Document Title:	**INTRODUCTION OF NEW TECHNOLOGIES AND PROCEDURES** (Previously contained in the Medical Device Policy)		
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Document type: (Policy/ Guideline/ SOP)	Policy	**To be followed by:** (Target Staff)	All staff involved with the purchase/use/introduction of new equipment or devices for direct use with patients
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Developed in response to:	Best Practice		
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Executive and Clinical Directors (Communication of minutes from Document Ratification Group	**Date:**	**Distribution Method:**	Intranet & Website. Notified on Staff Focus

Consulted With:	Post/ Approval Committee/ Group:	Date:
Rebecca Martin	Deputy Medical Director	August 2019
Manu Sood, Matthew Sweeting, Laura Harding, Anita Rao	Divisional Directors	
Steve Farndon	MEMS Technical Services Manager	
Helen Clarke	Head of Governance	
Wendy Matthews	Director of Nursing	
Suzanne Hawksworth, Hilary Bowring, Angela Wade, Jo Myers	Associate Directors of Nursing	
Deborah Lepley	Warner Library	

Related Trust Policies (to be read in conjunction with)	Policy and Strategy for Risk Management, Health & Safety Policies Decontamination Policy Safe Use of Medical Devices Policy Therapeutic & Diagnostic Medical Equipment Training Policy

Document Review History:			
Version No:	**Authored/Reviewer:**	**Summary of amendments/ Record documents superseded by:**	**Issue Date:**
1.0	Deirdre Miller		23 April 2009
2.0	Deirdre Miller		14 June 2012
3.0	L Teare		5 February 2016
3.05draft		Update with new structures and groups	9th August 2019

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1. Purpose

1.1 This policy outlines the process to be followed by all staff when considering introducing a new technology or procedure. This policy provides guidance to support clinicians and managers in managing the clinical and financial risks associated with both procurement of new clinical equipment and the introduction of new and modified clinical procedures.

2 Introduction - introduction of New Technologies and Procedures

2.1. New clinical procedures and treatments are constantly emerging in all specialties. New procedures or treatments may be:

- Entirely new and innovative (see 3.4 below)
- Those which are new to the Trust
- These include the introduction of new drugs, new diagnostic procedures and minimally invasive surgical procedures and new expanded roles in Nursing, Midwifery and Professions Allied to Medicine.

3. Scope

3.1 The Trust is keen to foster innovation and advances in medical and nursing practice and in doing so needs to ensure that developments are within an explicit framework that will minimise the potential for adverse patient outcomes. The greatest risk for the Trust is the indiscriminate introduction of new techniques where clinicians try a procedure without always being equipped with the relevant skills or without ensuring systems and processes are adapted in line with it.

3.2 **Clinical procedures and treatments to which this policy applies include, for example**:

- The introduction of new surgical or medical techniques which have not previously been performed in the Trust
- Introduction of new clinical skills by any health care professional

3.3 **Procedures or treatments may be**:

- Entirely new and innovative (see below)
- Those which are new to the Trust
- Those which are new to a particular operator (performing the procedure for the first time in the Trust)

3.4 **Entirely new and innovative procedures**

If the profession considers a procedure or treatment is sufficiently novel as to require special training and assessment before being introduced into clinical practice, then its use should be limited to a number of specified centres for clinical trials. Health care professionals are encouraged to participate in clinical trials. During the clinical

trials, methods of training and training requirements should be developed and identified and the Local Research Ethics Committee (L.R.E.C) and the Research & Development (R&D) co-ordinator should be involved.

3.5 **Procedures or treatments which are new to the Trust**

3.5.1 When the value of such a procedure or treatment has been shown to be effective through clinical trials and/or approved by the appropriate Royal College or other accrediting body. The healthcare professional wishing to use it must show evidence of learning through prescribed courses and by appropriate supervised practice. A risk assessment of the new procedure should also be undertaken.

3.5.2 Procedures or treatments which are new to a particular operator performing the procedure for the first time

3.5.3 It is essential that healthcare professionals who wish to undertake such work show evidence of training. Health Care Professionals to maintain a training portfolio or training log book.

