification regarding the developing of P&Gs or the approval process, please contact:

- Corporate Policies – The Corporate and Committee Services Office – (0116 5027137)
- Clinical Policies & Guidelines – Chief AHP or Head of Quality Assurance
- Category C and D P&Gs – PAGL Team (0116 258)4307 paggs@uhl-tr.nhs.uk.

6.2 Training sessions on policy and guidance development, literature searching and reviewing the clinical evidence is available via UHL Libraries –http://www.uhl-library.nhs.uk/

7. PROCESS FOR MONITORING COMPLIANCE

The audit criteria for this policy and the process to be used for monitoring compliance are given in the table below:

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
All P&Gs will have a Trust Reference Number	HCG	Report run from PAGL on annual basis to cross match with Corporate and Committee Services P&G category A, B, E Register, and the PAGL Team category C & D register	Annually	PGC
All P&Gs will be reviewed to monitor that they are within their stated review date	HQA	Report run from PAGL on monthly basis to confirm which P&Gs are within review timescales	1 mthly	PGC
No P&Gs to be visible outside the permitted Library	HQA	Audit	Quarterly	PGC

8. EQUALITY IMPACT ASSESSMENT

The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

As part of its development, an Equality Analysis on this policy have been undertaken and its impact on equality have been reviewed and no detriment was identified.

EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

9. SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

9.1 Related Policies

a) Equality Diversion and Inclusion Policy (Trust ref to be added once issued)

10. PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 Once this Policy has been approved by the UHL P&G Trust Board, Corporate and Committee Services will allocate the appropriate Trust Reference number for version control purposes.

10.2 The updated version of the Policy will then be uploaded and available through Insite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trust's PAGL system.

10.3 This Policy will be reviewed by the Trust Board and it is the responsibility of the Trust Lead for this Policy to commission the review.

New Policy/Procedure

Seek approval before the policy/procedure is written from the Appropriate Approval Body.

Using the correct template (see appendices within the policy) the Nominated writer to draft the policy/procedure seeking to consult with expert colleagues, patients/carers and stakeholders where appropriate.

Request an Evidence Search from (insert details here)

Amended or Reviewed policy/procedure

Nominated writer to contact the appropriate policy team to obtain the correct Word version of the Policy/guideline.

Nominated writer to amend or review (or both) the policy/guideline seeking to consult with the expert colleagues, patients/carers and stakeholders where appropriate. Request an Evidence Search Report from (insert details here).

Nominated writer to commence consultation process which is to last for a minimum of two weeks.

Nominated writer to email the final draft of the policy/guideline to the appropriate Approval Body along with governance proforma (Appendix 6). Category A, B and C to (insert details here). Category C and D to appropriate CMG Approval Body.

