University Hospitals of Leicester NHS
NHS Trust

POLICY FOR THE INTRODUCTION OF NEW INTERVENTIONAL PROCEDURES

Approved By:	**Policy and Guideline Committee**
Date of Original Approval:	**14 June 2005**
Trust Reference:	**B17/2005**
Version:	**6**
Supersedes:	**5 – March 2019 Policy and Guideline Committee**
Trust Lead:	**Marwan Habiba – Consultant Gynaecologist, Chair of New Interventional Procedures Authorisation Group (NIPAG)** **Nicola Baker - Deputy Head of Outcomes and Effectiveness**
Board Director Lead:	**Andrew Furlong – Medical Director**
Date of Latest Approval	**6 May 2022 – Policy and Guideline Committee**
Next Review Date:	**June 2025**

CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

February 2019 – Interventional Procedure Authorisation Group (IPAC) Status box in appendix 1 has been simplified quoting NICE Interventional Procedure Guidance (IPG) and specific requirements

February 2019 - NIPAG Preparing Patient Information Leaflet for New Intervention Procedures has been added as Appendix 6

March 2022 – reference to Baroness Cumberledge report first do no harm and relevant NICE guidance added

Conflict of interest statement added

NICE Interventional Procedure Authorisation Committee (IPAC) status box in appendix 2 has been updated in order to give clarity to IPAC catagories

Monitoring arrangements and outcome measures box's has been added to appendix 1

KEY WORDS

NIPAG, intervention, procedure, NICE

1 INTRODUCTION AND OVERVIEW

UHL values innovation and has introduced many new interventional procedures to improve patient care. Innovation is integral to clinical progress and improved patient care.

The Trust is committed to supporting innovation provided it is underpinned by research evidence and appropriate safety considerations, including evidence base, training and patients' informed consent.

1.1 The policy is also applicable to modifications of existing procedures if this involves the need for special additional training or if it is linked to a different risk profile. Such cases require NIPAG approval.

1.2 This policy is intended to support clinical staff when they introduce a New Interventional Procedure (NIP).

1.3 The policy provides a checklist of the steps needed and covers appropriate training, mentoring and those aspects of patient safety that need to be in place.

1.4 The NIP Notification Process also covers:

- Whether the procedure has been reviewed by the National Institute for Health Care Excellence (NICE).
- Patient information.
- All relevant staff training.
- Arrangements for monitoring safety and outcomes.
- Involvement of other clinical areas or colleagues.

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

This policy applies to all qualified staff who are not in a training post, including nurses and other practioners as difined in section 4.0

2.1 The policy describes the process through which all new interventional procedures are introduced into use within UHL. It does not cover the introduction of medicines, which should be introduced via the Therapeutics Advisory Service (TAS) in line with the Policy for the Introduction of New Medicines into the Trust: Trust Document Reference number B28/2011

2.2 This policy aims to avoid unintentional harm to patients and to ensure that information on NIP's are communicated to patients in a way that is clear and meaningful. This will be supported by the monitoring arrangements outlined in this policy.

2.3 NIPAG has the authority to authorise the introduction of new procedures once all appropriate governance and safety requirements have been met. However, CMG approval must also be obtained to ensure the appropriate commissioning and financial implications have been considered, if appropriate. If a new tariff agreement is required, the contracting team should agree this with commissioners. Clinical coding must agree how the new procedure will be represented in data.

2.4 NIPAG will normally request an audit of initial procedures and determine subsequent audit requirement.

2.3 The policy is aligned to the key recommendations of the report of the Independent Medicines and Medical Devices Safety Review: 'First Do No Harm' chaired by Baroness Julia Cumberlege (https://www.immdsreview.org.uk/Report.html) and relevant NICE policies.

2.4 This policy does not apply to those procedures that are already established within UHL but are undertaken by a new member of the team – see 4.3, on condition that agreement is given by Specialty Leads to ensure the appropriate internal proctorship arrangements are in place to support the new operator.

3 DEFINITIONS AND ABBREVIATIONS

3.1 For the purpose of this policy, an **interventional procedure** follows the definition adopted in the HSC 2003/011:

'One used for diagnosis or treatment that involves incision, puncture, entry into a body, electromagnetic or acoustic energy.'

3.3 For the purpose of this policy, a new **interventional procedure** also includes:

A procedure being used for the first time in the University Hospitals of Leicester Trust even if the practitioner has been trained in the procedure elsewhere.

3.4 A **'new operator'** is a qualified practitioner, no longer in a training post, who is using a procedure for the first time in their NHS clinical practice.

4 ROLES – WHO DOES WHAT

4.1 Executive Lead

4.1.1 The Medical Director is Executive Lead for this policy and has overall responsibility for ensuring new interventional procedures are introduced in line with 2003/011.

4.2 The role of the New Interventional Procedures Authorisation Group (NIPAG)

4.2.1 NIPAG's role is to support CMG Clinical Directors & Deputy Clinical Directors by confirming that appropriate clinical governance and audit arrangements are in place for any NIP notified to NIPAG: including appropriate authorisation in line with section 5.2.2 below. The tools to evidence this will be the NIPAG audit programme and NIPAG meeting minutes.