4.0 Training and Education

4.1 It is required that all health care practitioners practising new surgical and invasive techniques within the Trust, will be properly trained in these techniques.

4.2 All trainees involved must complete a basic skills training course under the supervision of a certified trainer. Those trainees found to be incapable or physically unable to accomplish these basic skills after a suitable period of training should be advised not to undertake the procedure.

4.3 If a newly appointed Consultant is expected as part of their work in the Trust, to undertake a particular specialised procedure, then it is mandatory that this doctor has been awarded the appropriate Certificate of Specialist Training (CST) and is able to provide evidence of training in this particular procedure. Should this doctor not possess that expertise then he/she must be sent on a certified course to acquire that skill. The same scrutiny applies to locum Consultant appointments and to Specialist Registrars where this is relevant.

4.4 Introduction of training and certification for Healthcare Professionals in procedures that are developed after they have completed their training (see also Scope of professional Practice).

4.5 The Group will expect evidence of training and education for ALL team members who use a new intervention to be provided to the Divisional Director and Associate Director of Nursing Nurse within a month of the procedure being used. For nursing and Allied Health Professional evidence of competency will be required.

4.6 It is required that all health care practitioners practising new surgical and invasive techniques within the Trust, will be properly trained on the correct use of any associated equipment.

5.0 Process for the Introduction of New Technology

5.1 **Stage 1**

5.1.1 Any clinician wishing to introduce a new procedure, treatment, or new clinical skill which they have not undertaken before, must first discuss this with their line manager and the relevant Divisional Director or Associate Director of Nursing according to their professional background. The Divisional triumvirate and Clinician proposing must:

- Make an assessment of the risks and benefits of introducing a new technique, seeking the advice of the Health Technologies Appraisal Group as required. This must include the evidence base for the new technique. If Procurement is approached to order equipment they will refer the issue to the Chairman of HTAG to establish the need for an assessment

- Provide evidence that appropriate risk assessment has happened as far as reasonably possible

- Check the technical skills and training required to make the technique safe

- Ensure consent information is available that highlights the benefits and risks

- Set parameters for the safe introduction of the technique and agree a monitoring mechanism for example an agreed audit plan to monitor patient outcomes and complications, the audit plan to specify a number of cases or over a specific time period. To report audit findings back to the Patient Safety Group within the audit period. High risk technologies should be reported back to the group after 6 months

- Identify financial and service implications (e.g. equipment repair, maintenance, decontamination and sterilisation). The financial implications of any new clinical procedure must be identified and supported before implementation of any new clinical procedure or technique. Effects on current activity and contracts should also be considered by the Divisions.

- Divisions should ensure applications for the introduction of new technologies are incorporated into their business planning arrangements and are signed off by the Divisional Director and relevant senior managers within the Divisions before submission to the Health Technologies Appraisal Group

- Ensure the process and requirements for decontamination are considered and approved. Please refer to the Infection Prevention and Control Team.

- Complete the Health Technologies Appraisal Template (Form 1 – Appendix 1)

- Ensure completed proposal is reviewed at Divisional Governance Meeting and approved by the Divisional Director or Associate Director of Nursing before submission to the Health Technologies Appraisal Group.

Submit completed approved proposal (including completed audit pro forma) to the Chair of the Health Technologies Appraisal Group. The Chair of the HTAG should circulate for

approval to the designated members of HTAG. This can be done via email and if an application is complex the Chair of HTAG can formally request a meeting

5.2 **Stage 2 (Approval)**

5.2.1 The Health Technologies Appraisal Group will be formed virtually to consider the proposal and make one of the following decisions:

- Approve the proposal based on the information given. The responsibility for implementation lies with the division
- Refer proposal back to the Division named person with suggestions for reconsideration, further information etc
- Reject the proposal providing reasons for decision
- The Chair will reconsider applications in light of new evidence and provisions.
- Submissions approved by HTAG will be sent to the Medical Director and Director of Nursing for final sign off

5.3 **Stage 3**

5.3.1 The Chair of HTAG will notify the Clinician and Division of the outcome of the application, pending approval by Medical Director and / or Director of Nursing. Once the MD and DON have approved, the Division Triumvirate will be notifed.

5.3.2 The Clinician should ensure that where a new procedure involves use of new equipment the Head of MEMS is informed and the equipment included on the Directorate/Trust Electronic Equipment Register and staff training records maintained accordingly.

5.3.3 New equipment for this purpose should be acceptance tested by MEMS before being used. Refer to the Safe Use of Medical Devices Policy.

5.3.4 **Loan / Lease or Rental Equipment**

- All loan / lease and rental medical equipment must conform with all relevant standards pertaining to the type of medical equipment, the location and function for which it is to be used.
- Loan equipment / Lease equipment will be subjected to acceptance testing and other medical equipment management procedures accordingly, including indemnity number, equipment competency and maintenance support and included on the Electronic Equipment Management System
- Accompanied by appropriate Information and training instructions

5.4 **Stage 4 (Monitoring and evaluation)**

Once approval has been given, the responsible Clinical Director will report at 6 months providing assurance of the initial audit findings and satisfactory training records. This report will be shared with HTAG, Divisional Board and the Patient Safety Group.

6.0 Monitoring

6.1 The Chair of HTAG will ensure compliance with this policy is monitored through 6 monthly review of procedures submitted for approval. As a minimum this will include:

- The number of proposals received
- The number of proposals approved
- Any instances where new procedures have been undertaken with no formal approval

6.2 This report will be submitted to the Patient Safety Group. Where indicated, actions will be developed by HTAG and progress with implementation monitored by the chair of the HTAG.

7.0 Review

The policy will be reviewed three yearly or earlier in response to national or local initiatives.

8.0 Equality Impact Assessment

8.1 Mid Essex Hospital Services NHS Trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals.
(Refer to Appendix 2)

Appendix 1

Health Technologies Appraisal Group (HTAG)

'New' interventional procedures application form

In order to ensure the delivery of clinical and cost effective care, the Trust requires that all Interventional Procedures new to the Trust are submitted to the Chair of the HTAG for approval, using this application form.

An Interventional Procedure is defined by the National Institute for Clinical Excellence (NICE) as one:

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

An Interventional Procedure should be considered ***new*** if a doctor, not previously trained to perform the procedure and no longer in a training post is using it for the first time in his or her NHS clinical practice .

Further information and guidance as to what constitutes an interventional procedure and this application process is available from the chair of HTAG, Mr Mark Puvanendran, or the Site Medical Director.

Such procedures should be introduced in the Trust in a planned manner, through a standard application process.

Please complete this application form and submit to Mr Mark Puvanendran

The procedure must not be introduced in the Trust before endorsement of this approval.

If the procedure is a new interventional procedure without current NICE guidance then NICE require that they are notified of the intention to introduce. This must be included in the application form.

'New' interventional procedures application form

Please refer to supporting notes for assistance in completing this application form.

Name of the Clinician submitting application

Specialty

1. Introduction and Proposal Summary

Name of procedure

Proposal Summary

Relevant NICE recommendations and / or Department of Health requirements

Is the procedure new to NICE without current NICE Guidance – confirm NICE have been notified of the intention to introduce Yes ☐ N/A ☐

2. Patient and Service Benefits

Summary of benefits to patient / trust including any published supporting evidence

3. Resource Implications

Funding Agreed ☐

Business case submitted / pending approval ☐

IT Requirements – please specify and explain how this will be managed

Decontamination Arrangements – please specify these arrangements

Training Requirements – please specify and explain how this will be managed and note that evidence of training and education for ALL team members who use a new intervention must be provided to the Divisional Director and Associate Director of Nursing within a month of the procedure being used.

Other

4. Consequences of not implementing

Details of risks to the Trust of not introducing procedure

5. Completed audit proposal form

Please complete a clinical audit proposal form identifying on the audit form when analysis of the data collected will occur eg after 6 months / first 6 patients. The outcome of the initial audit should be fed back to the HTAG. The audit form may be downloaded from the intranet.

Please confirm submission of audit form, post dated has been sent to clinical audit ☐

6. Patient Information and Patient consent

Details of the patient information available for patients and evidence that patients can give fully informed consent (patient information should be developed in accordance with the Trust Patient Information policy and registered with Communications)

7. Experience Elsewhere

Please provide details of successful or otherwise use of the procedure at other sites and include full evidenced based references with this submission

8. Supporting signatures

HTAG will not approve an application without the signature of the appropriate Divisional Director. There is therefore a requirement that full discussion has taken place within the Division to demonstrate professional and managerial support for the introduction of the procedure and awareness of the likely financial consequences.

Divisional Director **Signature** **……**

Please print name **……**

Date

Please forward completed form to the Chair of HTAG

Supporting notes for the HTAG interventional procedures application form

1. Introduction and Proposal Summary

To include an overview of the proposed procedure

To include the review of any existing procedures of a similar type used within the Trust and whether the intention is to replace such existing procedures.

To include any relevant NICE recommendations and DOH requirements (eg turn-round times). Please refer to www.doh.gov.uk and www.nice.org.uk If the procedure has had NICE guidance issued please indicate the relevant IPG number and append the relevant guidance to the application.

2. Patient and Service Benefits

For example:-
Less invasive procedure, safer procedure, improvement in diagnosis, staging, prognosis, future management, reduced bed-stay etc.

Please also include any published evidence including audit.

3. Resource Implications

The group does not give financial approval but it is strongly recommended that a business case has been produced in accordance with current Trust requirements. If a business case is in the process of being produced then the current stage of development must be indicated in this application but this must be approved prior to commencing any new procedure.

- Capital costs – this must include equipment costs and also indicate the costs of any building or service works.
- Revenue Implications - (maintenance, consumables, etc).
- Information Technology Implications.
- Training and certification/accreditation costs. If training has already taken place then evidence of such training should be submitted with this application.
- Extra staff including any specialists from outside of the Trust who may assist with the introduction of the new procedure – if so such specialists will require an Honorary Contract.

4. Consequences of not implementing

This may include failure to meet any targets, to meet requirements of NICE guidance, failure to not take advantage of appropriate new technology, miss an opportunity to increase Trust income etc.

5. Acceptance of the need for on-going audit and how this audit will be reported

The committee will normally require audit (registered with the Trust Audit department) of the new procedure and will indicate at the time of approval the length of the audit or specify a number of procedures. An interim Audit report will be required after an appropriate period following the introduction of the procedure**.**

Does the procedure require prior discussion by a Multi-Disciplinary Team – please check relevant IPG, if available.

6. Patient Information and Patient consent

The committee will expect evidence that patients will receive adequate explanation of the procedure. Where NICE guidance has not been issued then it must be demonstrated that the patient will be made aware that they will be undergoing a procedure "for which the benefits and risks are uncertain".

7. Experience Elsewhere / Full, evidence based, references

Has anyone also done this and found problems – MDA Reports (www.mhra.gov.uk), e.g other users have been contacted and confirmed that equipment performs satisfactorily etc.

The Committee will expect to have attached at least one paper (in English) from a peer-reviewed Journal which details the procedure and outcomes.

8. Training and Education

The Committee will expect evidence of training and education for ALL team members who use a new intervention to be provided to the Divisional Director or Associate Director of Nursing within a month of the procedure being used.

9. Supporting signatures

The HTAG will not approve an application without the signature of the appropriate Divisional Director. There is therefore a requirement that full discussion has taken place with both the Divisional Director and Executive Lead and a signatures from the Divisional Director demonstrates professional and managerial support for the introduction of the procedure and that both are aware of the likely financial consequences.

Appendix 2: Preliminary Equality Analysis

This assessment relates to: Introduction of New Technologies and Procedures (09032)

A change in a service to patients		A change to an existing policy	**X**	A change to the way staff work	
A new policy		Something else (please give details)			

Questions	Answers
1. What are you proposing to change?	Full Review
2. Why are you making this change? **(What will the change achieve?)**	3 year review
3. Who benefits from this change and how?	Patients and clinicians
4. **Is anyone likely to suffer any negative impact as a result of this change?** If **no**, please record reasons here and sign and date this assessment. If **yes**, please complete a full EIA.	No
5. a) Will you be undertaking any consultation as part of this change? **b) If so, with whom?**	Refer to pages 1 and 2

Preliminary analysis completed by:

Name		**Job Title**		**Date**	March 2019