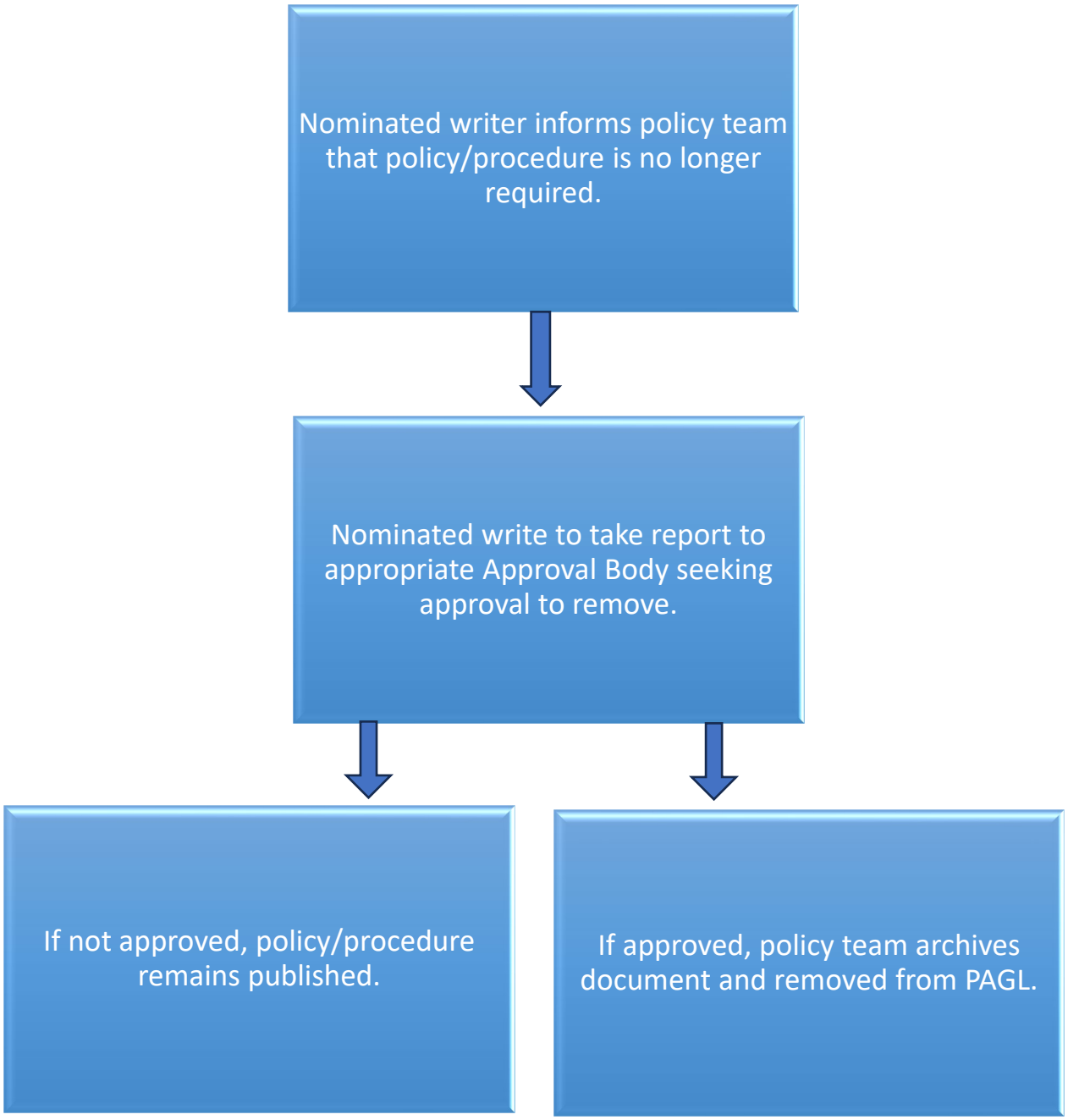
Where the policy/guidance is ratified without a requirement for amendments, the appropriate Approval Body sends it to the appropriate team (CCS for Cat A,B or E or PAGL Team for Cat C or D) for uploading into PAGL. Where further amendments are required by the Approval Body, the policy/guidance is returned to the nominated writer for amendment.

Nominated writer to review the comments of the Approval Body, make any necessary changes and to then send to the appropriate Team (CCS Cat A,B, or E PAGL Team Cat C or D) together with minute of the Approval Body referring to the required changes.

Policy team check the policy/guideline to ensure fully complete. If not complete, it is returned to the Nominated Writer.

Where the policy/guideline to be uploaded fully accords with the required amendments from the Approval Body then the Policy team to upload onto PAGL.

Removing and Archiving Policies/Procedures



APPENDIX 2

POLICY TEMPLATE (available as a stand alone document on INsite)

University Hospitals of Leicester NHS
NHS Trust

Policy Title

Approved By:	
Date of Original Approval:	
Trust Reference:	
Version:	
Supersedes:	
Trust Lead:	
Board Director Lead:	
Date of Latest Approval	
Next Review Date:	

CONTENTS

Section		Page
1	Introduction and Overview	
2	Policy Scope – Who the Policy applies to and any specific exemptions	
3	Definitions and Abbreviations	
4	Roles- Who Does What	
5	Policy Implementation and Associated Documents-What needs to be done.	
6	Education and Training	
7	Process for Monitoring Compliance	
8	Equality Analysis	
9	Supporting References, Evidence Base and Related Policies	
10	Process for Version Control, Document Archiving and Review	

Appendices		Page

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

Details of changes made to the policy since the previous version must be clearly identified here or if significant changes are made these should be attached as a separate Appendix. If the document is a complete re-write then this must also be documented here.

KEY WORDS

List of words, phrases that may be used by staff searching for the Policy in PAGL

FOOTER

The Policy 'footer' must contain details of Policy Title and approval date, etc as per example in this template

In addition to guidance in section 6.2 of the main policy please note the following:

Unless otherwise stated a heading with an underline must be used as it is integral to the template.

