University Hospitals of Derby and Burton
NHS Foundation Trust

TRUST POLICY AND PROCEDURE FOR THE APPROVAL OF CHANGE IN CLINICAL PRACTICE

Reference Number CI 2009 014	**Version:** 8	**Status** Final	**Author:** Lara Raworth **Job Title:** Medical Directors Office Manager

Version / Amendment History	**Version**	**Date**	**Author**	**Reason**
	1	March 2001	Lynne Fryatt	New Policy
	8	April 2024	Lara Raworth	Revised according to new governance structure

Intended Recipients: All clinical staff

Training and Dissemination:
Dissemination will be via the quality governance structure e.g. Clinical Advisory Group and Divisional Clinical Governance Groups. The revised Policy will also be available via the Intranet

To be read in conjunction with:

Trust Policy for the Management of NICE Guidance

Expansion and Implementation of Developing a Scope of Professional Practice

In consultation with:
All clinical staff
Divisional Medical Directors
Clinical Directors
Associate Clinical Directors
Divisional Directors General Managers

EIRA Stage One Completed Yes
Stage Two Completed N/A

Approving Body and Date Approved	Trust Delivery Group / April 2024
Date of Issue	March 2001
Review Date and Frequency	March 2027 - Every 3 years
Contact for Review	Medical Directors Office Manager
Executive Lead Signature	Dr Gisela Robinson, Executive Chief Medical Officer 

Contents

1. Introduction

This Policy identifies the process for clinicians wishing to undertake techniques which are:

- New to the Trust and new to the clinician (covered in Appendix 2)
- New to the Trust, but not to the clinician (covered in Appendix 2)
- New to the clinician but already established within the Trust (covered in Appendix 2).

This Policy applies to:

- Any change that has an impact on an individual's training needs or the training needs or resources of other team members including financial resource
- A service evaluation (including trial of new equipment). Prior to embarking on the completion of the Change in Clinical Practice process, colleagues who are embarking on a service evaluation / trial of new equipment need to contact the Medical Directors Office to discuss the proposal to understand the scope of the service evaluation.

This Policy does not apply to:

- Research studies, which will continue to be assessed and approved through research governance regulatory bodies eg Health Research Authority (HRA) and National Research Ethics service (NRES)
- Medical staff in training undergoing development under supervision.

2. Purpose and Outcomes

The purpose of this Policy is to ensure that the correct authorisation procedures are followed before a clinician embarks upon techniques that are new to the Trust and which are not part of a Local Research Ethics Committee approved research programme.

In 2003 the Secretary of State issued a Health Circular (2003 / 011) defining for the NHS in England the process for the introduction of new Interventional Procedures (IPs) into clinical practice.

National Institute Clinical Excellence (NICE) defines IPs as:

- 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 radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems.

NICE guidance on IPs highlights the importance of establishing Policies and protocols to manage the introduction of all new IPs so that risks to patients and staff can be reduced.

This Policy will also ensure that relevant training is made available and undertaken before any clinician embarks upon techniques which are new to them but already established within the Trust. Please refer to section 4.3 of this Policy.

It must be emphasised that the procedural requirements for seeking approval for new techniques should not be seen as a means to restrict clinical freedom. It is part of the Trust's Clinical Governance assurance process to assist clinicians to make an informed decision on the safety issues prior to performing the new technique in line with national guidance.

3. Key Responsibilities / Duties

3.1 Chief Executive

The Chief Executive (CE) is ultimately responsible for clinical governance arrangement's throughout the Trust and ensuring that any changes in clinical practice have been through and appropriate governance process. For the purposes of this Policy, the CE has delegated this responsibility to the Executive Medical Director.

3.2 Executive Medical Director

The EMD will be informed as soon as reasonably practical of circumstances where a procedure has been used in response to a clinical emergency by the clinician carrying out the procedure. The EMD will ensure that approval of the procedure for use in the future is considered at the next available Business Unit and Divisional Governance meeting.

3.3 Senior Divisional Team (SDT)

The Senior Divisional Team consists of the Divisional Medical Director (DMD) / Divisional Director (DD) / Clinical Director (CD) / Assistant Clinical Director (ACD) / Divisional Nurse Director / General Manager (GM). The SDT will:

- Approve an innovation in consultation with the respective Business Unit and Divisional Clinical Governance Groups using the standard template – See Appendix2
- Forward the relevant documentation on their approval to the Business Unit Clinical Governance Meeting for information
- Forward the outcomes of all (approvals and non-approvals) application forms which are considered at Divisional Governance Meetings to Lara Raworth, lara.raworth@nhs.net for onward reporting at the CAG.

