Introduction of New Interventional Clinical Techniques & Procedures in the Trust Policy

Post holder responsible for Procedural Document	
Author of Policy	
Division/Department responsible for Procedural Document	Governance
Contact details	
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Please *specify* standard/criterion numbers and tick ✓ other boxes as appropriate

Monitoring Information		**Strategic Directions – Key Milestones**	
Assurance Framework		Privacy and Dignity	
Monitor/Finance/Performance		Efficiency and Effectiveness	
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		Infection Control	
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NHSLA CNST Maternity Clinical Risk Management Standards:			
Other *(please specify)*:			
Note: This policy has been assessed for any equality, diversity or human rights implications			

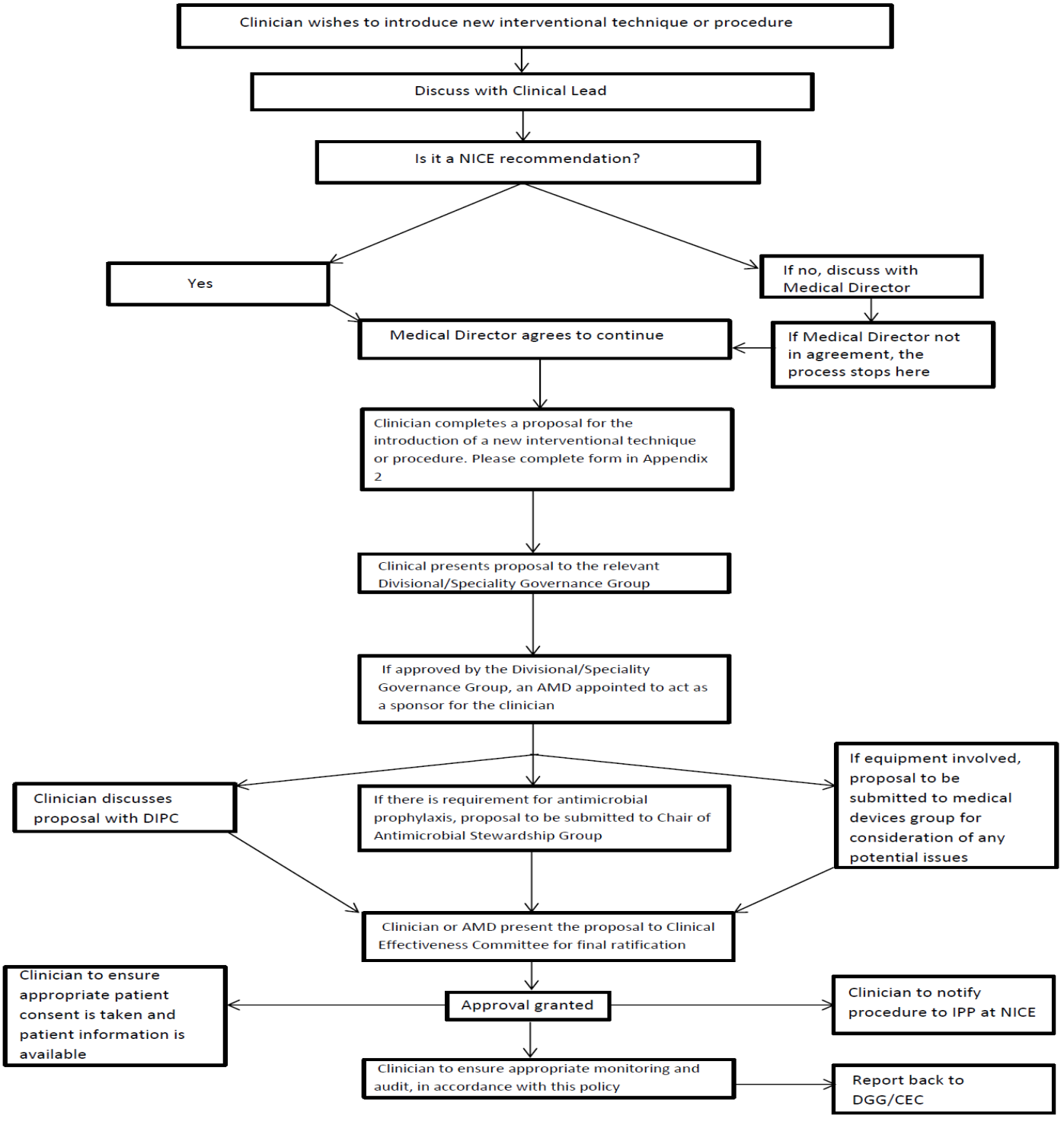
Full History:		Status: Final	
Version	Date	Author (Title not name)	Reason
0.1	02.04.19	Head of Governance	To align this policy to the divisions and processes of NDHT
0.2	15.04.19	Head of Governance	Send out for Consultation
1.0	18.07.19	Head of Governance	Approved by the Clinical Effectiveness Committee at the meeting held in May 2019.M