If a heading is not underlined this is to be removed from the template as this is for information only

1 INTRODUCTION AND OVERVIEW

Overview of the document/setting the scene – example of opening sentence given below.

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for …….

2 POLICY SCOPE –WHO THE POLICY APPLIES TO AND ANY SPECIFIC EXCLUSIONS

Who does this policy apply to?

2.1 All UHL Policies must clearly state the staff groups / professions that they apply to.

2.2 They should also identify whether there are any qualifications and competencies that must be held by staff using the Policy and cross reference made to the education and training section if specific training is required.

2.3 Where Policies relate to patient care, the scope should also clearly state which group of patients, areas of the Trust are covered by the document

2.4 If it would be helpful to emphasise that certain areas are excluded from the policy then do so here and signpost where further guidance can be sought for those areas.

3 DEFINITIONS AND ABBREVIATIONS

A description of any terms used in the document – remove this section if none state 'None'. If there are any then place them in alphabetical order for ease of identification.

4 ROLES – WHO DOES WHAT

An overview of the individual, departmental and committee roles and responsibilities, including levels of responsibility and any education and training requirements

4.1 Responsibilities within the Organisation

Include all those who are required to support/use/comply with the policy for example (use job titles rather than names):

a) Identify the Board Director Lead- every Policy must have one.

b) Does a Non-Executive Director have a role to play?- if so state it.

Consider who will support the implementation process and if appropriate describe their roles so that it is clear who is responsible forwhat.

c) All staff-if your policy applies to all staff (or a broad range) then describe what the least knowledgeable staff member will need do-if only to state who they to

seek further guidance from eg their Line Manager

d) If relevant describe the role of committees that support the policy.

5 POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS –WHAT TO DO AND HOW TO DO IT

This section should detail the requirements of the policy and how they will be achieved.

Where appropriate include details of Associated Documents. If there are no Associated Documents state: Associated Documents –None.

6 EDUCATION AND TRAINING REQUIREMENTS

Identify whether there are any training requirements or required competencies needed to implement your policy. Where it is safe to do so you may wish to simply cross- reference to the

7 PROCESS FOR MONITORING COMPLIANCE

7.1 All Policies must include details of audit standards or key performance indicators that will be used for monitoring compliance and effectiveness and the frequency of monitoring / audit. These must be set out in the Policy Monitoring table set out below.

7.2 Key indicators should relate to the aims and objectives of the policy and be based on policy standards

7.3 The monitoring table must also identify who is responsible for conducting and or leading the monitoring, the methodology to be used and process for reviewing results and taking action to improve performance where appropriate.

7.4 Advice on the most effective methodology, both in terms of measuring the success of the document and using the minimum resources in doing so, can be sought from the Clinical Audit Team.

8 EQUALITY IMPACT ASSESSMENT

8. 1 The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

8.2 As part of its development, an Equality Analysis on this policy have been undertaken and its impact on equality have been reviewed and no detriment was identified.

OR if 8.2 above does not apply seek wording from The Head of Equality on equality@uhl-tr.nhs.uk

EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

Part of the Policy development should be to review other similar documents and published literature in order to ensure the P&G recommendations are based on latest evidence.

Policy documents should include details of any evidence used, this will be particularly relevant to clinical policies.

Any supporting Policies or Guidelines referred to in the P&G document should be 'signposted'.

Key supporting references should be cited in full and should include name of author, title of article / book and publisher / date of publication

Provide details of supporting references and the type of evidence used, as applicable.

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

This section should identify the process for tracking version control and archiving both current and previous versions of the document.

Example wording:

Review details must be described in the Policy and must give details of timescale and who will be responsible for review and updating of the document.

The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trust's PAGL system

POLICY MONITORING TABLE

The top row of the table provides information and descriptors and is to be removed in the final version of the document

What key element(s) need(s) monitoring as per local approved policy or guidance?	Who will lead on this aspect of monitoring? Name the lead and what is the role of other professional groups	What tool will be used to monitor/check/ observe/asses/ inspect Authenticate that everything is working according to this key element from the approved policy?	How often is the need to monitor each element? How often is the need complete a report ? How often is the need to share the report?	How will each report be interrogated to identify the required actions and how thoroughly should this be documented in e.g. meeting minutes.
Element to be monitored	**Lead**	**Tool**	**Frequency**	**Reporting arrangements Who or what committee will the completed report go to.**

Category A or B or E GUIDELINE TEMPLATE (available as a stand alone document on INsite)

……..Guideline..	University Hospitals of Leicester NHS NHS Trust

1. Introduction and Who Guideline applies to

*Brief explanation of purpose of guideline **and users**, i.e. does it cover all staff, specific groups of staff or specific patient groups and in what circumstances i.e. when*

2. Guideline Standards and Procedures

This section may include or comprise a flow chart but in any event should be set out in a logical order.

