Heart of England NHS
NHS Foundation Trust

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Policy for Introduction and Development Of Novel Techniques and Interventional Procedures V4.0

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Purpose:	To explain the introduction of techniques and interventional procedures that are new/novel to the Trust and/or the Individual. A systematic approach to ensure effectiveness, patient safety and appropriate training.
Responsible Directorate:	Safety and Governance
Executive Sponsor:	David Burbridge, Director of Corporate Affairs
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Related Controlled documents	Incident Reporting and Management Policy and Procedure Consent to Examination or Treatment Policy Corporate Records Policy Clinical Audit policy Medical Devices Policy
Relevant External Standards/ Legislation	N/A
Target Audience:	Applies to all staff responsible for the introduction and development of techniques and Interventional Procedures.
Further information:	Clinical Audit Lead

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Version History

Version	Status	Date	Consultee	Comments
2.0	Final	09/01/09	Members of the NTIP Group	Approved
3.0	Final	01/11/12	Director of S&G	Approved
4.0	Draft	TBC	NTIP Group , PRG	TBC

Summary of changes from last version:

- Requirement for proposers to audit the outcomes of the first 25 cases, or over a 6 month period
- Flow chart has been updated and condensed down to fit on to one page
- NTIP is now the sole acronym when referring to the Group
- 'Benners competency framework' attachment has been removed
- Group/Committee names have been updated to reflect the changes in structure.

Table of contents

1 Policy Statement

This policy should be read by all staff responsible for the introduction and development of a technique or interventional procedure that is either new to the trust or the individual. This policy applies equally to staff in a permanent, temporary, voluntary or contractor role acting for or on behalf of Heart of England NHS Foundation Trust.

The Trust recognises and encourages innovation and views the introduction of NTIPs as a vital part of clinical practice which is necessary to ensure patient care keeps pace with technological advances in clinical medicine. This should, however, be balanced with the Trust's responsibility for ensuring its duty of care and patient safety. All relevant trust staff must ensure that when NTIPs are introduced, they are safe, appropriate, effective, communicated to patients in a manner that enables full consent to be obtained and that staff undertaking these procedures are appropriately trained.

2 Scope

This policy applies to the introduction of all Novel Techniques and Interventional Procedures (NTIPs), both clinical and laboratory-based which have never been performed in the Trust before but which have undergone assessment as part of a formal peer-reviewed research process involving clinical trials, and are deemed safe for clinical practice. The policy also applies to procedures which are not new to the Trust but may not have been performed by an individual before.

NTIPs will fall into one of the following categories:

1. The application of existing proven techniques to new indications
2. A variation in technique or a new device used during the course of a standard procedure
3. A technique that is already practised widely but has not yet become accepted routine practice.

In particular, it does not apply to requests for new drugs and novel uses of existing formulary drugs. These should be referred to the Formulary Working Group. It does not apply to techniques that have never been tested through a clinical trial. These types of NTIPs should be evaluated as part of a formal research programme and should be referred to the Trust's Research and Development policies and procedures.

3 Definitions

For the purpose of the policy, an Interventional Procedure is a procedure used for diagnosis or for treatment that involves one of the following:

- Making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel
- Gaining access to a body cavity such as the digestive system, lungs, womb or bladder without cutting into the body for examination or carrying out treatment

- Using electromagnetic radiation such as X-rays, lasers, gamma-rays and ultraviolet light.

An Interventional Procedure should be considered new when:

- A doctor no longer in a training post is using it for the first time in his or her NHS clinical practice
- The procedure has not previously been performed in the Trust
- A significant variation in technique, new equipment or new device is used during the course of a standard procedure i.e. where the novel technique is likely to have a different safety and efficacy profile from that of the original procedure.

4 Policy Framework

The aim of this policy is to ensure that the Trust has a systematic approach to the introduction of NTIPs that ensures they are appropriate and effective, staff have an appropriate level of skill and training to perform these techniques and patients are not exposed to unnecessary risk.

The following standards apply to the introduction of NTIPs within the Trust:

- **Clear mechanisms are in place to assess competency of staff introducing NTIPs**. All staff involved in the introduction of NTIPs should receive appropriate training and have necessary expertise. Assurance will be required by the Novel Techniques and Interventional Procedures Group (NTIPG) that the responsible clinician has received adequate training. There may be a need for a period of supervision using a visiting expert.