4.2.2 NIPAG may authorise an intervention under one of three categories: Standard arrangements, special arrangements, or research.

- Authorisation for research will be limited to the duration of research recruitment.
- Authorisation under special arrangements is limited to a maximum of three years after which NIPAG will consider the renewal or withdrawal of authorisation based on emerging evidence.
- Authorisation under standard arrangements is not time limited.

4.2.3 The role of NIPAG is also to act as an advisory body for individual clinicians around the governance and safety requirements of introducing any new interventional procedure.

4.2.4 NIPAG will keep a Register of all NIPs notified to NIPAG.

4.2.5 NIPAG will align its recommendations with those of NICE and/or other relevant national guidance.

4.3 NIPAG members are responsible for:

4.3.1 Actively participate in reviews of all NIPAG notifications.

4.3.2 Fully reviewing NIP notifications as per the NIPAG rota.

4.3.3 Re-affirming their membership annually.

4.3.4 Attending a minimum of 4 meetings per annum.

4.4 CMG Clinical Directors' responsibilities with respect to NIPs:

4.4.1 CMG Clinical Directors (or their deputies) are responsible for:

- ensuring the overall governance and safety arrangements within their CMG
- the financial management for introducing new interventional procedures are in place
- ensuring all NIPs planned in their CMG are notified to NIPAG
- fostering innovation in clinical areas and for providing appropriate support for clinicians
- approving commencement of a NIPAG authorised procedure

4.4.2 In addition, CMG Clinical Directors are responsible for ensuring that no communication about a new interventional procedure is released to the media without prior specific authorisation from the Medical Director. If such authorisation is granted, NIPAG should be notified.

4.5 Lead clinician's responsibilities with respect to NIPs:

4.5.1 The lead clinician has overall responsibility for the introduction of any NIP to their patients' treatment.

4.5.2 Lead clinicians are responsible for completing and submitting a NIP Notification Form to NIPAG if planning to introduce a new interventional procedure, or if they make significant changes to an existing procedure (Appendix 1).

4.5.3 Clinicians are responsible for ensuring that changes made to an already established procedure, which may impact the benefit or risk profile or that are outside peer practice, are discussed with clinical and managerial colleagues and to consider if NIPAG notification is required.

4.5.4 Consideration must be given to whether notification to NIPAG is appropriate. If in doubt, clinicians can contact the NIPAG Chair or their CMG NIPAG representative for advice before completing the Notification Form.

4.5.4 When introducing a new interventional procedure to UHL, the lead clinician is responsible for:

- Seeking the support of their CMG Clinical Director (or Deputy Clinical Director if so delegated). If the notifying clinician is the

CMG Clinical Director, support must be sought from the Medical Director.

- Confirming that commissioning and financial implications of introducing a NIP have been considered and that they have obtained CMG support to submit a Notification to NIPAG.

- Ensuring an appropriate patient information leaflet is provided and that special consent arrangements are in place. Both must emphasise that this is a procedure new to the trust.

- Acquiring the necessary skills prior to independent practice of a NIP. This may entail proctorship arrangements with local or visiting experts. Visiting experts may require honorary contracts as per UHL HR policy B8/2019 Policy for Unpaid Placements

- Ensuring other relevant departments or practitioners are informed. This may include for example: Infection Prevention, Radiation Protection and relevant clinical or surgical teams.

4.5.6 Clinicians must not schedule any patient for a new intervention procedure without obtaining prior written Authorisation from NIPAG and approval from their CMG.

4.5.7 If a NIP that has not been authorised by NIPAG is to be performed as an emergency, the CMG Clinical Director or Deputy must give clear permission beforehand. The Chair of NIPAG must be notified within 48 hours of such procedure being carried out.

4.5.8 Clinicians trained elsewhere, who may have been recruited with a view to introducing a new procedure to the UHL, must liaise with the Clinical Lead and/or the Heads of Service and seek CMG support towards completing NIP Notification process.

4.5.9 The Lead Clinician will be the contact point for NIPAG.

4.5.10 The Lead Clinician is responsibe for ensuring that all relevant information is submitted to NIPAG and for providing additional information if requested

4.5.11 The Lead Clinician should advise NIPAG when an authorised/approved procedure is first commenced and for providing audit data as per agreed timescales (see 6.5)

4.5.12 The Lead Clinician should inform NIPAG of any adverse events or deaths that occur whilst the NIP is under the NIPAG process or if the NIP is suspended or withdrawn.

4.5.13 NIPAG must be informed if the lead clinician leaves the Trust before the procedure is well established. Such occurrences will usually require NIPAG approval of another nominated lead. No additional cases should take place untill the new lead has been approved.

5.1 NIP Notification Process

5.1.1 Clinicians wishing to introduce a NIP must ensure they have the support of their CMG and fully complete and submit a NIP Notification Form (Appendix 1) to NIPAG.

5.1.2 Advice as to how to complete the Form or any other queries should be addressed to the NIPAG Chair or Deputy Head of Outcomes and Effectiveness via the Clinical Effectiveness Project Support Officer (CEPSO).

5.1.3 Details of the Notification Procedure and timescales are given in Appendix 2. Authorised NIPs will need to be audited using the NIP Audit Template (Appendix 4,5). See Section 10 for more details.