3. Education and Training

Are there any new skills required to implement the guideline? Is a training programme being provided to support implementation or is it more a case of 'awareness raising'

If there are no education or training requirements please state 'None'.

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements

5. Equality Analysis Assessment

5.1 The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

5.2 As part of its development, an Equality Analysis on this policy have been undertaken and its impact on equality have been reviewed and no detriment was identified.

OR if 5.2 above does not apply seek wording from The Head of Equality on equality@uhl-tr.nhs.uk

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It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

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Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

6. Supporting references (maximum of 3)

If None say NONE

7. Key Words

List of words, phrases that may be used by staff searching for the Guidelines on PAGL If none – state none.

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title)	**Executive Lead**
Details of Changes made during review:	

APPENDIX 4

Category C or D GUIDELINE TEMPLATE (available as a stand alone document on INsite)

Insert Title which must include details of the CMG / Directorate that it applies in.	University Hospitals of Leicester NHS NHS Trust **Insert Trust Reference Number here**

1. Introduction and Who Guideline applies to

*Brief explanation of purpose of guideline **and users**, i.e. does it cover all staff, specific groups of staff or specific patient groups and in what circumstances i.e. when*

2. Guideline Standards and Procedures

This section may include or comprise a flow chart but in any event should be set out in a logical order.

3. Education and Training

Are there any new skills required to implement the guideline? Is a training programme being provided to support implementation or is it more a case of 'awareness raising'

If there are no education or training requirements please state 'None'.

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements

5. Equality Analysis Assessment

5.1 The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

5.2 As part of its development, an Equality Analysis on this policy have been undertaken and its impact on equality have been reviewed and no detriment was identified.

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Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

6. Supporting References (maximum of 3)

If None say NONE

7. Key Words

List of words, phrases that may be used by staff searching for the Guidelines on PAGL. If none – state none.

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title)	**Executive Lead**
Details of Changes made during review:	

APPENDIX 5

UHL *Insert name of procedure(s)* Standard Operating Procedure (LocSSIPs)

Change Description	**Reason for Change**
□ Change in format	□ Trust requirement

APPROVERS	**POSITION**	**NAME**
Person Responsible for Procedure:		
SOP Owner:		
Sub-group Lead:		

Introduction and Background:
Include some narrative about what this LocSSIP covers (area -where it happens, and procedure types) and what national guidance it is based on. Similar procedures can be grouped together under one LocSIPP

Specifically reference the National Safety Standards for Invasive Procedures.

Include some description of the indications and contraindications for the procedure

Referral process

List management and scheduling:

Describe how patients are booked for a list

List the minimum dataset required for scheduling a patient on the list

State who can sign off the list and when this should happen

State who is responsible for ordering the list

Describe how the list is published and who is informed

Describe how list changes are communicated

State that abbreviations of laterality (i.e. L and R for left and right) will not be used

Describe any special arrangements that need to happen at list booking stage (e.g. ensuring a lab technician is available to process sample)

Describe how DNAs are handled to prevent loss to follow-up

Flow charts might be useful

Patient preparation:

Describe the fasting and hydration arrangements for patients pre-operatively

Describe what information patients will be provided with

Describe what pre-procedural investigations and work-up are required eg.

- Blood tests – and list any critical parameters for proceeding (e.g. INR<1.5, platelets >50 etc)
- Imaging requirements
- ECG, lung function tests etc

Describe any special requirements

Describe how you handle patients with special requirements such as:

- Diabetes
- Use of anti-platelet agents
- Use of anticoagulants (refer to Anticoagulant Bridging therapy Policy – see refs)