Associated Policies	Incident Reporting, Analysing, Investigating and Learning Policy and Procedures Consent Policy Infection Control policies
In consultation with and date: Clinical Effectiveness Committee 13th March 2019	
Review Date *(Within 3 years)*	May 2021
Contact for Review:	Head of Governance/Deputy Head of Governance
Executive Lead Signature: (Only applicable for Strategies & Policies)	 Mr Adrian Harris, Medical Director

Policy Summary

This policy sets out the process for the introduction of all interventional techniques and procedures that are new to the Trust. Its scope includes the processes involved in the development of a new interventional technique and procedure, with particular emphasis on clinical governance, including initial training requirements and assessment of competence.

Readers should read the whole policy. However, the flow chart below summarises the process in brief.



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1. INTRODUCTION

1.1 The Northern Devon Healthcare Trust (hereafter referred to as "the Trust") recognises the need for innovation, and views the introduction of new techniques and procedures as a vital part of practice to improve patient care and enhance the patient experience.

1.2 However, this must be balanced with the corporate responsibility for ensuring the safety of patients involved in the introduction of such techniques and procedures. The Trust must ensure that when new techniques and procedures are introduced, they are appropriate, effective and all staff undertaking or involved in the procedure are trained.

1.3 The cost pressures of a new technique or procedure may make it unacceptable for the Trust to take on.

1.4 This policy does not include the use of new techniques in the context of research projects managed under the Research Governance Framework (Department of Health, 2005); nor does it relate to changes in practices that can be considered minor incremental changes or developments.

1.5 This policy applies to all clinical professional groups practicing at all levels.

1.6 Failure to comply with this policy could lead to disciplinary action.

2. PURPOSE

2.1 This policy sets out the process for the introduction of all interventional techniques that are new to the Trust. Its scope includes the processes involved in the development of a new interventional technique, with particular emphasis on clinical governance, including initial training requirements and assessment of competence.

2.2 Its overall purpose is to permit timely introduction of innovative techniques whilst safeguarding patients against unacceptable risk and ensuring responsible use of available resources.

3. DEFINITIONS

3.1 An **interventional technique** refers to any interventional therapeutic and diagnostic procedure (see below in paragraph 3.2), and any other non-pharmaceutical technology requiring specific skills and knowledge to apply to healthcare that may impact significantly upon patient experience, outcome and/or exposure to risk. New pharmaceutical interventions should be addressed via the Formulary Interface Group or Medicines Management Group.

3.2 **An interventional procedure** is one used for diagnosis or treatment which involves the following:-

- Making a cut or 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 or

- Gaining access to a body cavity, such as the digestive system, lungs, womb or bladder, without cutting into the body. For example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth
  or
- Using electromagnetic radiation, including x-rays, lasers, gamma-rays and ultraviolet light. For example, using a laser to treat eye problems.

3.3 **A new clinical procedure** is any clinical intervention which involves new techniques which have not previously been undertaken by the Trust; it may also include the use of new equipment.

3.4 A technique should be considered new if any clinician or group is using it for the first time in the Trust and it is not considered to be a minor incremental change to existing practice, this also includes a technique being used on a new patient group.

3.5 As part of the application process, clinicians should determine whether or not an interventional procedure is listed on the National Institute for Health and Care Excellence (NICE) website - http://www.nice.org.uk (National Institute for Health and Care Excellence, 2014). If it is not listed, the Associate Medical Director (AMD) will notify the procedure to NICE via the website.

3.6 A judgement may be required as to whether or not the technique has been altered in some minor incremental way, or whether sufficient alteration has been made for it to constitute a new technique. This should be judged according to whether the altered technique is likely to have a different safety and efficacy profile from that of current alternatives. If there is uncertainty about whether a procedure or technique constitutes a minor incremental development, the development should be discussed at the Divisional/ Speciality governance meeting for further assessment of possible patient risk. If it is agreed via this route that a proposal is an incremental development, no formal process for its introduction is required.