5.1.4 Upon completion of the NIP Notification process, ongoing governance arrangements for procedures given standard arrangements will become the responsibility of the relevant CMG.

5.1.5 Conflicts of interest have the potential to arise for example in the complex financial links between NIPs, medical device companies, hospitals and other health organisations and private practice. The Lead Clinician should ensure clear governance arrangements are in place to cover any potential conflicts of interests for any individual who participates in NIPs.

5.2 Introduction of NIPs through Research

5.2.1 NIPAG must be notified when a NIP is being introduced to the trust through a research protocol. NIPAG will consider all training implications of such research.

5.2.2 At the end of research recruitment, no patients should undergo a new procedure that was first introduced to UHL through research without specific authorisation from NIPAG.

5.2.3 Where NIPAG has authorised a NIP as part of a research protocol, further authorisation must be sought to undertake the procedure outside of the protocol once the research study has completed.

5.3 Resubmissions

5.3.1 NIPAG will consider resubmissions of previously unsupported applications once the areas of concern have been addressed or following the emergence of new clinical evidence.

5.3.2 Resubmissions should be presented by the relevant CMG Clinical Lead.

5.4 Adverse Events

5.4.1 Serious and unexpected adverse events relating to a NIP must be notified via the Trust's Incident reporting process and should also be copied to the Chair of NIPAG.

5.4.2 All mortalities within 30 days of a NIP must be reported to NIPAG within 48 hours.

5.5 Monitoring Arrangements for NIP Notifications

5.5.1 Developing a robust process for the review, monitoring mechanisms and implementation is core part of the NIP process. When considering a new notification, NIPAG may determine in favour of one of the following options.

Type of recommendation	Available Evidence	Monitoring Arrangements
Regular/Standard arrangements	**Sufficient evidence needs to available for a procedure to be considered as an option.**	**Please see 5.5.2 to 5.5.4 below.**
Special Arrangements*	**Insufficient evidence available: which means there may be uncertainties about whether a procedure is safe and/or effective.**	**The clinician/service will be responsible for ensuring special arrangements are in place for the continued audit/review of the NIP. This may be through a special register/on-going audit - for instance.**
Brand New/Research only	**Weak or no evidence of efficacy. Clinicians should only carry out these procedures in the context of formal research studies.**	**A research ethics committee needs to have approved the research project.**
Do Not Use	**NIPAG will make this recommendation if there is risk of harm or if not suitable in the context of the UHL . This recommendation will include those NIPs for which NIPAG consent has been withdrawn, please see point 6.6 below.**	

***special arrangement would normally include on-going register of cases, outcomes and risks. This may engage a national or regional register or one that is set-up locally. The duration of follow-up can vary but is expected to be long term and till emerging evidence or assessment by NICE indicate that it can transit to one of the other categories.**

- **The service will be responsible for working with the clinical lead to ensure that such arrangements are in place.**
- **The clinical lead is responsible for providing NIPAG with an update of significant emerging evidence no later than 3 years after the original approval.**
- **Unless an extension is granted, NIPAG authorisation for NIP will cease after three years and no further cases are to be undertaken.**

5.5.2 Recommendations may vary depending on the intervention, but NIPAG will usually requires a report on the first 20 patients treated. For less frequently performed interventions NIPAG requires a report after every 6 months of introducing the procedure.

5.5.3 The Lead Clinicians will be asked to confirm the number of procedures undertaken and to provide an audit report (either after the first 20 procedures or 6 months after the first procedure).

5.5.4 Audit reports must be provided within 4 weeks of request. Delayed audit reports will be RAG rated ‘Amber’.

5.5.5 NIPs with 'special' or 'research only' arrangements are to be proactively reviewed after 3 years by the clinician/service area and NIPAG should be updated with new evidence to ensure continued authorisation. This may be done sooner if there is significant new evidence or if there are emerging safety concerns.

5.5.6 NIPs with a 'do not use' recommendation will not be proactively reviewed, and so would not be updated unless there is a significant change in the evidence base.

5.5.7 The NIPAG audit report form (Appendix 4) must be used for reporting initial audit data. It is also recommended that the NIP be included in the CMG Clinical Audit schedule.

5.5.8 One reminder will be sent to the Notification Lead for delayed audit and a report must be provided within 2 weeks of reminder for NIPAG’s review.

6.5.9 Continued non-receipt of a report will be RAG rated ‘Red’ and classified as a ‘Defaulted Audit’

6.5.10 If no patients have been treated by six months, NIPAG should be notified by completing one NIP Audit form (Appendix 5) entering the date and NONE under patient ID.

5.6 Withdrawal of NIPAG Authorisation

5.6.1 Where audit data has not been received after one reminder this will be classed as a DEFAULTED AUDIT and NIPAG authorisation for the undertaking the NIP may be withdrawn.

5.6.2 NIPAG authorisation may also be withdrawn if there were a high number of adverse events.

5.6.3 A decision to withdraw authorisation may also be made based on emerging evidence around safety and/or efficacy.

5.6.4 Withdrawal of NIPAG authorisation will be reported to the CMG Clinical Director with the expectation that the procedure be suspended

5.6.5 NIPAG will also escalate any withdrawals and suspensions to the Trust’s Executive Quality Board (EQB).

5.6.6 Re-instation of NIPAG authorisation will be dependent upon the reason for withdrawal and remedial actions taken.

Dormant applications

Unless otherwise agreed by the committee, if no procedures are carried out over one year, the procedure will be classed a dormant.
Procedures classed a dormant should not be undertaken without prior NIPAG approval.