Describe pre-operative MDT involvement in the patient pathway

Describe how patients will be consented and by whom

Describe the requirements for delegated consent for this procedure and how this is recorded, audited and monitored for compliance (if relevant) Describe the specific complications and mortality risks that patients should be informed of in the consent process Describe infection prevention strategies – e.g. hair removal, warming, antibiotic prophylaxis, use of gowns, drapes, skin preparation required Describe any special steps for prevention of safety incidents e.g. ensuring stoppers/bungs are in an "off" position to prevent air embolism; ensuring antiseptic preparations are not kept in open Gallipots to prevent inadvertent injection etc. Provide a copy of the patient pathway or any associated checklists in an Appendix
Workforce – staffing requirements:
State minimum safe staffing standards for a procedure list. Define number and skill-mix of staff, including specific practice qualifications where applicable. Define for in hours and out of hours (NB. Out of hours standards should be no less than the minimum for in hours) State escalation procedures if a clinical situation overwhelms available resources State how learners or students will be supervised in area State how newcomers to area have an induction and summarise what this induction includes State how workforce levels will be maintained and monitored to provide assurance that procedures can safely proceed
Ward checklist, and ward to procedure room handover:
Describe the formal handover process from the ward to the procedure team List the content of this handover Provide a copy of the checklist required in an Appendix to this SOP
Procedural Verification of Site Marking:
Make clear what site and side marking is required for this procedure. If none is required justify why not and what other procedures are to be used instead

Surgical site marking is mandatory for all procedure for which it is possible.

Site marking should be performed with an indelible marker designed for that purpose and must be:

- Performed shortly before the procedure by the operator or nominated deputy
- Must remain visible in the operative field and not be obscured by drapes

State how site marking is documented

Team Safety Briefing:

The Team Safety Briefing must occur at the start of any elective, unscheduled or emergency procedure session. Use this section to:

Define who must be present at the team safety briefing, where it will happen and at what time.

Provide a copy of the team briefing documentation showing the content as an appendix to this SOP.

Describe the process for archiving, storing and collating information from team briefings.

Describe how this information will feedback into improving safety and processes

List the content of the team brief

Sign In:

Sign in refers to the checklist completed at the patient's arrival into the procedure area.

In this section please state:

- Where the Sign In will happen
- Who will perform it – minimum of two people required (if under GA anaesthetist and anaesthetic assistant must take part)
- That the patient will be encouraged to participate where possible
- That omissions, discrepancies of uncertainties must be resolved before proceeding

List the components of the check

Add in a "Stop Before you Block" reminder if the procedure is performed under regional anaesthesia

Provide a copy of the checklist in an Appendix to this SOP

Time Out:

Time out is the final safety check that must be completed for all patients undergoing invasive procedures just before the start of the procedure. The WHO checklist is the Gold Standard and may be adapted for local

use with the deletion or addition of elements to suit the procedural requirements. Some Royal Colleges or other national bodies have checklists for their specialties.

This section should have a description of your Time Out procedures:

State:

- That the patient will be encouraged to participate where possible
- Who will lead it (any member can)
- That all team members must be present and engaged as it is happening
- That is will occur immediately before the procedure start
- That separate time out checklist will be completed if there is a separate or sequential procedure happening on the same patient
- That any omissions, discrepancies or uncertainties must be resolved before staring the procedure

List the components of the time out checklist (see example on page 38 of the NatSSIPs guidance)

Provide a copy of the checklist in the appendices to this SOP.

NB. For procedures under local anaesthetic where the patient is fully conscious Time Out can be combined with the Sign In in one checklist.

Performing the procedure:

Describe any special safety features that are important for performing the procedure e.g. positioning of the patient, technique, equipment used etc.

Monitoring:

Describe how the patient will be monitored throughout the time in the procedural area. Consider:

- O2 Sats
- ECG
- Blood Pressure
- Pulse rate
- Respiratory rate
- GCS
- Temp
- BMs

Ensure that this is compliant with the UHL Sedation Policy if relevant (see references below)

Prosthesis verification:

In this section you must document the procedures required to ensure that the correct implants or prostheses are selected and used for an invasive procedure. The safety procedures that need to be followed can be

broken down into before, during and after surgery. Your summary of these procedures must include where relevant:

Before:

- How stock is ordered
- How specific requirements are communicated to the operating theatre or procedural team in good time to ensure stock is present (eg. on operating list, by e-mail)
- How stock is checked, ordered and expiry dates maintained appropriately
- How the safety team briefing is used to highlight the need for prostheses
- The need for inspection of the prosthesis by the operator prior to the patient being sent for

During:

- How the implant is confirmed with the operator to be the correct one – this should include a check of type, design, style, material, size, laterality, manufacturer, expiry date, sterility, compatibility with other multi-component prostheses and any other required characteristics (sometimes called a Critical Prosthetic Pause)
- How this verification check is documented
- State that all prostheses not destined for use in the patient will be removed from the immediate area to avoid the wrong implants being selected

After:

- How a record of the implant is made, including how it will be recorded in any registry

Prevention of retained Foreign Objects:

Describe in this section the procedures that are followed to prevent foreign objects being retained unintentionally. You may refer to over-arching SOPs on safe practice.