- **All ethical issues are referred to the Trust Clinical Ethics Advisory Group (CEAG) for examination.** The introduction of NTIPs may raise ethical concerns and issues. The Trust will take steps to ensure that it fully considers the ethical impact of the introduction of NTIPs where necessary.

- **Patients who receive care involving NTIPs should give informed consent for the procedure.** The patient must be given the choice to have other alternative treatments where available. Comparative risks must be clearly explained and documented. When written consent is not normally needed for the usual procedure; it should still be obtained for the Novel Technique as a means of documenting the information given to the patient and their agreement to it.

- **NICE guidance on the procedure is made available to the patient**. If no NICE guidance on the procedure is available, all patients offered the procedure should be made aware of its special status. This should be done as part of the consent process and should be clearly documented.

- **Effective communication is maintained.** This is to ensure the entire multidisciplinary team (including appropriate managerial staff, primary care teams

and staff in other Directorates) are informed about the NTIP and understand the impact that this may have on service delivery and patient care.

- All NTIPs should be subject to evaluation after their introduction, and audited to ensure that they are effective.

- **Consideration should be given to inviting an acknowledged expert in the field to visit and assist or supervise when an NTIP is carried out for the first time**. This should be normal practice unless good reason can be given why it is unnecessary. (NB: Travelling and subsistence expenses for such a visit should be funded through the Directorate's budget).

4.1 Training

There are clear mechanisms to assess competency of staff introducing NTIPs. All staff involved in the introduction of NTIPs should receive appropriate training and have necessary expertise. Assurance will be required by the Novel Techniques and Interventional Procedures Group (NTIPG) that the responsible clinician has received adequate training. There may be a need for a period of supervision using a visiting expert.

5 Introduction of NTIPs which are new to the Trust

Prior to introducing a Novel Technique or Interventional Procedure (NTIP) to the Heart of England NHS Foundation Trust, all staff should submit a proposal for evaluation by the Novel Techniques and Interventional Procedures Group.

All applications should be supported by the Clinical Director and will need to take the following into account:

- The safety and efficacy of introducing the Novel Technique or Interventional Procedure
- Potential benefits
- Training implications
- Cost implications
- Implications to the Directorate / supporting departments
- Whether the proposed procedure is covered by existing NICE Interventional Procedure guidance, including any NICE recommendations.

NTIPs should not be undertaken within the Trust until the Novel Techniques and Interventional Procedure Group has evaluated them and formal approval been given.

The arrangements for this process are detailed in Section 6.1. See Attachment 1 for the procedure for the introduction of NTIPs.

5.1 Submission of proposals for evaluation

Prior to submitting proposals for evaluation, any clinician wishing to introduce a Novel Technique or Interventional Procedure should take the following steps before submitting their proposal to the Novel Techniques and Interventional Procedure Group:

1. Consult the register of interventional procedures held by NICE (www.nice.org.uk/ip) to identify whether NICE has a record of this procedure:

   - If the procedure is not listed, the Trust will need to notify NICE that we intend to introduce this procedure. The Novel Techniques and Interventional Procedures Group Chair is responsible for notifying NICE
   - If the procedure is listed with NICE and is new to the Clinician, the Novel Techniques and Interventional Procedure proposal proforma should be completed and submitted to the Safety and Governance department
   - If the procedure is listed with NICE and is not new to the individual but is new to the Trust, the Novel Techniques and Interventional Procedure proposal proforma should be completed and submitted to Safety & Governance department.

2. If the procedure is not registered with NICE, clinicians must identify sources of clinical research evidence to support the use of the NTIP. In cases where there is no research evidence available, a research protocol must be submitted for approval through the Trust's Research & Development policies and procedures. The Research and Development (R&D) department can provide advice on this process.

   If it involves a new medical device, it needs to go through Medical Devices Group to provide input and assurance to NTIP if appropriate and safe to introduce.

3. The proposal should be discussed with Directorate colleagues and all relevant parties involved in delivering this new service or for whom there may be an impact (e.g. increased workload; changes to discharge practice; special medication/treatment requirements requiring input from GPs).

4. Gain support from the Directorate Management Team and formal approval from appropriate Clinical Director.

5. Complete the Novel Techniques and Interventional Proforma and collate the supplementary evidence that is requested. All applicants are required to complete this form and to submit a supporting paper (in a format of the applicant's choice). The Proforma is used to provide an audit trail and to facilitate monitoring.

6. Submit the proposal to the Safety & Governance Directorate who will ask the Novel Techniques and Interventional Procedures Group to assess the NTIP. Proposals should be submitted in an electronic format where possible. The proposal will be electronically circulated to group members. If deemed necessary (i.e. the group members are unable to virtually approve the proposal due to it being of a complex

nature) the proposer will be invited to attend an arranged Novel Techniques and Interventional Procedure Group meeting to present the proposal and answer any questions raised by the NTIP Group.

7. Whilst the Novel Techniques and Interventional Procedure Group will not comment on financial implications, it will expect to see evidence that discussion of financial implications has been appropriately held with the Divisional Finance Manager (Corporate).

5.2 Evaluation of proposals by the NTIPG

The NTIP Group will consider the following criteria for all applications that are submitted:

- Nature of the intervention
- The evidence base
- Previous/ current use at other sites
- Whether proposed use complies with the guidance set out by NICE
- Proposed application
- Benefits over existing treatment(s) for patients
- Risks over existing treatments for patients
- Experience/training requirements of the operator
- Competency assessment of the operator
- Implications for other clinical staff
- The need to refer the proposal to the Clinical Ethics Advisory Group
- Proposals to audit/evaluate the intervention.

Where procedures are not listed by NICE and no NICE guidance is available, the NTIP Group will pay particular attention to ensuring:

- The clinician has met externally set standards of training.
- All patients offered the procedure are made aware of the special status of the procedure and the lack of experience of its use. This should be undertaken as part of the consent process and should be clearly recorded. Patients need to understand that the procedure's safety and efficacy is uncertain and be informed about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment.
- The Group is satisfied that the proposed arrangements for clinical audit are sound and will capture data on clinical outcomes that will be used to review the continued use of the procedure. NTIP proposers will be required to carry out a clinical audit on the effectiveness of the procedure. The outcomes and morbidity/mortality will need to be audited on the first 25 cases, or over a 6 month period which will be extended as appropriate and reported to the Clinical Standards Group 12 months after approval of the NTIP. These reports will also go to the divisions' quality processes and assurance will be provided to the NTIP Group.
- All complications that occur (recognised complications and new complications) must reviewed after each case. If there are any concerns or if a recognised complication occurs more frequently than expected, the NTIP must be suspended whilst an

investigation is undertaken. The complication/issue must be reported onto the Datix Incident Management System.

The Group will aim to review within 4 weeks of a proposal being submitted. In the event that the Chair decides an expert opinion is required, the Group will co-opt an expert with appropriate experience, to advise the Group.

Following receipt of the Group responses, the Chair of the Group will make a decision and provide a written response to applicants within six weeks of receipt of a proposal.

Applicants should not undertake NTIPs until formal approval has been received.

In circumstances where approval is given and NICE are known to be collecting data on a particular NTIP, the proposer of the NTIP will assist NICE by supplying information on every patient undergoing the procedure. The collection of data from patients will be governed by the Data Protection Act.

5.3 Monitoring the implementation of NTIPs

The Group will agree appropriate time-scales and outcomes for monitoring the effectiveness and safety of the NTIP by the practitioner. The time-scales will be dependent on the type of intervention, skill of the practitioner and patient throughput. The practitioner will report to the Group, who in turn report to the Medical Directors and Clinical Standards Group.

Any adverse incidents associated with a new Interventional Procedure should be reported using the Trust's Incident Reporting. Also, all serious adverse incidents must be reported to the Novel Techniques and Interventional Procedure Group and Clinical Standards Group; any adverse incidents will also be reported to the National Patient Safety Agency. Safety & Governance will monitor any incidents reported on Datix by conducting a search of key words and report this to the Clinical Standards Group through the bi-annual report.

The Trust will maintain a record of all NTIPs and audit the introduction of NTIPs that have been considered. NTIP's audits will be included in the Forward Audit Programme for the appropriate Directorate.

Safety & Governance will maintain a central record of all NTIPs on behalf of the Trust and will liaise with practitioners and the Novel Techniques and Interventional Procedures Group to ensure these interventions are followed up in accordance to Novel Techniques and Interventional Group recommendations.

The Quarterly Divisional Quality Governance Report will include all of the NTIPs that have been approved within the Division and the progress of the clinical audit being undertaken to measure the effectiveness of the procedure.

Safety & Governance will report details of NTIPs under implementation; audit status; and issues of concern, on a six monthly basis to the Clinical Standards Group.

5.4 Process for introduction of NTIPs in an emergency situation

In exceptional circumstances, it may be necessary to expedite approval for the use of an NTIP. This should only occur in an emergency situation where there is a clear clinical need for the management of a patient and where delay in using the intervention would be life-threatening or detrimental to the patient. Under these circumstances, practitioners should seek the advice of the Trust Medical Director (or a nominated deputy), who will approve the intervention for use in that emergency situation. The Clinical Quality Monitoring Group must be notified within 72 hours that this procedure was undertaken. The practitioner should then proceed to submit a proposal for evaluation to the Novel Techniques and Interventional Procedure Group and follow the usual arrangements for approval of the intervention in routine situations.

5.5 Introduction of NTIPs which are not new to the Trust but have not been performed by an individual Clinician before

Where Clinicians wish to undertake an NTIP that is new to them, but is already conducted within the Trust by colleagues, individual Clinicians must discuss the matter with the relevant Clinical Director and Divisional Director.

Clinicians who are undertaking NTIPs must:

- Have appropriate training in undertaking the NTIP
- Demonstrate their competency to undertake the NTIP
- Evaluate and audit their effectiveness with undertaking this NTIP.

The Clinical Director should agree an appropriate training programme and devise a clear set of skills which must be acquired to demonstrate that the practitioner is competent. Arrangements should be put in place to ensure that the Clinician undertaking the NTIP has appropriate levels of supervision while he/she is undergoing training.

The Clinical Director should agree appropriate time-scales and outcomes for monitoring the competency of the Clinician. The time-scales will be dependent on the type of intervention, skill of the Clinician and patient throughput. The Clinical Director will advise the Novel Techniques and Interventional Procedure Group when the Clinician is signed off as competent who will in turn report to the Clinical Standards Group.

Once this has been agreed, the relevant sections of the Novel Techniques and Interventional Procedures Proforma should be completed and forwarded to Safety & Governance.

A formal record of the training programme; supervisory arrangements; and evaluation of the Clinician's competency should be recorded on the Clinician's Personal File and held within the Directorate.

6 Role and Responsibilities

6.1 Individual Responsibilities

6.1.1 Executive Medical Director

The Executive Medical Director, on behalf of the Chief Executive, is responsible for ensuring the implementation and monitoring of this policy and procedure, through the Novel Techniques and Interventional Procedures Group. Exceptional reporting should go through the Clinical Quality and Monitoring Group via the Clinical Standards Group.

6.1.2 Chair of the NTIPG

The Chair of the Novel Techniques and Interventional Procedures Group is responsible for reviewing all NTIP proposals and consulting with group members to reach a decision on approval. Also, the Chair is responsible for notifying NICE of any plans to carry out procedures not listed on NICE's website under the guidance of the Head of Clinical Safety and Governance

6.1.3 Divisional Directors

The Divisional Directors are responsible for ensuring that NTIPs within their areas of responsibility are referred for review to the Novel Techniques and Interventional Procedures Group. They are responsible for ensuring appropriate liaison has taken place regarding the implications for implementation at an operational level, including financial requirements.

6.1.4 Clinical Directors

Individual Clinical Directors are responsible for assuring that appropriate training programmes are developed and agree appropriate timescales and outcomes for monitoring the competency of the practitioner. They are also responsible for ensuring a formal record of the practitioners training programme/supervisory arrangements and evaluation of the practitioner's competency are recorded in the personal file. In addition, the Clinical Directors will be responsible for ensuring that the clinical audit is completed and any actions implemented. The position relating to the approval of NTIPs and subsequent audit for each Division will be outlined within the Divisional Quality Governance Report.

6.1.5 Clinical Staff

All Clinical staff who are carrying out the NTIP across the Trust are responsible for familiarising themselves with this policy and ensuring that they comply with the policy and procedures set out within this document.

6.1.6 Safety & Governance

The Safety & Governance Directorate will submit plans of new procedures via the notification form found on the NICE website (www.nice.org.uk/ip).
Safety & Governance is responsible for ensuring that all NTIPs implemented within the Trust are placed on directorate audit plans and Divisional Governance Framework.

6.2 Group responsibilities

6.2.1 Clinical Quality Monitoring Group

The Clinical Quality Monitoring Group (CQMG) receives a quarterly report from the Clinical Standards Group and reports to the Trust Board.

6.2.2 Clinical Standards Group

The Clinical Standards Group is responsible for monitoring the implementation of this policy through the Novel Techniques and Interventional Procedures Group. It receives a bi-annual report from the Novel Techniques and Interventional Procedures Group on new procedures that have been approved and their audit status.

6.2.3 NTIPG

The Novel Techniques and Interventional Procedures Group reports to and is accountable to the Clinical Standards Group.

The Novel Techniques and Interventional Procedures Group are responsible for the implementation of this Policy and Procedure, formally approving introduction of all NTIPs and has particular responsibility for ensuring:

- the appropriateness and effectiveness of NTIPs with respect to their proposed application in the Trust;
- the level of skill and training of the individual or team responsible for delivering the intervention;
- that ethical issues are appropriately referred to the Trust Clinical Ethics Advisory Group;
- their findings are reported to the Clinical Standards Group and Clinical Quality Monitoring Group.
- the introduction of NTIPs to the Trust is monitored and it is ensured they are subject to an audit process.

The Group will not authorise, or advise on the ethical or financial implications of NTIPs. Assessment of the financial implications is the responsibility of the Divisional Directors and Heads of Operations, in conjunction with Clinical Directors.

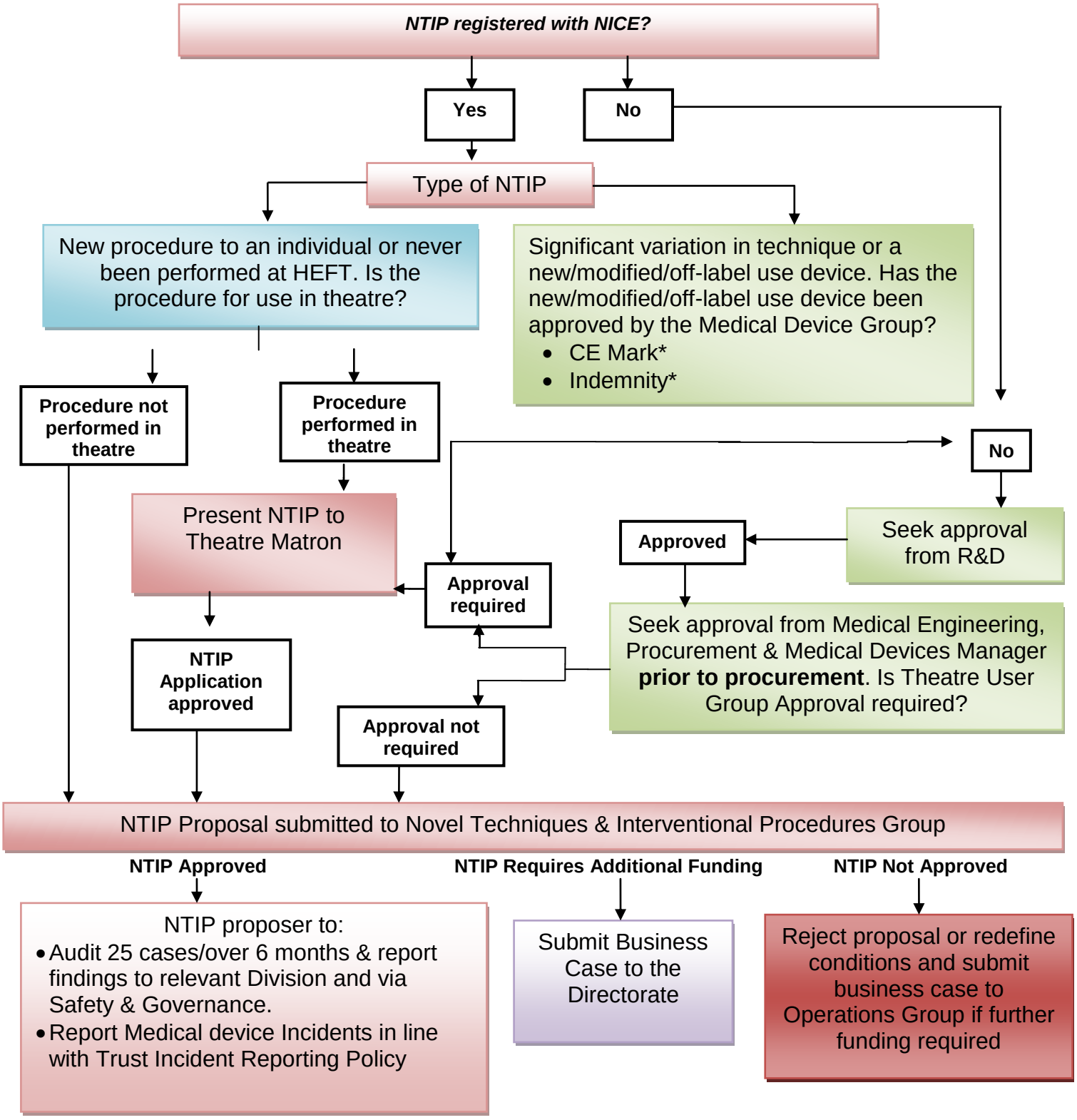
7 Monitoring

See **Appendix A**

Appendix A Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING FREQUENCY	MONITORING PROCESS
All staff involved in the introduction of NTIP's have the appropriate training/expertise required	Clinical Audit Lead	Clinical Standards Group	Bi-annual report	Scrutiny of NTIP proposal form provides this assurance and is reflected in bi-annual report
All NTIP's which raise any ethical concerns are referred to the Trust Clinical Ethics Advisory Group for examination				
All approved NTIP's have information leaflets available to ensure that the patient can give informed consent				
All approved NTIP's are audited after their introduction to ensure they are effective				All NTIPs are included in the appropriate Directorate forward audit program and are recorded on the Clinical Audit system. Review of Divisional Quality Governance Report which will record progress of NTIP audits.
Any adverse incidents following a NTIP are reported via the Trust Incident Reporting system				Review of incidents on Datix as and when they occur. Appropriate actions plans are produced and followed up. These are recorded in the bi-annual report.

Appendix B Flow charts describing the process for introducing an NTIP (that has not been performed in the Trust before or by an individual.)



Note: If the NTIP is no longer used/required, Chair of Theatre User Group and the Safety and Governance Department should be notified (Novel Technique leads to review 2 yearly)

Appendix C Questions to consider before you introduce an NTIP.

COMMUNICATION CHECK

- Have you discussed this with clinical & managerial colleagues in your department, including nurses and other clinical health professionals?

- Have you considered the implications for other departments?
  e.g. Theatres
  Radiology and Ultrasound
  Laboratories
  Therapies (Physiotherapy; Dietetics; Speech Therapy etc)

- Are there implications for general practitioners after discharge?
  e.g. Drug costs
  Home visits
  District nursing

VISITING EXPERTS CHECK

- What experience does the visiting expert have in this field?

- Is he/she an existing consultant in the UK?

- Does he/she have current GMC Registration?

- Is his/her hepatitis B status known?

- For non-medical professionals, has the Director of Nursing approved the status of the expert

- Honorary contracts are required if the visiting surgeon will do anything other than observe and feedback to the surgeon.

- If an honorary contract is required then it should be accompanied by occupational health clearance and GMC clearance as required.

- Fully informed patient Consent should clearly include details about who is operating, their expertise and outcomes (and alternatives to treatment).