3.4 Clinicians

The clinician will:

- Seek approval from the Business Unit and Division through the process described in Appendix 1
- Attend a recognised training scheme, course or clinical attachment
- Work under the supervision of a mentor until trusted by that mentor to operate independently
- Work with colleagues to ensure:
    - Informed consent of patients, their families or carers
    - Risks to patients and staff have been identified, assessed, reduced or managed
    - Compliance with national standards or guidance on new IPs
    - Staff training needs are identified and met, including their own
    - Effective audit of clinical outcomes and monitoring of the process are in place.

Clinicians who wish to undertake new IPs that have not done before within the Trust will:

- Identify and appraise the evidence for the procedure. Literature searches can be undertaken by the Library & Knowledge Services Team if support is required

- Use the business planning process if additional resources are needed or there is an opportunity cost
- If the intervention includes a new drug, or a novel use of a currently used drug, it must first be approved by the Drugs and Therapeutics Committee what is this called now?
- If the new intervention includes the use of a medical device, it must first be approved by the Medical Devices Group
- If the new intervention includes the use of a radiation, it must first be approved by the Lead Consultant Radiologist
- If the new intervention requires sign off at more than one of the Groups detailed above, ensure that it has been to all of the appropriate Groups prior to seeking Business Unit and Divisional approval using the forms in Appendix 2.

3.5 Clinical Advisory Group

The Clinical Advisory Group will:

- Be responsible for providing assurance to the Operational Performance Groupin all matters relating to changes in clinical practice at the Trust
- Monitor and record details of all application forms for a change in clinical practice.

4. Implementing the Change in Clinical Practice Process

4.1 Prior to Application for Approval

In seeking approval for any new technique the clinician must show that they have considered all of the following:

- The effectiveness and safety assessment of the proposed technique
- If it is NICE approved
- The wider evidence base for the proposed technique
- The capital and recurrent cost consequences
- Probable efficiency gains / cost savings
- The training / support that the applicant has received
- The training / support that the support staff (nurses, professionals allied to medicine)will require and how this will be met
- Arrangements made for audit or clinical trials
- The impact on existing Trust Policies or Guidelines
- The financial / tariff income implications of undertaking the procedure.

4.2 The Approval Process

See Process for Approving Change in Clinical Practice Flow-chart – Appendix 1.

4.3 Undertaking techniques which are established within the Trust but are new to the Clinician / Professional Group.

The SDT will need to:

- Agree that it is warranted for the clinician to undertake this technique giving consideration to the existing service needs especially with regard to the numbers to be undertaken and whether competence can be maintained

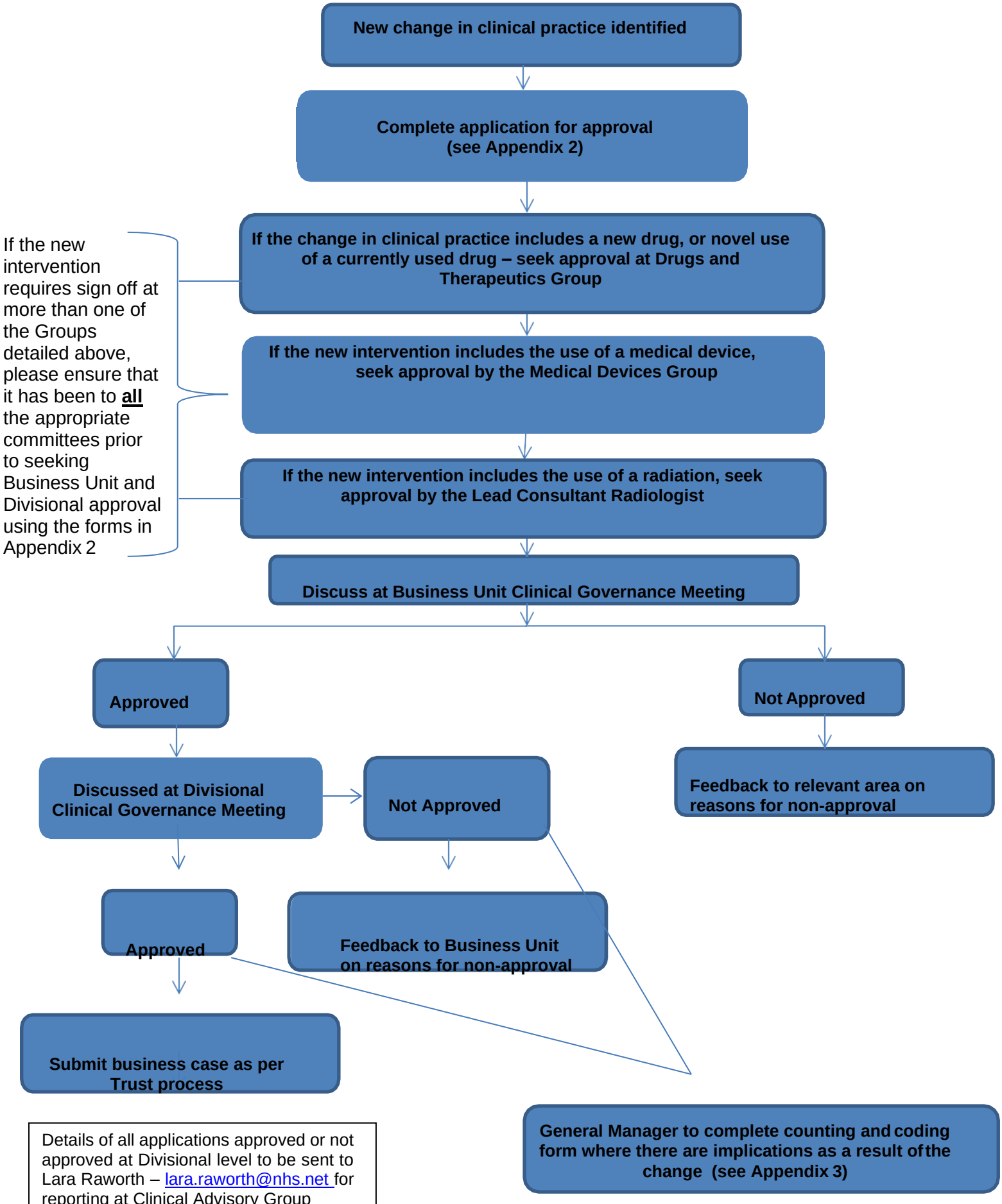
- Ensure that consideration is given to implications relevant to other Business Units / Divisions and support departments
- Once agreement has been secured, reflect the training requirement in the clinician's Personal Development Plan
- Training may be undertaken through an externally accredited course or internally with the support of a colleague competent in the identified technique
- When internal training is provided a colleague competent in the identified technique will be identified to support and monitor the individual's development until satisfactory competence is attained
- A copy of the training programme and assessment of competence will be retained by the individual clinician and within the Business Unit. The individual will thereafter be responsible for maintaining their own competence and identifying any further training needs.

5. Monitoring Compliance and Effectiveness

Each clinician must make arrangements for clinical audit and / or clinical trials within their application to the Business Unit and Divisional Governance Meeting detailing how the outcomes of the proposed new technique will be monitored. This will be monitored by the Clinical Advisory Group.

The effectiveness of this Policy will be monitored via the Clinical Advisory Group who will present a report on a quarterly basis to Operational Performance Group.

APPENDIX 1PROCESS FOR APPROVING NEW CHANGE IN CLINICAL PRACTICE



APPENDIX 2

APPLICATION FORM FOR A CHANGE IN CLINICAL PRACTICE

Name of change in clinical practice:	
Lead clinician supporting the change:	
Business Unit:	
Division:	

Section 1: Brief description of new change in clinical practice and its purpose – include details of patient / service outcomes / impact

Section 2: Which clinicians (individuals or other professional group) are likely to be directly involved?

Section 3: Does this change in clinical practice impact on other service areas / specialties? If so, describe how and are the services / specialties able to support?

Section 4: Evidence of effectiveness, quality and safety (reports, randomised trials, safety assessments etc). Is there a national standard or guidelines which encompasses this change in clinical practice and who is it issued by e.g. NICE?

Section 5: In the absence of national standards or guidelines, what local arrangements and structures are in place for this change in clinical practice? Identify lead clinicians, working arrangements with specialist centres or other services within the Trust. Highlight any existing structures or arrangements.

Section 6: Financial implications

Financial benefit analysis
Consult your General Manager and Divisional Finance and Information teams to support with completing this section.

Include details and financial values in the following sections:

6.1 Capital

Cost of new equipment

Describe the funding stream e.g. charitable funds

6.2 Income and Expenditure

Recurrent / Non-recurrent impact on income
Consider:

- How any current procedure / treatment is coded / costed and how the new procedure / treatment will be coded / costed
- Will there be any change in procedure setting i.e. in-patient stay to day case, day case to in-patient stay
- Will there be any changes in the number of follow up appointments required by the patient.

If there are changes to any of the above then following approval of the change in clinical practice and any associated business case, a Counting & Coding proforma (see Appendix 3) will be need to be completed by the General Manager to ensure the change is captured and reflected in activity plans.

6.3 Recurrent / Non-recurrent impact on expenditure (pay, drugs, non-pay including maintenance of new equipment as detailed in section 6.1)

6.4 Net Income and Expenditure

Describe the funding stream if any additional costs are not covered by additional income e.g. charitable funds, research information etc.

6.5 Commissioning

Have Commissioners agreed to this change? If not, at what stage are the discussions?

Section 7: Details of training or experience the relevant clinician will receive

- Is competency intrinsic to the post held by the clinician or encompassed by a basic qualification / examination e.g. MC, ChB, MRCP etc? (Yes / No)

- Is self-assessment and certification appropriate and can you explain why?

- What training courses have been attended to support this change in clinical practice in this area?

- What level of supervision is intended for this change in clinical practice, both in development and on a daily basis?

- Outline how competency will be established (for example number of supervised procedures) and how it will be maintained

- Are new / revised guidelines required? Please refer to the Clinical Guidelines Group.

Section 8: For more specialised procedures (e.g. surgical intervention or a medical therapy), has this been approved by the lead clinician and / or Assistant Clinical Director/ Clinical Director? Is there a consensus amongst relevant clinicians within this Trust on the appropriateness of the proposed change?

Section 9: Detail likely material complications (i.e. in excess of 1 in 1000 reported cases) and outline how these will be effectively managed. Detail any supporting services and individuals identified as supporting this project
(Material complications are those to which the patient would attach significance)

Section 10: What actions are intended in the event of adverse outcome results?

Section 11: Details of training or experience the support staff will require including any financial costs (Nurses, AHPs, other medical staff)

Section 12: Arrangements for Clinical Audit and / or Clinical Trials

- How will the outcomes of this change in clinical practice be monitored and what Clinical Audit arrangements will be made? Detail specific outcome data to be collected

- Do you plan to review this change? Please provide an outline of the schedule

Attach supporting documentation on each section as appropriate.

*Where applicable

Authorising Committee/Group/Person	Date	Agreed Yes/No
*Drugs & Therapeutics Group		
*Medical Devices Group		
*Lead Radiologist		
Business Unit Governance Meeting		
Divisional Clinical Governance Meeting		
Has this change in clinical practice been approved? (If No, please complete "Reasons for non-approval section below)		

Reasons for non-approval

Local Approval Mechanism

DMD Sign…….. Name……..…. Date…….

DD Sign…….. Name……..…. Date…….

CD Sign…….. Name……..…. Date…….

ACD Sign…….. Name……..…. Date…….

GM Sign…….. Name……..…. Date…….

THIS FORM WILL BE RETAINED BY THE BUSINESS UNIT RESPONSIBLE FOR IMPLEMENTING THE CHANGE. A COPY TO BE SENT TO THE CLINICAL AUDIT MANAGER FOR CENTRALISED RECORDING AND MONITORING

Change to Counting / Coding Request

Title:

Author: Date:

Business Unit(s) affected:

Introduction

Background about the issue, how it has been picked up, who is involved etc.

Who it has been discussed with and any ICB involvement to date (Improvement Groups, Planned Care Board, conversation with named individual etc.)

Outline of changes proposed

Detail of current system of counting and income generated and proposals for change including activity and income per month / annum explaining benefits and risks summarised as per table below:

Date of change	POD / SLAM POD	Activity & £ value per month / year	National change	Impact on block	Impact on ERF	Reflected in Activity Plan	SLAM Impact	SUS Impact

A full dataset is required to support the change as per attached template – this is to enable the activity to be built into annual plans.

Feedback from Panel

Area	Comments
Contracts	
Income	
Business Intelligence	
Costing	
Clinical Coding	