Describe the equipment used:

- Use of lists of equipment
- Equipment and how often it is checked for loose parts etc., how many component parts there are
- Type of swabs used - size, colour, number and whether radio-opaque markers are used
- Sharps used

Describe how counts are done

- Two staff members
- Use of whiteboard
- Staff changes
- Reconciliation before closure of a body cavity

Describe procedures to follow if items are unaccounted for

Describe how patients and other staff will be made aware of the intentional retention of a foreign object (eg. Vaginal swab) and how this will be handed over and documented

Describe any special standardisation that is aimed at minimising error – eg. standardisation of vaginal packs
Radiography:
Include a section on radiography and how this is used safely in the area if this is relevant Describe how contrast will be used safely without having open Gallipots as a reservoir
Sign Out:
Sign out must occur before the patient leaves the operative/procedure area. In this section include a description of the content of the sign out which should include: • Confirmation of procedure • Confirmation that counts (instruments, sharps and swabs) are complete • Confirmation that specimens have been labelled correctly • Discussion of post-procedural care and any concerns • Equipment problems to include in team debriefing Describe how this is documented and provide a copy of the checklist in an Appendix.
Handover:
Describe content required for handover to post-procedural team or ward
Team Debrief:
A team debrief should occur at the end of all procedure sessions. State where and when it will occur State who should be present (all team members) Describe the content of the debrief which should include: • Things that went well • Any problems with equipment or other issues • Areas for improvement • An action log • A named person for escalating issues Provide a copy of the debrief checklist as an Appendix to this SOP

State how the team debrief will be documented Describe the process for archiving, storing and collating information from team debriefings. Describe how this information will feedback into improving safety and processes
Post-procedural aftercare:
Describe monitoring arrangements Describe possible complications and how to recognise them Describe where patients will be nursed
Discharge:
Describe criteria for discharge (including nurse led discharge) Describe discharge letter requirements Describe follow-up Describe how any results will be communicated
Governance and Audit:
Define what constitutes a safety incident in this area State that all incidents will be reported on Datix State the procedures for review, investigation, dissemination, and learning from incidents after a Datix is submitted State how will this SOP be audited – how often, where will results be presented and acted upon? Include a table of standards and KPIs that will be monitored
Training:
State how staff will be trained in this SOP State how you will incorporate a Human Factors approach into training State how the multidisciplinary team will be trained together

Documentation:
Describe how this pathway is documented in the patient record Describe any other records that will be kept e.g. theatre management system Provide a copy as an Appendix to this SOP
References to other standards, alerts and procedures:
Insert reference to all other trust SOPs that are relevant Insert references to national standards that apply eg. Royal College standards Insert references to any CAS alerts that apply to the procedure For procedures involving sedation please reference the sedation policy For all procedures include reference to NatSSIPs and the UHL Safer Surgery Policy: National Safety Standards for Invasive Procedures, NHS England 2015: https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/09/natssips-safety-standards.pdf UHL Safer Surgery Policy: B40/2010 UHL Sedation Policy: Safety and Sedation of Patients Undergoing Diagnostic and Therapeutic Procedures B10/2005 UHL Consent to Treatment or Examination Policy A16/2002 UHL Delegated Consent Policy B10/2013 UHL Guideline: Anticoagulant Bridging Therapy for Elective Surgery and Procedures B30/2016
END

APPENDIX 6

P&G GOVERNANCE PRO FORMA	University Hospitals of Leicester NHS NHS Trust Appendix 6 updated 2024

Name of P&G:			
P&G Author / Reviewer		**Senior Responsible Officer / Committee**	**Board Lead**
Is it a New or Reviewed P&G?	**New / Review**	**If Review, is this because due for Review or because of Local/National Changesetc?**	
If Review, Have any changes been made?	**Y / N**	**If Changes, are these clearly indicated at the beginning of the document, to include removed sections if applicable?**	**Y / N**

Key Words to be assigned to the document in the P&G Library in order to facilitate searching *(to include frequently used/recognised words not in the title but in the document content):*

Who does this document apply to?