In order to activate dormant applications, the Lead clinician should notify NIPAG with their intention and include any update of published evidence.

6 Educational Requirements of this Policy

6.1 There are no new skills involved with implementing this policy. All Heads of Service will be sent details of the policy upon approval of the revised version.

6.2 Advice and guidance on the NIP notification process is available from NIPAG.

7 Process for Monitoring Compliance

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
All NIPs notified to NIPAG	NIPAG Chair, supported by CEPSO	Datix incidents	Annually	NIPAG
NIP Audits reported to NIPAG	NIPAG Chair, supported by CEPSO	NIP Audit Returns	Quarterly	NIPAG – EQB CMG Q&SB
Withdrawal of NIPAG authorisation or suspension of the procedure	NIPAG Chair, supported by CEPSO	NIPAG Minutes	Quarterly	NIPAG – EQB CMG Q&SB

8 Equality Impact Assessment

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

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

9 Supporting References, Evidence Base and Related Policies

Healthcare Circular - HSC 2003/011 - The Interventional Procedures Programme - Department of Health, November 2003.

NICE. Interventional Procedures Programme Manual Process and Methods Published 1 Feb 2016> www.nice.org.uk/process/pmg28.

First do No Harm. The report of the independent medicines and medical devices safety report, 2020. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

10 Process for Version Control, Document Archiving and Review

10.1 The previous NIP Policy will be archived on SharePoint

10.2 The next review of this policy will be in March 2025

Appendix 1

University Hospitals of Leicester NHS Trust NOTIFICATION OF NEW INTERVENTIONAL PROCEDURE1

Title/name of procedure	**NIPAG use** Reference number
Description and indication of procedure: please note the NIPAG approval may be granted only for the specified indication:	

Intended benefits for patients – compared to alternatives (list alternatives):

Possible complications (include expected incidence of each):

Summary of evidence base (please submit references as attachments with this document):

When do you aim to first perform this procedure*?	
*A NIP must not be scheduled prior to NIPAG authorisation AND CMG approval	
How many procedures do you anticipate carrying out per year?	
Please list all colleagues who will be carrying out this procedure during this introductory phase and give details of relevant training. All named clinicians should sign the declaration below.	
Please list colleagues who support this procedure:	

***Individual clinicians retain ultimate responsibility for the introduction of new interventional procedures. Their responsibilities include ensuring minor changes are discussed with colleagues and that more significant changes or a new procedure is notified to their Head of Service and/or Clinical Director and NIPAG using this form.**

LEAD CLINICIAN **(person submitting Notification)**	**Name:** **CMG:** e-mail: Telephone:

Declaration

I have assessed the potential value of this procedure and am satisfied that it is indicated. I consider myself suitably trained and capable of applying such a procedure to patients.
I have ensured that there is a specifically written information leaflet for patients undergoing this new procedure which conforms to UHL standards and I consider that a patient will be able to understand what is being offered and why.

Signed …… Print …… Date ……..……..
Lead Clinician

Signed …… Print …… Date ……..……..
Clinician 2

Signed …… Print …… Date ……..……..
Clinician 3

I consider the above applicant(s) suitably trained and capable of applying such a procedure to patients.

Signed …… Print …… Date ……..……..
CMG Clinical Director/Deputy CMG Clinical Director /Head of Service (delete/ score through as applicable)

CMG …… Specialty……

Introduction of this procedure has been discussed within the CMG and support is given for this Notification.

Signed …… Print …… Date ……..……..
CMG Clinical Director/Deputy or CMG Head of Operations/Deputy (delete/ score through as applicable)

Advisor: Who from your specialist society would be able and willing to advise NIPAG if necessary Name/Position held

Telephone : Email:

IPAC status

Has there been any IPG/NICE guidelines on the procedure? Yes / No
If yes – Is your application in line with issued guidance? If not please explain:

IPG classification

Standard arrangements **Report due date……..**

Special arrangements

Research only **Please attach copy of Report**

Do not do **Please give details**

If the procedure has not been registered, have you notified IPAC at NICE Yes/NO

Is the procedure referred to by any other nomenclature? If so, please provide detail:

NICE IPAC Category Reference

CATEGORY REF	IPAC ARRANGEMENT CATEGORY*	ARRANGEMENTS
A	Standard	Apply normal consent, audit and clinical governance arrangements
B	Special	Notify clinical governance leads, ensure patients understand the uncertainties referred to in the guidance, and audit and review clinical outcomes of all patients having the procedure
C	Other (see individual guidance)	Includes additional recommendations, for example, on training, service delivery or data collection
D	Research only	Use only in the context of a formal research protocol
E	Do not use	The procedure should not be used in the National Health Service (NHS)

TRAINING NEEDS

What new skills are required by which team members (to include ward/theatre nursing staff and/or AHPs as applicable)

What training have you and your team had, or plan to undertake in respect of this procedure? Include date and venue.