4. DUTIES AND RESPONSIBILITIES OF STAFF

4.1 Chief Executive

The Chief Executive has overall responsibility for ensuring there are appropriate processes in place for the introduction of new techniques, but has delegated this responsibility through the Medical Director.

4.2 Medical Director

The Medical Director/Deputy Medical Director has responsibility for ensuring there are appropriate processes in place for the introduction of new techniques and updating the Trust Board of the introduction of any new intervention or technique.

4.3 Associate Medical Directors (AMDs)

The AMDs are responsible for supporting individual clinicians in the introduction of a new interventional technique or procedure, i.e. by acting as a sponsor.

4.4 Individual Clinicians

Individual clinicians have responsibility for:

- Providing adequate research-based evidence in support of the safety and efficacy of the technique when used in the proposed way for the proposed patient population, or that there is current NICE Interventional Procedure Guidance that

permits use, and that proposed use is within the context of any defined clinical governance arrangements that NICE sets out.

- Demonstrating that the technique is within their job description and scope practice of their role.
- Demonstrating that they have had or have arranged training of an adequate standard. What constitutes adequate standard should be agreed with the AMD; where training is to be provided by a mentor, the competence of the proposed mentor must be assured and the availability of the mentor to sufficiently supervise must be established.
- Identifying any, or additional, resource requirements as a result of the new intervention or procedure, ensuring authorisation to proceed (spend) is received from the budget owner & Divisional Management Team.
- Communicating the introduction of any new intervention technique or procedure to their patients, including providing appropriate information (or leaflets produced in line with the Patient Information Leaflets Procedure and gaining appropriate consent.
- Ensuring that before any new interventional technique or procedure is introduced Trust agreement is obtained in accordance with this policy.
- Ensuring an audit of the effectiveness and outcomes of any new interventional technique or procedure is undertaken and registering that audit with the Clinical Audit Department.
- Reporting the results of the audit to the relevant Divisional/Specialty Governance Group and the Clinical Audit Department

4.5 **Directors of Infection Prevention and Control(DIPC)**

The DIPCs are responsible for ensuring that risk of healthcare associated infection is minimised. One of the Joint DIPCs must be consulted to assess and advise on infection prevention and control aspects of any new clinical procedure. This also applies to the selection of any new equipment which is classified as a medical device.

4.6 **Clinical Effectiveness Committee(CEC)**

The CEC has responsibility for final approval of the introduction of any new intervention or technique. New clinical procedures following research should go to CEC for approval but not new clinical procedures as part of a research project.

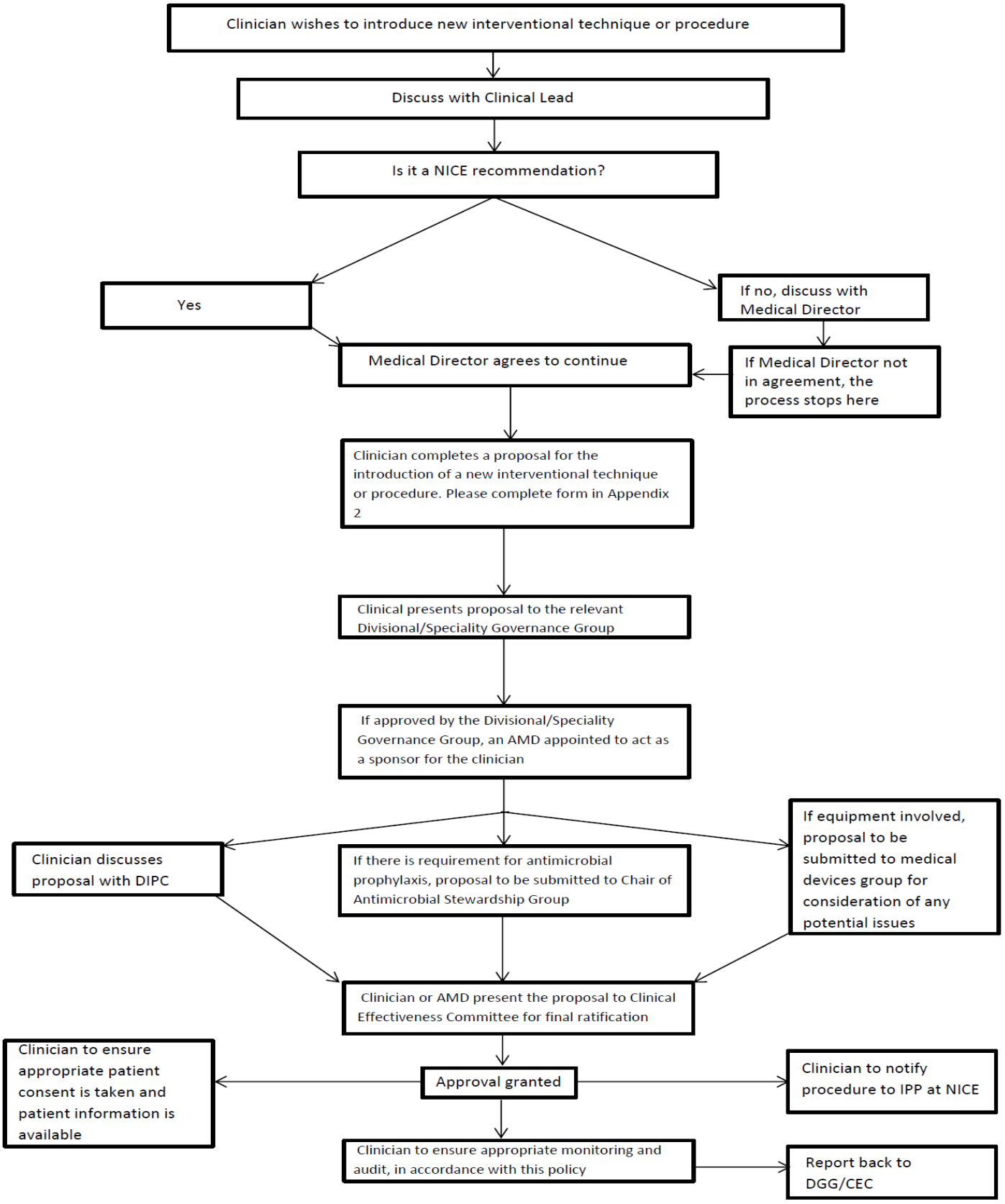
4.7 **Divisional/Specialty Governance Groups**

Divisional Governance Groups have responsibility for the initial consideration and approval or rejection of a proposal for the introduction of any new intervention or technique, prior to submission to the CEC.

4.8 **Clinical Audit Department**

Members of the Department are responsible for providing advice and support to individual clinicians on audits undertaken in relation to the introduction of any new intervention or technique.

5. PROCESS see comments on page 3



5.1 All financial benefits/implications should be considered for the proposed procedure/treatment, compared with the existing alternatives and approval for funding obtained from the commissioners (Clinical Commissioning Group or NHS England) if required.

5.2 The approval of a new procedure/technique may necessitate the purchase of a medical device, consumable (s) or point of care testing equipment (see Medical Devices Management Policy). The purchasing process will not commence until formal confirmation has been received and identified funding agreed via existing Trust processes. Therefore the outcome of the request will routinely be communicated to the following:

- Chair of the Medical Equipment and Products Group
- Lead for Point of Care Testing
- Joint DIPC
- The requester
- The relevant Divisional Director, Associate Medical Director, Divisional Nurse, and Governance Co-ordinator.

5.3 Infection Prevention and Control (see Standard Infection Control Precautions Policy)

Any new procedure needs to be assessed for the risk of hospital acquired infection. The risk must be minimised and acceptable.

- This assessment must consider the risk to the individual patient undergoing the procedure and to other patients. Risk may result from changes in the normal pattern of patient flow.
- Any new equipment must have a validated method of decontamination which is appropriate to that required for the procedures e.g. are sterile tissues involved or non-sterile sites. Also an assessment for the use of patients who are a risk of Creutzfeldt Jacob disease.
- If there is a requirement for antimicrobial prophylaxis this should be agreed with the Chair of the Antimicrobial Stewardship Group.

5.4 Consent (Consent Policy)

The information given prior to consent by a patient must include specific reference to the fact that the technique or procedure is new. Patients need to understand that the procedure's safety and efficacy may be uncertain, and must be informed of the anticipated benefits and possible adverse effects of the treatment and of the alternatives, including no treatment. If written consent is not usually required for the normal procedure, consideration should be given to seeking written consent as a means of documenting the information given to the patient and their agreement to it.

5.5 Audit

Any new technique or procedure introduced to the Trust must have guidance developed to accompany it and must be subject to ongoing monitoring and audit. The proposal for introduction must include arrangements for that audit. Results of the audit must be reported to the CEC. The frequency of audit will depend on the intervention. Under normal circumstances, the CEC will ask for a report from the clinician on the first 20 patients treated. For less frequently performed interventions or procedures, CEC will require a report from the clinician after the first 6 months of introducing the intervention or procedure, if 20 patients have not been treated by that time.

5.6 Adverse Incident reporting

Any adverse incident or near miss which occurs when undertaking a new

intervention or procedure must be reported immediately on the Trust electronic incident reporting system via the intranet in accordance with the Trust's Incident Reporting, Analysing, Investigating and Learning Policy and Procedures. When entering details on the electronic incident form it must be clearly stated that the incident occurred during the course of a new interventional technique or procedure.

6. TRAINING

6.1 Any clinician who wishes to introduce a new interventional technique or procedure will:

- Provide evidence of training of an adequate standard and competency to undertake the new procedure
- Identify the training needs of all other staff who will be involved in the new procedure and how those needs have been, or will be, met.
- These expectations are basic requirements of many practitioners' codes of professional practice and should be overseen via existing performance management and risk processes, including Performance Development Reviews and Audits.
- In the case of some surgical procedures, national recommendations have been made for the minimum annual caseload necessary for an individual operator to maintain competence. In this case an explicit review should be undertaken. Only if caseload is assessed as adequate to justify an extra operator, should training proceed.

7. ARCHIVING ARRANGEMENTS

The original document will remain with the author, the Head of Governance/Deputy Head of Governance. An electronic copy will be maintained on the Trust Intranet– Policies – N –New Clinical Procedures. Archived copies will be stored in the "trust policies" shared drive, will be stored for 10 years.

8. PROCESS FOR MONITORING COMPLIANCE WITH AND EFFECTIVENESS OF THE POLICY

8.1 In order to monitor compliance with this policy, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by	NHSLA standard
1.	All new interventional techniques or procedures have been approved by CEC	Minutes of meetings	
2.	All new interventional techniques or procedures have been approved by the Divisional Governance Group	Minutes of meetings	
3.	An audit has been performed and reported to CEC where appropriate	Minutes of meetings	

8.2 Frequency

In each financial year, the Head of Governance/Risk Lead will audit all new interventional techniques or procedures to ensure that this policy has been

adhered to and a formal report will be written and presented at the CEC.

Undertaken by

Head of Governance/Risk Lead

8.3 Dissemination of Results

At the CEC which is held bi-monthly.

8.4 Recommendations/ Action Plans

Implementation of the recommendations and action plan will be monitored by the CEC, which meets bi-monthly.

8.5 Any barriers to implementation will be risk assessed and added to the risk register.

8.6 Any changes in practice needed will be highlighted to Trust staff via the Divisional Governance system.

9. REFERENCES

Department of Health (2003). *HSC 2003/011 - The Interventional Procedures Programme: Working with the National Institute for Clinical Excellence to Promote Safe Clinical Innovation*. London: DoH. Available at: http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4064922 [Accessed: 10-12-2014]

Department of Health (2005). *Research Governance Framework for Health and Social Care*. (2nd edition, 2005). London: DoH. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf [Accessed: 10-12-2014]

National Institute for Health and Care Excellence (2014). *NICE interventional procedures guidance*. [online]. Available at: http://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance [Accessed: 10-12-2014]

National Institute for Health and Care Excellence (2009). *Interventional Procedures Programme - Process guide*. London: NICE. Available at: http://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance [Accessed: 10-12-2014]

10. ASSOCIATED TRUST POLICIES

Consent Policy

Incident Reporting, Analysing, Investigating and Learning Policy and Procedures

Patient Information Leaflets Procedure

Medical Devices Management Policy

Standard Infection Control Precautions Policy

APPENDIX 1: NATIONAL BACKGROUND

Why does NICE develop guidance on interventional procedures?

NICE issues guidance on interventional procedures to ensure that:

Patients and carers are reassured that new interventional procedures are being monitored and reviewed to protect their safety and have access to public information about notified procedures.

Clinicians, healthcare organisations and the NHS as a whole will be supported in the process of introducing new procedures

The Institute can foster innovation by facilitating data collection and analysis, conducting rapid reviews and providing advice on the safety and efficacy of new procedures.

What is an interventional procedure?

NICE makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use. An interventional procedure is a procedure used for diagnosis or 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 example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth

Using electromagnetic energy (which includes X-rays, lasers, gamma-rays and ultraviolet light) or ultrasound – for example, using a laser to treat eye problems.

What is meant by a ‘new' procedure?

For the purposes of the programme, NICE considers an interventional procedure to be "new" if a fully trained clinician is considering the use of the procedure/technique for the first time in the NHS outside of a Research Ethics Committee approved protocol. Performing an established procedure using a new device would not usually fall within the remit of the programme unless the use of the new device appeared to alter the safety and efficacy profile of the procedure. NICE does not need to be notified when a clinician is considering performing a procedure that is considered standard practice and where the benefits and risks are sufficiently well known; but that had not been performed previously by that particular clinician.

Procedures will not fall within the Institute's remit if they are considered standard practice within the health care sector. The Institute acknowledges that with any surgical procedure there is always a degree of risk: it is the extent of uncertainty surrounding these risks that the interventional procedures programme is set up to investigate.

What about procedures that have already been in use for a number of years, or procedures where safety concerns have been raised?

Although many of the procedures the programme will investigate are new, NICE will also scrutinise more established procedures where there is uncertainty about patient safety and efficacy. NICE will alert the NHS Commissioning Board Special Health Authority where concerns are raised about a specific procedure during the development of NICE guidance, who will refer procedures to NICE for investigation when concerns are raised through the systems for long-term monitoring of adverse events.

The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates medicines and medical devices in the UK, will also notify NICE of any concerns over the safety of a device that is used in an interventional procedure.

What is expected of Clinicians?

Any clinician considering use in the NHS of a new interventional procedure, which he/she has not used before, or only used outside the NHS, should seek the prior approval of their NHS Trust's Governance Committee.

How does NICE develop guidance on an interventional procedure?

The guidance development process begins when a procedure has been notified to NICE by a clinician, or by another individual or organisation.

Once notified, NICE prepares an 'overview' of the procedure, including a brief, non-comprehensive literature search and consults at least three Specialist Advisors nominated by healthcare professional bodies

The independent Interventional Procedures Advisory Committee (IPAC) then considers the procedure, and decides either to produce guidance, or that more information is needed before guidance can be produced.

a) If no further information is needed – guidance is produced

IPAC produces a consultation document that is published on the NICE website for a four week consultation period. Individuals and organisations that have expressed an interest in the procedure are informed when consultation begins and can submit comments via the NICE website or by post.

IPAC reviews the consultation document in the light of comments received following consultation, and produces a final document containing recommendations for the procedure. The NICE Guidance Executive receives and considers final recommendations from the committee on behalf of the NICE Board. NICE then issues guidance to the NHS in England, Wales and Scotland.

Who can notify NICE or express an interest?

Although procedures are most commonly notified by clinicians and other healthcare professionals, any individual or organisation may notify procedures that are being performed or are likely to be performed within the NHS. When developing each piece of interventional procedures guidance, a consultation document is published on the NICE website for a four-week consultation period. Professionals, patients and any other interested person or group may identify themselves as a consultee by expressing an interest via the NICE website. All consultees are informed by e-mail when consultation begins and are able to submit comments via the NICE website or by post.

What should clinicians do if they wish to carry out a procedure in the period between the notification of a procedure to NICE and the issuing of guidance on its use?

Clinicians who wish to undertake a procedure during this period should:

Inform the chief executive of their Trust of their intention; whether they need the agreement of the Trust is for local determination.

Appropriately inform patients/carers of the status of the procedure and the uncertainty around its safety and efficacy. This should be done 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 to be informed about the anticipated benefits and possible adverse effects of this treatment and alternatives, including no treatment.

Does the medical profession have to follow NICE's guidance?

Healthcare professionals are expected to take NICE guidance fully into account when exercising their clinical judgement. NICE guidance does not however override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient and/or carer.

The Department of Health's Health Service Circular to the NHS states that the Healthcare Commission will assess how well clinical governance is working in trusts by, amongst other things, how trusts' Governance Committees introduce new interventional procedures.

Should the NHS fund new procedures that haven't been notified to NICE or where NICE have said that the safety and efficacy is unproven?

CCGs and Trusts should have in place their own local policy for managing and funding particular procedures. Local decision makers should not regard the lack of NICE guidance, or guidance that a procedure is of uncertain safety and efficacy, as a reason to automatically resist use of the procedure, but they should satisfy themselves that local use of the procedure fulfills all the conditions on use that NICE stipulates. When NICE is undertaking data collection, local NHS organisations should provide resources to enable clinicians to supply data.

NICE has published advice on the legal implications of its guidance including interventional procedures

This re-iterates the requirements of all clinicians to follow the Health Department Guidance on introducing new procedures, and discusses the probability that claims against a clinician are less likely to succeed where guidance has been followed than if it is ignored, or ignorance is claimed. There is no case law as yet, but it is important for all clinicians to recognise that failure to follow these principles seems likely to result in test cases.

APPENDIX 2: PROPOSAL FOR THE INTRODUCTION OF A NEW CLINICAL PROCEDURE OR TECHNIQUE

Email or post to your Associate Medical Director or Divisional Nurse as appropriate. Copies of all applications should go to the Head of Governance.

Section 1 – Submitting Clinician	
Name	
Status	
Specialty	
Section 2 – New Procedure/Technique	
a) Name of procedure (and any alternative names)	
b) Entirely new procedure, new to Trust, or new to you	
c) NICE listed or approved?	
d) Similar to, or different from, established procedure	
e) Which existing procedure/s might it replace?	
f) Brief description of what is involved in the procedure	
Section 3 – Clinicians involved	
a) Individual names/job titles of clinicians proposed	
b) Is training required (how will it be obtained)?	
c) Is competence assured (how is it confirmed)?	
Section 4 – Patients	
a) Which patients are likely to benefit?	
b) The clinical indications for its use	
c) Reason for introducing this particular intervention?	
d) What are the intended health benefits?	
e) Possible adverse effects (and level of risk?)?	
f) Can you estimate numbers/potential impact on NHS?	
Section 5 – Evidence base	
a) Is this procedure in use elsewhere?	
b) Details of conference proceedings/communications	
c) Details of peer reviewed papers	
Section 6 – Surveillance	
a) Is the procedure part of a clinical trial?	
b) How will it be audited?	
c) What patient information will be provided?	
d) Confirm patients will be told status of new procedure	
e) Confirm adverse events will be incident reported	
f) Confirm NICE is aware of procedure/personnel	
Section 7 – Resources	
a) Any financial benefits/implications have been considered for the proposed procedure/treatment, compared with the existing alternatives and approval for funding has been obtained from the commissioners (CCG or NHSE) if required.	Yes / No
b) What are the cost implications (capital/revenue)?	

c) How will costs be met?	
d) Do devices comply with EC standards?	
e) Are devices certified for this use?	
f) Is a commercial organisation involved?	
Section 8 – Probity	
a) Could there be any commercial interests?	
b) Could there be any intellectual rights?	
c) Could there be any conflicts of interest?	
Section 9 – Impact on other services	
a) Could there be any impact on other services i.e. pharmacy, radiology, pathology etc?	Yes/No Service(s) affected:
b) Has this been assessed and agreed with those services?	Agreed by:

APPENDIX 3: APPROVAL FOR THE INTRODUCTION OF A NEW CLINICAL PROCEDURE OR TECHNIQUE

Section 1 – Submitting Clinician (from submission)	
Name	
Status	
Specialty	
Division	
Section 2 – New Procedure/Technique (from submission)	
a) Name of procedure (and any alternative names)	
Section 9 – Approval	
To be completed for applications from Medical Staff	
Associate Medical Director Approval Granted? Yes ☐ No ☐ If no, please state reason **Signature:** **Date:**	
Medical Director Approval Granted? Yes ☐ No ☐ If no, please state reason Signature: Date:	
To be completed for applications from non-medical clinical staff	
Chief Nurse Approval Granted? Yes ☐ No ☐ If no, please state reason Signature: Date:	
To be completed for all applications	
Divisional Director Approval Granted? Yes ☐ No ☐ If no, please state reason Signature: Date:	
Comments	

APPENDIX 4: RAPID IMPACT ASSESSMENT SCREENING FORM

RAPID IMPACT ASSESSMENT SCREENING FORM

Name of procedural document	Policy for the Introduction of New Clinical Procedures in the Trust
Directorate and Service Area	Patient Governance and Legal Services/Corporate Governance
Name, job title and contact details of person completing the assessment	Head of Governance
Date:	

EXECUTIVE SUMMARY

This section summarises:

- the impacts identified for action
- mitigating action
- the likely severity of the impact as a result of that action ("result").

Impact	Action	Result
None identified		

1. What is the main purpose of this policy / plan /service?

This policy sets out the process for the introduction of all interventional techniques that are new to the Trust. Its scope includes the processes involved in the development of a new interventional technique, with particular emphasis on clinical governance, including initial training requirements and assessment of competence.

Its overall purpose is to permit timely introduction of innovative techniques whilst safeguarding patients against unacceptable risk and ensuring responsible use of available resources.

2. Who does it affect? Please tick as appropriate.

Carers ☐ Staff ☒ Patients ☒ Other (please specify)

3. What impact is it likely to have on different sections of the community / workforce, considering the "protected characteristics" below?

Please insert a tick in the appropriate box √

Protected Characteristics	Positive impact -- it could benefit	Negative impact -- it treats them less favourably or could do	Negative impact -- they could find it harder than others to benefit from it or they could be disadvantaged by it	Non-impact – missed opportunities to promote equality	Neutral -- unlikely to have a specific effect
Age	☐	☐	☐	☐	☒
Disability	☐	☐	☐	☐	☒
Sex *including Transgender and Pregnancy / Maternity*	☐	☐	☐	☐	☒
Race	☐	☐	☐	☐	☒
Religion / belief	☐	☐	☐	☐	☒
Sexual orientation including Marriage / Civil Partnership	☐	☐	☐	☐	☒

In identifying the impact of your policy across these characteristics, please consider the following issues:

- **Fairness -** Does it treat everyone justly?
- **Respect -** Does it respect everyone as a person?
- **Equality -** Does it give everyone an equal chance to get whatever it is offering?
- **Dignity -** Does it treat everyone with dignity?
- **Autonomy -** Does it recognise everyone's freedom to make decisions for themselves?

If you have any negative impacts, you will need to progress to a full impact assessment.

In sections 4 and 5, please copy and repeat the tables below, for each "protected characteristic" considered. Alternatively, you can use one table for more than one "protected characteristic", if the outcomes are similar.

4. **If you have identified any positive impacts (see above), what will you do to make the most of them?**

"Protected characteristic" affected:		
Issue		
Who did you ask to understand the issues or whose work did you look at?	What did you find out about?	What did you learn or confirm?
	Action as a result of above	
Action	By who?	When?

5. **If you have identified any missed opportunities ("non-impacts"), what will you do to take up any opportunities to promote equality?**

"Protected characteristic" affected:		
Issue		
Who did you ask to understand the issues or whose work did you look at?	What did you find out about?	What did you learn or confirm?
	Action as a result of above	
Action	By who?	When?

6. **If you have a identified a neutral impact, show who you have consulted or asked to confirm that this is the case, in the table below:**

Who did you ask or consult to confirm your neutral impacts? (Please list groups or individuals below. These may be internal or external and should include the groups approving the policy.)
Equality and Diversity Manager

If you need help with any aspect of this assessment, please contact:
TonyWilliams Equality and Diversity Lead for staff
Linsey.clements@nhs.net

Please note:
This impact assessment needs to be sent, with the policy, to the Equality & Diversity Lead at the following stages: as part of consultation, prior to final ratification of the policy and when final ratification has been given.

BRIEFING SHEET FOR MANAGERS

Name of Procedural Document: Policy on the Introduction of New Clinical Procedures in the Trust

1. Overview of the policy etc.

1.1 The policy sets out the process for the introduction of all interventional techniques that are new to the Trust. Its scope includes the processes involved in the development of a new interventional technique, with particular emphasis on clinical governance, including initial training requirements and assessment of competence.

1.2 Its overall purpose is to permit timely introduction of innovative techniques whilst safeguarding patients against unacceptable risk and ensuring responsible use of available resources.

2. Changes to existing document etc.

2.1 Minor revisions to existing Policy i.e. update into new template, amendments to reflect revised job titles etc.

3. Specific issues to be raised with staff

3.1 All staff involved in the introduction of new techniques should read this policy and be aware of their role and responsibilities under section 4 of the Policy.

4. Manager and staff action

4.1 Managers to cascade information to staff they have a responsibility for and whom the policy applies.

5. Issues following Equality Impact Assessment (if any)

5.1 None

6. Location of Hard / Electronic copy of the document etc.

On Trust intranet – Policies – P – Policy on the Introduction of New Clinical Procedures in the Trust

COMMUNICATION PLAN

Staff groups that need to have knowledge of the policy	All staff involved in the Introduction of new clinical techniques within the Trust.
The key changes if a revised policy	Minor revisions to policy, flow chart in section 5 and new procedure proposal form at Appendix 3
The key objectives	To ensure that the Trust has a standardised approach for the introduction of all interventional techniques that are new to the Trust. To permit timely introduction of innovative techniques whilst safeguarding patients against unacceptable risk and ensuring responsible use of available resources.
How new staff will be made aware of the policy, e.g. induction process, cascade etc.	The policy will be cascaded by email. A message will be displayed on the front page of Bob. (Trust intranet) Managers are responsible for advising staff of Policies at local induction.
Training available to staff	No specific training.
Any other requirements	N/A