CONSULTATION Process Key Individuals; Committees/Groups; Specialties/Departments Staff Groups, Patients and Others that have been consulted with *(please specify each of the above as applicable. Add more rows if required)*	**Comments made by Consultee**	**Accepted Yes / No***
Clinical Library Service		

*If No, please provide details below or on separate sheet.

P&G Governance	**Under-taken?**	**Approving Senior Responsible Officer / Committee or Board Level Lead**
Education/Training Requirements Assessed and Plans to address made		
Equality Analysis Assessment		
Process for Monitoring Compliance/Risk Assessment of non-compliance		
Associated Local/National Guidelines/Policies and Published Literature Reviewed and any relevant changes reflected in the Document		
Where this is not a new policy/guideline/SOP etc please attach the latest evidence to support every element of the Monitoring Compliance requirements as set out in the current version of the document		

Does this document include antimicrobial guidance? If yes it must have been seen and supported by the Antimicrobial Working Party		
Does this document alter the medication set up in protocols on Nervecentre? If yes please contact the emeds team to ensure changes are made.		
Plans for Implementation and Dissemination – *this should include consideration as to how relevant staff will be made aware of either a new or revised P&G - in addition to uploading in the P&G Library on Sharepoint* **Indicate the teams to which this will be specifically disseminated by the Trust Lead, managers and include details of all CMG/Directorate meetings it will be circulated to and whether it merits inclusion in the CEO Bulletin.**		

All documents within PAGL are also published automatically on the Trust's external website, **unless** such publication would enable a person to endanger their own health/safety or that of another person. An example of this is the Anti Ligature Policy, which is not available on the Trust's external website due to a national Patient Safety Alert.

Publication on the Trust's external website	
Will publishing this guidance document on the Trust's external website enable a person to harm themselves or others? If YES please explain.	**Yes/No*** (delete as appropriate)

In submitting this Governance Assurance Template I confirm that the above governance process has been endorsed by [INSERT Name and Job Title of Senior Responsible Officer / Committee or Board Level Lead].

Author Name: Job Title Date

P&G GOVERNANCE ASSURANCE TEMPLATE – COMPLETION GUIDE

Name of P&G:	*Title of the Policy or Guideline that is being submitted to* the *appropriate Approving Committee*

P&G Author / Reviewer	**Senior Responsible Officer / Committee**	**Board Lead**
Name of the person who has been asked to write the P&G or review it	*Name of the Senior Manager/Clinician (eg Head of Service, CMG Director/Head of Ops, Corporate Head of Department, Head of Nursing, Director) who has senior responsibility for the area of scope covered by this P&G or Committee which has 'commissioned' the P&G and oversees implementation and monitoring*	*Member of the Trust Board who has this P&G in their Portfolio (eg Medical Director, Chief Nurse, Director of OD)*

Is it a New or Reviewed P&G?	**New / Review**	**If Review, is this because due for Review or because of Local/Changes etc?**	*Eg New NICE Guidance, Changes to Legislation, 3 year Review*

If Review, Have any changes been made?	**Y / N**	**If Changes, are these clearly indicated at the beginning of the document, to include exclusions?**	**Y / N**

If using the old P&G format template, a summary of key changes should be described at the beginning of the Policy after the Title, Author etc or at the end of the Guideline. In the new template changes are at the bottom for both P&Gs

Key Words to be assigned to the document in the P&G Library in order to facilitate searching:
For example in the Guidelines to Prevent Venous Thrombo-embolism document these could be VTE Prevention, Thromboprophylaxis, LMWH,

Who does this document apply to and who therefore needs to have been consulted prior to submission for approval?

Key Individuals; Committees/Groups; Specialties/Departments - to include Staff, Patients and Others ***(add more rows as applicable)***	**Consulted Yes/No**	**Accepted Yes / No***
Departments/Specialties – to consider if applies specifically to just one area of the Trust or will apply to multiple Departments/Specialties, all areas of the Trusts. *To also consider if associated Departments will need to support implementation eg Nutrition Guidelines may apply to Facilities, Catering Department as well as Medical, Nursing, Dietetic and Speech and Language Therapy staff.* *Note requirement to consult with AWP where the P/G includes antimicrobial guidance.* Note requirement to consult with emeds team where r the medication set up in protocols on Nervecentre are to be altered..	*Consultation should be a proactive process, particularly for any new P&Gs* *Even if no changes made following Review of a P&G, it would still be appropriate to consult key 'stake holders'. It may be they are aware of other associated guidance that has changed or have experienced implementation challenges.* *The amount of consultation will obviously depend on the scope of the P&G.*	*Where Consultees feedback any concerns or queries regarding the P&G, these should be considered by the Author / Reviewer, with input from the Senior Responsible Officer / Committee as applicable* *Where concerns raised or changes suggested are not considered to need action or to be appropriate, this information and rationale should be included in the Proforma*
Key Individuals – staff groups eg Nursing, Portering Staff, All Clinical Staff, All UHL Staff, All staff working in xxxxxxxxxx Department, All Staff caring for xxxxxxxx patients *Think about which level of management needs to have been consulted - Director, Head of Department, All staff in Department*		