Are there any guidelines or standards agreed by professional bodies? YES / NO

If yes, state which organisation and attach a copy with this Notification

Who will Proctor you? Name/Position held Organisation Telephone : Email:
Please give details of type of proctorship arrangements agreed with the Proctor, to include how many numbers of procedures they will attend. You are advised to include a letter from your Proctor, confirming this agreement.
Is this procedure already carried out within UHL (ie for another indication) Yes / No If yes, by whom

CE MARKING/UKCA Please confirm whether all equipment and devices are CE / UKCA Marked YES / NO
RESEARCH Is this intervention subject to research ethics application YES / NO
MEDICAL PHYSICS Has Medical Physics been informed YES / Will be Informed at a Later Date / Not Applicable
THERAPEUTICS ADVISORY SERVICE (TAS) Does this interventional procedure involve medication? YES / NO If yes, please advise if TAS advice has been sought.

PATIENT INFORMATION AND CONSENT

What information will be given to patients about this procedure

Is there a NICE or Professional Body Patient Information Leaflet Yes/No

Please provide copy of Information Leaflet to be used (this should be in UHL format)

Infection Prevention

The operator must ensure that any re-usable equipment can be adequately decontaminated to an appropriate level and that appropriate decontamination services for any re-usable equipment are available within UHL. It is also the duty of the clinician to consider the risk of exposure of the patient or staff to infection; an infection risk assessment may be required to achieve this.

What infection control precautions need to be considered in respect of this procedure?

Have infection prevention been notified Yes/No

Formal audit is required and must include every case. An audit report to NIPAG is required after the first 20 cases or after 6 months if 20 cases have not been completed. Any untoward events must be reported using the UHL Incident Form and copied to NIPAG. NIPAG authorisation should be referred to in the Incident Reporting Form.

What audit processes are in place in respect of monitoring outcomes of this procedure?

Is the audit on your CMG's Audit Programme Yes/No

SUPPORTING INFORMATION PROVIDED WITH THIS NOTIFICATION

Please state which of the following is being submitted with this Notification: NICE Interventional Procedures Guidance
Summary of Evidence Base / Research Articles Professional Body Standards/Guidelines
Copy of Proctor's Letter

NICE IPG Patient Information Leaflet UHL Patient Information Leaflet

Other …….

Monitoring Arrangements

Is there a National or Local Registery for this procedure Yes/No
Please give details

All procdeures involving insertion of devices / implants must be registered.

If the procedure involves the insertion of a device or prosthesis, is there a national registery Yes/No/Not Applicable

Outcome Measures

Are there any proposed outcome measures and risks that could be incorporated into the audit

Once completed, this Notification should be discussed with the appropriate Speciality / CMG Clinical Director and following their signature, sent to the NIPAG Chair, c/o Clinical Effectiveness Project Support Officer Clinical Audit & Effectiveness Office, Red Brick House, LGH
Electronic copies should also be sent via email to claire.stanley@uhl-tr.nhs.uk

University Hospitals of Leicester NHS
NHS Trust

New Interventional Procedures Authorising Group (NIPAG) Terms of Reference (revised)

Date of Origin:	2005
Date:	Reviewed and Revised - March 2015
Author:	Mr Marwan Habiba, Consultant Obstetrician and Gynaecologist and Chair of the New Interventional Procedures Advisory Group (NIPAG)

Revisions Approved by: New Interventional Procedure Authorisation Group (NIPAG)

1 Purpose of Group:

To act as an advisory and authorising body to clinicians (including medical, nursing and therapy staff) who intend to introduce a new interventional procedure (NIP).

To support CMG Clinical Directors & Deputy Clinical Directors by confirming that appropriate clinical governance and audit arrangements are in place for any NIP notified to NIPAG.

To support the Medical Director and Trust with meeting the Department of Health Health Services Circular 2003-011[1]

Scope of responsibilities

To promote patient safety and support innovation with respect to new interventional procedures.

To receive and review Notifications of planned NIP's and to seek additional information or clarification where any safety, training or monitoring arrangements are not clear.

To provide advice to clinicians, Clinical Leads and CMG Clinical Directors, on ways to consider and implement new interventional procedures.

To be informed by the quality of published evidence and the opinion of national bodies or professional association as provided by the lead clinician.

To authorise the introduction of new procedures within UHL once assured that all appropriate governance and audit arrangements are in place.

To determine if a new application can be introduced under standard arrangements, special arrangements or research only.

To determine the requirements for any procedure introduced under special arrangements.

To review procedures introduced under special arrangements no longer than 3 years following initial authorisation.

To refuse the introduction of procedures based on safety concerns or lack of fit within UHL.

To suspend procedures authorised under its remit if deemed necessary for patient safety.

To receive and review audit reports for all NIPs.

To receive and review reports of adverse events.

To compile quarterly reports on notification rates of NIPs by CMG to inform Quality & Safety Boards (Q&SB) and the Executive Quality Board (EQB) on introduction of interventional procedures within UHL.

To inform the Medical Director of any decision to refuse or suspend authorisation.
To liaise with relevant CMG's to explore ways of supporting clinical and training needs for staff involved in introducing NIPs.

NIPAG is not concerned with the introduction of drugs and therapeutics which should be notified to the UHL Therapeutics Advisory Service (TAS).

To receive an update of guidance published by the NICE Interventional Procedures Advisory Committee (IPAC) and to review the Trust's compliance with this guidance where applicable.

To enquire with the HoS AND/OR CMG CLINICAL Leads that appropriate measures are in place for those interventions ranked by NICE as requiring special arrangements.

To compile quarterly report on the Trust's compliance with NICE IPGs for reporting to the EQB

NIPAG does not consider issues of cost or cost effectiveness of procedures and NIPAG authorisation does not imply that a procedure has been assessed as being cost effective. Decision around cost effectiveness should be taken by CMG management teams, in conjunction with Commissioners, where applicable. See Appendix 1.

[1] Healthcare Circular - HSC 2003/011 - The Interventional Procedures Programme - Department of Health, November 2003

Establishment of Group and Appointment of Members

The Chair of the Group shall be appointed by the Medical Director.

Membership will include:

Director of Clinical Quality or nominated deputy
Assistant Director of Research & Development or nominated deputy
Deputy Head of Outcomes and Effectiveness
Nursing Representation

Clinical representative from each CMG Clinical NIPAG members are

required to:

- be nominated by their CMG Clinical Directors
- feedback relevant information within their CMG's
- be actively involved in taking forward any required actions within their CMG's and reporting back to the Committee accordingly

All members are required to:

- actively participate in reviews of NIPAG notifications
- re-affirm their membership annually
- attend a minimum of 4 meetings per annum or send an appropriate deputy

Other members of staff and external advisers may be invited to attend meetings of the Committee at the Chairman's discretion to discuss specific issues or notifications under consideration by the Group.

Meetings of the Group

The Group shall meet not less than every two months.

Notes of the meetings shall be presented at each subsequent meeting for approval as an accurate record of the meeting.

Notes of the meetings shall be submitted to the Executive Quality Board

Approval of any motion shall be by simple majority. The Chairman shall have a casting vote.

Quorum

The Committee will be quorate when 5 or more members are present of which no fewer than 2 members are from CMG's, in addition to the NIPAG Chair.

For the Committee to be quorate, where nursing or therapy notifications are being considered, at least one member from a nursing background must be in attendance.

NIPAG Reporting process

The chairman of NIPAG will report to the Medical Director, with specific support from the Deputy Head of Outcomes and Effectiveness as required.

list of new NIP Notifications and the RAG status of ongoing NIP notifications will be included on CMG's monthly Clinical Effectiveness Dashboard and reported to the CMG Q&S Boards.

A quarterly summary report on all 'open' Notifications and the RAG status of ongoing NIP notifications will be submitted to the Executive Quality Board as part of the NIPAG report.

An annual report will be prepared and submitted to the Quality Assurance Committee and to the Director of Clinical Quality for consideration of inclusion in the Trusts' Annual Quality Accounts.

A quarterly summary report on all 'open' and recently published NICE IPGs will be prepared and submitted to the Executive Quality Board as part of the NICE report.

The RAG status of 'open' NICE IPGs will be included as part of the 'NICE indicator' on Trust's monthly Quality and Performance Scorecard.

NIPAG NOTIFICATIONS

Notifications received by NIPAG will be circulated to two members of the committee*, the Chair will then collate initial feedback and forward to the notifying clinician(s) for response and clarification, if needed.

NIPAG's preliminary response will be provided within 21 days.

In order for Notifications to proceed to the Committee, NIPAG should receive a response to any initial queries, as expressed in the preliminary opinion, at least 2 weeks before the schedule meeting. It is often helpful for the notifying clinician to attend the meeting and where possible they are encouraged to do so.

* For each application at least TWO members will be nominated (on a rotating basis) to lead the review. They will be responsible for presentation at NIPAG meeting.

NIPAG Decision

NIPAG with consider the level of available evidence and the training, safety and efficacy. Based on the data provided, NIPAG may:

1- Authorise the intervention with the requirement of initial monitoring. The duration of monitoring will be depend on the safety profile and the results of the initial audits
2- Authorise the intervention provided special arrangements are in place for ongoing audit and follow up after the initial introductory phase.
3- Authorise the intervention subject to patients being enrolled into a research protocol under the auspices of R&D and the research ethics committee.
4- Refuse authorisation and provide reasons.

All applications to NIPAG will be subject to initial audit for the first 20 cases. The durations of any subsequent follow up with be determined by the committee. This will be informed by the outcome of the initial 20 cases. Applications for procedures categorised as requiring special arrangements by NICE or those that have not been assessed by NICE but are of equivalent status will normally require ongoing monitoring and audit. Additional requirements will be determined by the committee.

Determining the safety and efficacy of some procedures may require long term monitoring. NIPAG will require satisfactory evidence that measures are in place to satisfy such requirements.

In making its decision, NIPAG may take into consideration issues of conflict of interest.

NIPAG Support

NIPAG will be supported by the Deputy Head of Outcomes and Effectiveness and the Clinical Effectiveness Project Support Officer.

Required audits of outcomes for NIPs will be prioritised for inclusion into the Trust's annual Audit Programme, which is overseen by the Clinical Audit Committee

Terms of Reference Review

Date of next review – March 2025 or earlier if HSC 2003-011 guidance updated.

Any amendments or additions to these terms of reference which may be proposed from time to time shall be considered for approval by the Group and the Medical Director, and submitted to the Executive Quality Board for ratification.

NEW INTERVENTION PROCEDURE ADVISORY GROUP (NIPAG)

PROCEDURE FOR SUBMITTING AND RESPONDING TO NOTIFICATIONS

NIPAG is concerned to receive notifications of new intervention procedures, defined as new to the TRUST or to the CLINICIAN NIP POLICY. NIP POLICY.

If in doubt as to whether a procedure should be notified to NIPAG, please contact Nicola Baker nicola.baker@uhl-tr.nhs.uk Marwan Habiba mah6@le.ac.uk
or your CMG Representative

1. **Final Approval for introduction of the procedure must be received from the CMG Clinical Director** (or nominated Deputy) before Scheduling the procedure.
2. Clinician proposing to introduce New Interventional Procedure (NIP) to submit to Clinical Effectiveness Project Support Officer claire.stanley@nhs-tr.nhs.uk the following:

a. Completed. NIPAG Notification Form and supporting information. This includes summary of the key research evidence.
We welcome electronic submissions, but require one copy of a signed notification form.

b. Patient information leaflet to comply with UHL Policy on the development of information for patients, carers and the public B18/2002
Ensure that the leaflet explains that the procedure is NEW, and that it includes a balanced explanation of risks and benefits, and that it could be readily understood by patients.

We advise a multidisciplinary approach to developing an information leaflet.

c. NICE guidance where applicable.
d. Supporting information – journal articles, manufacturer's information.

3. The completed submitted form will be scanned or otherwise circulated electronically to NIPAG members for their initial rapid review. Members' comments to be fed back to the Chair within 15 working days.

4. Two NIPAG members will be allocated on a rotational basis to lead the review of new applications. They will liaise with the Chair in undertaking the role.

5. The Chair will then send the clinician this interim letter of acknowledgement, and preliminary opinion outlining initial concerns/comments raised. This letter to be sent within 21 days of receipt of the initial Notification.

6. The notification and responses to (4) will be added to the agenda of the following NIPAG meeting NIPAG meetings' schedule for review and confirmation of interim advice. Clinicians may be invited to attend a meeting to discuss their proposal.

7. A further letter will be sent following the meeting either:

   a. confirming the content of the interim letter
   b. seeking additional information or

c. where there has been time for the Notifying Clinician to respond to the interim letter confirming that all queries have been satisfactorily resolved.

8. Once all additional information has been received or all queries resolved, a letter confirming NIPAG's authorisation of introduction of the procedure will be sent to the Notifying Clinician, copied to their CMG Clinical Director

9. Final Approval for introduction of the procedure must be received from the CMG Clinical Director (or nominated Deputy) before scheduling the procedure.

10. In order for Notifications to proceed to the Committee, NIPAG should receive a response to any queries raised in the preliminary opinion, at least 2 weeks before the scheduled meeting.

11. It is often helpful for the notifying clinician to attend the meeting and where possible they are encouraged to do so.

MONITORING ARRANGEMENTS

1. As part of the authorisation letter, NIPAG will request receipt of initial short term audit data on patient outcomes NIP Audit Form as minimum for the first 20 cases carried out.

2. NIPAG may request that the notifying clinician contributes to a local or national registry.

3. If fewer than 20 cases are carried out, an interim report on those patients who have undergone the procedure is required every 6 months

4. NIPAG may stipulate the need for additional and longer term outcome data. This will be informed by the risk and outcome profile of the new intervention.

5. Notification Leads will be asked to confirm the number of procedures undertaken and to provide an audit report accordingly.

6. Audit reports must be provided within 4 weeks of request. Audit data must be submitted using the NIPAG Audit Summary Report Template.

7. If no patients have been treated by six months, NIPAG should be notified by completing one NIP Audit form entering the date and NONE under patient ID.

8. One reminder will be sent to the Notification Lead if delayed audit and a report must be provided within 2 weeks of reminder for NIPAG's review.

9. Where audit data is not received after one reminder, this will be classed as a Defaulted Audit and, in the absence of an acceptable justification, NIPAG authorisation for undertaking of the NIP may be withdrawn. Withdrawal of NIPAG authorisation will be reported to CMG Clinical Director and to the Trust's Executive Quality Board

10. Following successful introduction of a NIP that falls under standard arrangements, ongoing monitoring will be according to the CMG's Governance Structures.

11. Following successful introduction of a NIP that falls under special arrangements, ongoing monitoring will be determined by NIPAG and may involve contribution to national or regional datasets or local long-term follow up.

12. All serious adverse events must be reported using the Trust's Incident Reporting Form and copied to NIPAG via Clinical effectiveness Project Support Officer.

13. All mortalities within 30 days of procedure must be reported to NIPAG.

14. NIPAG authorisation may also be withdrawn where there are a high number of adverse events with a procedure.

15. Re-instigation of NIPAG authorisation will be dependent upon the reason for withdrawal and remedial actions taken.

16. All correspondence will be copied to:
    CMG Clinical Director
    CMG Deputy Clinical Director
    CMG Head of Operations
    CMG Deputy Head of Operations
    Any other signatories on the notification

Appendix 4

NEW INTERVENTIONAL PROCEDURES AUTHORISING GROUP (NIPAG) Initial AUDIT DATA COLLECTION FORM

NIPAG reference number*	
Name of Procedure*	
CMG/Specialty*	
Lead Clinician*	

*** To be completed by Clinical Effectiveness Project Support Officer (CEPSO)**

Date of procedure	
Procedure Number **(NIPAG requests audit for 1st 20 cases)**	
Hospital number	

	Yes	No
1. Was Patient Information Leaflet issued?		1
2. Was consent obtained in line with proposed procedure?		1
3. Was the procedure carried out as planned?[2]		1
4. Were intended outcomes achieved?		1
5. Were there any complications?	1	
6. Were there any difficulties with equipment?	1	

1 Give detail/justification in box below (add more rows as applicable)

Issue	Detail/Justification

All serious unexpected events should be reported in accordance with UHL-Trust procedures and copied to NIPAG.

	Additional requirements to be deterimed by NIPAG

Appendix 5

NIPAG AUDIT SUMMARY REPORT FORM

NIPAG reference number*		**Date of NIPAG Approval**	
Name of Procedure*			
CMG/Specialty			
Lead Clinician*			
Brief Description of Procedure			
Date of 1st Procedure		**Date of Audit Report:**	
Number of procedures anticipated per year		**No of Procedures undertaken in total**	
Timescale covered in this report		**No of procedures covered in this report**	

		Yes[iv] (n / %)	No[v] (n / %)
1.	Was patient information leaflet issued?		
2.	Was consent obtained in line with proposed procedure?		
3.	Was the procedure carried out as planned?		
4.	Were intended outcomes met?		
5.	Are results in line with published literature?		
6.	Were there any complications?		
7.	Were there any difficulties with equipment?		

[1] or [2] Further details:

Case No	Issue	Detail

[iv] **Provide further details if 'No' to any Questions 1-5**

[v] **Or if 'Yes' to Questions 6 or 7**

Appendix 6

NIPAG Preparing Patient Information Leaflet for New Intervention Procedures

One of the most common causes for delayed NIPAG authorisation of new interventions is the lack of a satisfactory Patient Information Leaflet (PIL)

University Hospitals of Leicester NHS
NHS Trust

NIPAG regards the production of a patient information leaflet as an important element in gaining authorisation as it supports adequate consent. However, it is not NIPAG's role to co-produce or to proof read various versions.

The Trust has a Patient Information Librarian who can give training and support to staff who are producing information leaflets for patients. See policy and guidance on INsite

Ownership of the PIL must rest with the relevant clinical service.
A critical function of the PIL is that it supports the consent process and enables patients to choose between current standard of care (where applicable) and the proposed new intervention.

Clinicians must consider:

1-Information balance:

a.The leaflet should provide a realistic balance of expected outcomes and risk. Where this is unknown because it is a new procedure, this should be clearly and unambiguously stated and where applicable a best estimate is provided.

b. The leaflet should provide a balanced assessment of the pros and cons of the new intervention compared to current established techniques.

2-Candour:

a. It should be clear that the intervention is new to the UHL.
b. The leaflet should be clear in relation to interventions that may entail learning curves and those that require hands-on or close mentoring.

3- Use of material provided by manufactures or suppliers:

a. Some of the material provided by external sources can be useful, but more often these are produced as promotional leaflets and as such will require adaptation for the purpose of NIPAG. Appropriate acknowledgement and copyright permission to re-use content or diagrams must be obtained.

4- NIPAG will accept PIL that have been approved by Research Ethics Committee for those procedures introduced through R&D.

5- Language and layout:

a. The leaflet should be written in lay language and easy to read.

The layout should comply with the standard requirements of the UHL; they should be concise and easy to read. Contact InformationForPatients@uhl-tr.nhs.uk for guidance

b. You should allow plenty of time for drafts to be reviewed by the librarian and expect to make revisions based on health literacy best practice and patient consultation.

c. The Patient Information Librarian is responsible for final publication of leaflets on our public facing online store Your Health www.yourhealth.leicestershospitals.nhs.uk

6- Patient follow-up and pathway:

Where relevant, the PIL should explain patient aftercare and arrangements for follow-up or contact points in case of need.

Sources of help and support:
Communicating Risk
https://www.pifonline.org.uk/wp-content/uploads/2018/10/Communicating-Benefits-Risks- and-Uncertainties.pdf

http://researchbriefings.files.parliament.uk/documents/POST-PN-0564/POST-PN- 0564.pdf

https://www.nice.org.uk/guidance/cg138/chapter/1-Guidance#enabling-patients-to- actively-participate-in-their-care See 1.5.24

UHL Patient Information Librarian InformationForPatients@uhl-tr.nhs.uk 0116 258 8355

Checklist:

- Description of condition being treated
- Procedure description and preparation
- Alternative treatments available and reasons for being offered this treatment
- Risks with balanced statements and numerical data if possible
- After care advice (device specific instruction, i.e. washing/driving/travel advice/post procedure pain
- Who to contact for advice

Remember to talk to patients about what information *they* feel it is important to know