Patients – to consider which areas of the Trust patients may present and confirm if included or not eg, ED and Assessment Areas, Inpatient Areas only, Adults only, Children only. Patients with confirmed diagnosis *Whilst it may be not appropriate /practical to consult patients for all P&Gs, consideration of patient groups should prompt consultation of the staff involved in their care*		
Others – anyone not covered above		

Which of the following have been undertaken and approved by the relevant Senior Responsible Officer

/Committee or Board Lead?

P&G Governance	**Under-taken?**	**Approving Senior Responsible Officer / Committee or Board Level Lead**
Consultation Process – *as described above*		*Where there are Specialist Groups/ Committees overseeing work-streams covered by the P&G, then this should be asked to confirm that appropriate governance has been undertaken for both New and Reviewed P&Gs* *Where there are senior clinical / managerial leads (SROs), then they should be asked to review and confirm.* *If the P&G author/reviewer is a senior manager/clinician and there is not a relevant Committee, then the Board Level Lead should be asked to confirm.*
Education/Training Requirements Assessed and Plans to address made – *brief details may be included in the P&G document itself but where applicable a Training Needs Analysis and Education Programme should be discussed and approved by the relevant SRO or Committee or the Board Level Lead as applicable*		
Equality Analysis – *to confirm if any groups treated differently by the P&G*		
Process for Monitoring Compliance – *The current P&G format template includes a Monitoring table which must be used, details of the monitoring process must be included in the P&G document*		
Plans for Implementation and Dissemination – *this should include consideration as to how relevant staff will be made aware of either a new or revised P&G - in addition to uploading in the P&G Library on Sharepoint* **Indicate the teams to which this will be specifically disseminated by the Trust Lead, managers and include details of all CMG/Directorate meetings it will be circulated to and whether it merits inclusion in the CEO Bulletin.**		
Associated Local/National Guidelines/Policies and Published Literature Reviewed and any relevant changes reflected in the Document – *details of supporting references, relevant literature does not need to be included in the P&G but how these have been reviewed and considered should be discussed with the relevant SRO or Committee or Board Level Lead as applicable*		

APPENDIX 7

CAT C & D Policy & Guideline Approval Form

A – Document Details

New Review Trust Ref:

Clinical Non-Clinical

CMG/Directorate: Service Area:

Document Title:

Suggested Search Title (Max 100 Characters):

Document Lead: Role:

Document Type: Policy Guideline LocSSIP

Document Category: C D

B – Pre-Submission Checklist

1 Summary

Please provide a short summary of the purpose and contents of this document.

2 Consultation

Board Date:

Please list all contributing persons and their job role.

3 Amendments

No Changes Made

Please provide details of any changes from a previous version of this document.

Current	Amendment
1.	1.
2.	2.
3.	3.

4.	4.

4 Compliance

Please provide details on who this document applies to, how the information will be disseminated, and how compliance will be monitored.

5 Formatting

Please complete the standard formatting checklist below. If standard formatting has not been used, please explain why it was not able to be used for this document.

- Arial font type
- Size 12 font
- Table of content
- Page numbers
- Footer
- Key Words

6 External PAGL

All documents within PAGL are also published automatically on the Trust's external website unless such publication would enable a person to endanger their own health/safety or that of another person. An example of this is the Anti-Ligature Policy, which is not available on the Trust's external website due to a national Patient Safety Alert.

Will publishing this guidance document on the Trust's external website enable a person to harm themselves or others?

Yes No

If YES please explain.

C – Submission

Please sign and date below then return to the P&G Team at paggs@UHL-tr.nhs.uk

Document Lead: Date:

D – Approval Board Outcome

Approving Board: Board Date:

For example: Q&S Board, Cat C meeting, etc.

Comments:

Print Name:

Next Review Date: