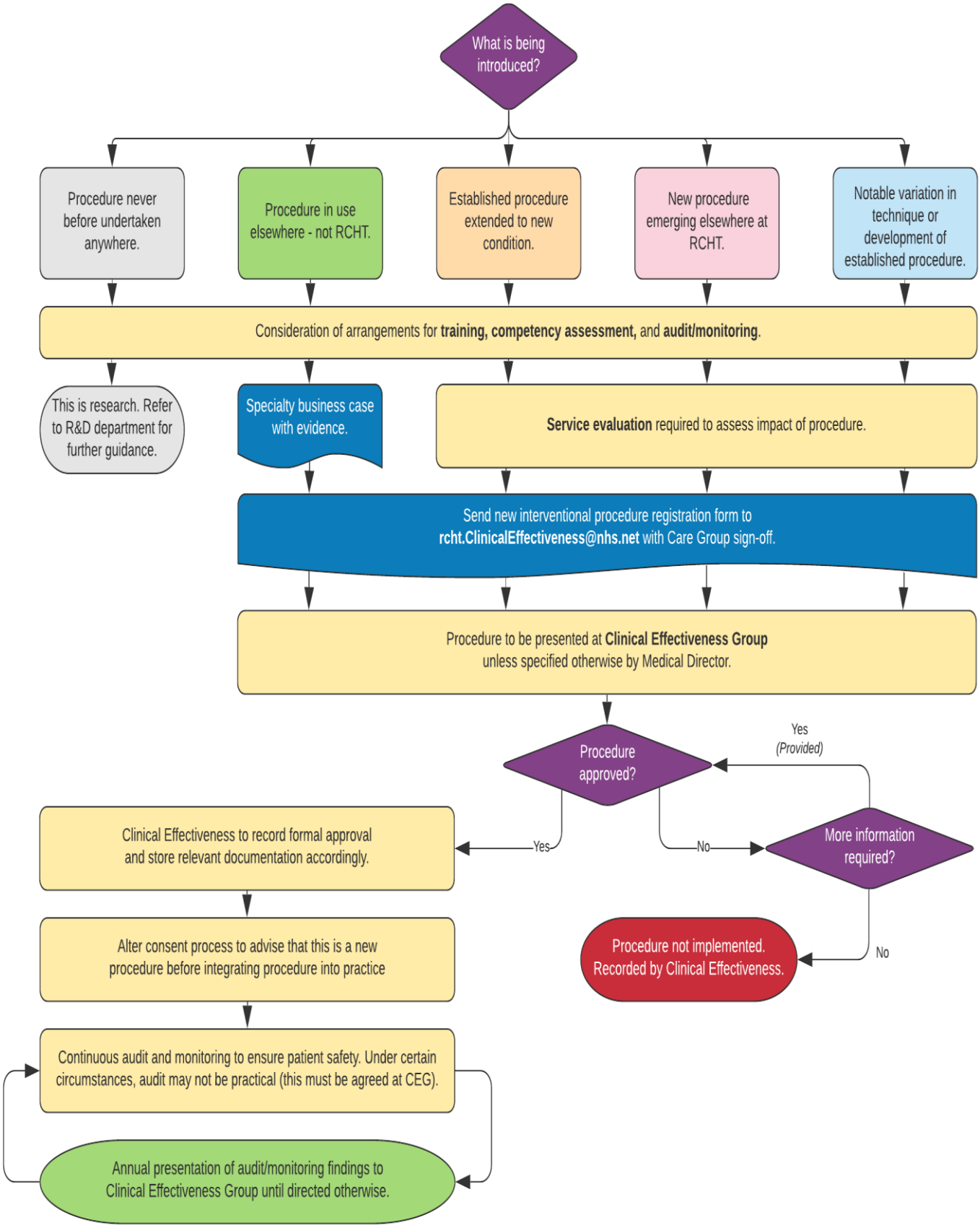
Royal Cornwall Hospitals
NHS Trust

The Introduction of New Interventional Procedures Policy

V6.0

June 2024

Summary


What is being introduced?
Procedure never before undertaken anywhere.
Procedure in use elsewhere - not RCHT.
Established procedure extended to new condition.
New procedure emerging elsewhere at RCHT.
Notable variation in technique or development of established procedure.
Consideration of arrangements for training, competency assessment, and audit/monitoring.
This is research. Refer to R&D department for further guidance.
Specialty business case with evidence.
Service evaluation required to assess impact of procedure.
Send new interventional procedure registration form to rcht.ClinicalEffectiveness@nhs.net with Care Group sign-off.
Procedure to be presented at Clinical Effectiveness Group unless specified otherwise by Medical Director.
Procedure approved?
Yes (Provided)
Yes
No
More information required?
No
Clinical Effectiveness to record formal approval and store relevant documentation accordingly.
Procedure not implemented. Recorded by Clinical Effectiveness.
Alter consent process to advise that this is a new procedure before integrating procedure into practice
Continuous audit and monitoring to ensure patient safety. Under certain circumstances, audit may not be practical (this must be agreed at CEG).
Annual presentation of audit/monitoring findings to Clinical Effectiveness Group until directed otherwise.

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. The clinical care of patients progresses through developments in equipment, investigation, and procedures; this progression will require clinicians to introduce new interventional procedures. To ensure safety and efficacy, the Trust must have established protocols and appropriate governance arrangements in place for the introduction of these changes in practice and the training of all staff involved.

1.2. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

2.1. Introduction of new procedures should be based on the following:

- Evidence based practice e.g. National Institute for Health and Clinical Excellence (NICE), national best practice guidance.
- Risk assessment.
- Audit to monitor success and measure outcome.
- Sound business case.

2.2. The Trust is committed to ensuring that the introduction of new interventional procedures is led by evidence-based practice and follows the Interventional Procedures Programme (HSC 2003/011).

3. Scope

This policy applies to all healthcare professionals who may be involved with the introduction of new procedures. This policy does not cover the training and competence of staff undertaking a procedure that is new to them but already in place in the Trust.

4. Definitions / Glossary

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

4.2. An interventional procedure should be considered new if it falls within any of the five categories detailed in the chart in the Summary section.

4.3. NICE's Interventional Procedures Programme protects patients' safety and supports people in the NHS in the process of introducing new procedures. Many of the procedures that NICE investigates are new, but they also look at more established procedures if there is uncertainty about their safety or how well they work. By providing guidance on how safe procedures are and how well they work, NICE makes it possible for new treatments and tests to be introduced into the NHS in a responsible way.

5. Ownership and Responsibilities

5.1. Role of the Clinical Effectiveness Group

The Clinical Effectiveness Group (CEG) is responsible for:

- Reviewing applications for introducing a new procedure and, if sufficient information and assurance are provided, giving Trust approval. This responsibility can be delegated to the Chief Medical Officer by the Group.
- Receiving regular reports on new procedures registered and approved.
- Agreeing whether a procedure will require ongoing audit/monitoring post-approval. This decision will be driven by characteristics of the procedure including—but not limited to—frequency, complexity, novelty, cost, and similarity to existing procedures.
- For all new procedures an audit will be required at either 6 months or when 20 cases have been completed. This audit will initially report through the Clinical Effectiveness Group. Ongoing governance will be monitored locally.
- Reviewing the report from the annual audit of processes and agreeing on recommendations, as well as identifying actions with leads and deadlines (see Section 8).

5.2. Role of Chief Medical Officer

The Chief Medical Officer is responsible for:

- Reviewing applications for introducing a new procedure on behalf of the Clinical Effectiveness Group and, if sufficient information and assurance are provided, giving Trust approval.
- Referring the approval of new procedures to the Clinical Effectiveness Group.
- Providing regular reports to the Clinical Effectiveness Group on new interventional procedures given approval, with support from the Clinical Effectiveness Team.
- Unless already listed, raise the procedure to the Interventional Procedures Programme at NICE, with support from the Clinical Effectiveness Team.

- Providing senior clinical input on whether a procedure requires ongoing audit or monitoring.

- Providing senior clinical input on whether it is appropriate to reduce the frequency of audits if a given procedure has been fully embedded into practice for a significant period.

5.3. **Role of Clinicians**

A clinician who wishes to carry out a new interventional procedure is responsible for:

- Completing the registration form for new interventional procedures (Appendix 3) and providing all the supporting information required:
    - Evidence base for introduction, if not NICE approved (approach Library Service for support).
    - Training information (competency of person/organisation providing training).
    - How ongoing competency will be maintained/assessed.
    - Risk assessment (following the risk scoring process laid out in the Risk Management Strategy).
    - Arrangements for clinical audit/monitoring of cases (particularly if mandated by the Group at the point of approval).
    - Business case if appropriate.
    - Evidence of Care Group approval.
- Ensuring all digital or physical forms are sent to the Clinical Effectiveness Team to obtain approval for the procedure from the Chief Medical Officer/Clinical Effectiveness Group.
- The lead clinician may be asked to present the case for the introduction of the new procedure at the Clinical Effectiveness Group.
- Receive confirmation of Chief Medical Officer/Clinical Effectiveness Group approval before carrying out any procedure.
- Develop plans for monitoring outcomes and planned clinical audit following the implementation of the new procedure to evaluate effectiveness and ensure patient safety. Audit and monitoring are mandated by the group at the point of approval.
- Use NICE IPG Tool to audit and monitor new procedure implementation. (Appendix 4).
- Reporting results of monitoring/audit and outcomes to Care Group Management Team, when either 20 cases have been completed or at 6 months annual basis (until agreed otherwise), to the Clinical Effectiveness Group.

- Where no other treatment options exist, there may be a need to use a new procedure in a clinical emergency so as not to place the patient at serious risk. If a clinician has performed a new interventional procedure in such circumstances, they must inform their Clinical Director and the Chief Medical Officer within 72 hours.

- If the new procedure is replacing an existing one, consider any issues with discontinuing the previous procedure (e.g., resources, support services, policies).

5.4. **Role of Care Group Management Teams**

The Care Group Management Teams are responsible for:

- Providing Care Group agreement to proceed with the new procedure (Appendix 3: New Interventional Procedures Registration Form).

- Reviewing any business case that may be necessary to implement the new procedure.

- Providing assurance to the Chief Medical Officer that new interventional procedures are monitored to ensure patient safety. This responsibility can be delegated to the senior clinicians that proposed (or regularly perform) the procedure for direct reporting via the Clinical Effectiveness Group.

5.5. **Role of the Clinical Effectiveness Team**

The Clinical Effectiveness Team is responsible for:

- Coordinating the process for the registration of new interventional procedures by ensuring the clinicians are sent the appropriate documentation (whether physical or digital) and that completed applications—with supporting evidence—are submitted to the Chief Medical Officer for review.

- Ensuring any cases that the Chief Medical Officer wishes to review at Clinical Effectiveness Group are included on the agenda for the next available meeting.

- Holding a central record of applications for new interventional procedures, including the post-approval audit and monitoring arrangements where applicable.

- Supporting the Chief Medical Officer in producing a regular report to the Clinical Effectiveness Group on new interventional procedures registered.

- Providing annual audit/monitoring updates for those procedures that specifically require it.

5.6. Role of Research, Development and Innovation Department

The Research and Development Department are responsible for:

- Ensuring that new procedures being used within a research protocol are approved through research governance processes.
- Informing the Chief Medical Officer of any approved research projects that involve a new interventional procedure.

6. Standards and Practice

6.1. New procedures should fit into one of the following categories (see summary):

- The procedure has never been undertaken anywhere. In this case, the proposal is research and should follow standard research governance protocols, registration with the RD and I Department and will include submission to the relevant Research Ethics Committee.
- In use elsewhere but not in this Trust. In this case a full evaluation including expected benefits must be planned for and commenced at the outset of the development.
- An established procedure extended to a new condition.
- A new procedure that is emerging in the Trust elsewhere.
- A significant variation in technique or development of an established procedure.

6.2. If the procedure is the subject of NICE guidance, the proposed use of the procedure must comply with the guidance.

6.3. There should be clear evidence base for the introduction of the new procedure (specifically if not covered by existing NICE guidance). This should be summarised in the Registration Form (Appendix 3). Proposer should contact the Library Service to access support for identifying the evidence base.

6.4. Approval must be obtained from the Care Group and then the Chief Medical Officer/Clinical Effectiveness Group before undertaking a new interventional procedure within the Trust by completing and submitting the Registration Form (Appendix 3).

6.5. With regard to new interventional procedures, the Chief Medical Officer/Clinical Effectiveness Group will require assurance that:

- The clinical professional has met appropriate standards of training to undertake the procedure in question.
- Indemnity has been checked.
- There is a sound evidence base for the introduction of the procedure.

- Proposed arrangements for monitoring and clinical audit are sound and will capture data on clinical outcomes that will be used to review continued use of the procedure and clinical competency for future use.

6.6. It is recognised that in rare circumstances, where no other treatment options exist, there may be a need to use a new procedure in a clinical emergency so as not to place the patient at serious risk. If a doctor has performed a new interventional procedure in such circumstances, the medical practitioner must inform their Clinical Director and the Chief Medical Officer within 72 hours. The Chief Medical Officer will then review the continued use of the procedure as set out in this policy.

6.7. Assurance will be required by the Chief Medical Officer/Clinical Effectiveness Group that the responsible clinician has received adequate training and assessment of competence. Training must involve the multidisciplinary team involved in the project and may be provided in the following ways:

- Attending a validated course run by a recognized organisation.
- By visiting experts who should have visiting Consultant status which can be awarded by the Chief Medical Officer for the duration of the visit.
- Visits to other centres where the procedures are already established.
- Mentorship by a practitioner experienced and qualified in the procedure.

6.8. In line with continuing professional development and accountability, details recording all new procedures undertaken must be kept in individual portfolios together with records of training received and maintenance of skills.

6.9. Visiting clinicians will require an honorary contract/indemnity, confirmation of GMC registration and Hepatitis B immunity by Medical Staffing. Visiting clinicians who work with children will require disclosure checking. A full evaluation of the introduction of new procedures by visiting clinicians or providers other than the Trust should include robust evidence to support the proposal.

6.10. If required, an evidence-based business case (indicating level of supporting evidence) describing the procedure, its benefits and the staff training required, should be developed within the Specialty, with the Specialty Governance Lead, Specialty Lead and Clinical Director. The procedure should be costed for capital and revenue with any potential sources of funding, or savings described, with support from the Care Group Finance contact.

6.11. The standard Trust consent form will be used, and the information given to patients prior to consent should include specific reference that the procedure is new. The patient should be offered alternative treatments where available and the comparative risks and benefits must be clearly explained and documented.

7. Dissemination and Implementation

7.1. This policy document will be held in the public section of the Documents Library and unrestricted access, replacing the previous version which will be archived in accordance with the Trust Information Lifecycle and Corporate Records Management Policy.

7.2. The policy will be disseminated to Care Group Management Teams and Specialty Governance Leads when it is published. The Chief Medical Officer, Chief Medical Officers Office and Clinical Effectiveness Team will ensure that any clinicians enquiring about the process are in receipt of the policy and the form. Word versions of the form will be available for download from the Clinical Effectiveness intranet site.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Provision of required information for approval of new procedures and monitoring/reporting of outcomes within Care Groups.
Lead	Coordinated by the Clinical Effectiveness Team.
Tool	Completion of registration forms by the relevant clinicians and monitoring in Specialities/Care Groups of patient outcomes.
Frequency	6 months or when 20 cases have been completed
Reporting arrangements	Report will be sent to the Chief Medical Officer and tabled at the Clinical Effectiveness Group.
Acting on recommendations and Lead(s)	Recommendations and actions arising from review will be agreed at the Clinical Effectiveness Group with leads identified and deadlines for completion.
Change in practice and lessons to be shared	Required change in practice will be identified and actioned by appropriate members of the relevant Care Group by agreed deadlines. Lessons will be shared with all the relevant stakeholders.

9. Updating and Review

9.1. This policy document will be reviewed no less than every three years or more frequently following any significant process changes or national policy instruction.

9.2. Consultation, approval and dissemination of subsequent revisions will follow the guidance set out in the Trust Organisation-wide Policy for the Development and Management of Knowledge and Procedural Documents (The Policy on Policies).

9.3. All revision activity is recorded in the Version Control Table as part of the document control process.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	The Introduction of New Interventional Procedures Policy V6.0
This document replaces (exact title of previous version):	The Introduction of New Interventional Procedures Policy V5.1
Date Issued / Approved:	26 April 2024
Date Valid From:	June 2024
Date Valid To:	June 2027
Author / Owner:	Claire Kemp, Clinical Effectiveness Coordinator/ Clinical Effectiveness Team
Contact details:	01872 252451
Brief summary of contents:	The Trust must have established protocols for the introduction of new interventional procedures that promote safe practice and reduce risks. The introduction of new procedures should be based on: • Evidence based practice. • Risk assessment. • Audit. • Sound business cases.
Suggested Keywords:	Interventional procedure, new procedure, NICE.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Clinical Effectiveness Group
Manager confirming approval processes:	Richard Johnson, Head of Clinical Effectiveness
Name of Governance Lead confirming consultation and ratification:	Richard Johnson, Head of Clinical Effectiveness

Information Category	Detailed Information
Links to key external standards:	Care Quality Commission (Registration) Regulations 2009
Related Documents:	• HSC 2003/011 The Interventional Procedures Programme, Department of Health. • Safety Alerts Management and Implementation Policy. • Development and Management of Knowledge, Procedural and Web Documents Policy. • Risk Assessment and Management Strategy and Policy.
Training Need Identified:	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Patient Safety and Clinical Effectiveness

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
16/03/09	V1.1	First Draft of revision of original (2005) document.	Paul Upton, Assistant Medical Director
20/03/09	V1.2	Update for Governance Committee.	Paul Upton, Assistant Medical Director
27/04/09	V1.3	Minor changes requested when approved by the Integrated Governance Committee.	Carol Beaman, Clinical Effectiveness Coordinator
21/05/10	V2.0	Review and changes made to reflect relevant publications and guidance.	Hazel Wright, Clinical Governance Manager
10/12/10	V2.2	Minor review – update of committees (full review postponed until Department of Health guidance updated).	Mandy Bryant, Clinical Effectiveness Coordinator
26/09/11	V2.3	Update of policy and revision to new Trust policy template.	Mandy Bryant, Clinical Effectiveness Coordinator
06/10/14	V3.0	Update to Committee structure, reporting and monitoring through the Medical Director's Office.	Mandy Gorton, Clinical Effectiveness Coordinator

Date	Version Number	Summary of Changes	Changes Made by
01/11/18	V4.0	Update to Committee structure, reporting and monitoring through the Clinical Effectiveness Team and refresh of the registration document.	Mandy Gorton, Clinical Effectiveness Manager
26/04/21	V5.0	Update to reflect recent organisational changes and opportunity to refresh Policy with Clinical Leadership.	Richard Johnson, Head of Clinical Effectiveness
15/10/21	V5.1	Additional information in relation to post approval auditing incorporated. Flowchart modified significantly to reflect changes. Changes to wording in section 3 (Definitions/Glossary).	Luke Williams, Clinical Effectiveness Coordinator/Project Manager (Compliance and Governance)
08/02/24	V6.0	Update of policy and revision to new Trust policy template. Refresh of the registration document and addition of NICE IGP tool.	Claire Kemp, Clinical Effectiveness Coordinator

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	The Introduction of New Interventional Procedures Policy V6.0
Department and Service Area:	Clinical Effectiveness
Is this a new or existing document?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Richard Johnson, Head of Clinical Effectiveness and Claire Kemp, Clinical Effectiveness Coordinator
Contact details:	01872 252451

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	The clinical care of patients progresses through the developments in equipment, investigation, and procedure. This progression requires clinicians to introduce new procedures. The Trust must have established protocols for the introduction of these changes in practice and the training of all staff involved.
2. Policy Objectives	To provide a clear process for the introduction of new interventional procedures.
3. Policy Intended Outcomes	To ensure that a robust process is in place for the introduction of all new procedures and that staff are appropriately trained.
4. How will you measure each outcome?	Annual audit of the policy.
5. Who is intended to benefit from the policy?	Clinical teams and ultimately patient safety.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Consultation was through Clinical Effectiveness Group members and all Specialty Governance Leads.
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Claire Kemp, Clinical Effectiveness Coordinator.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3: New Interventional Procedures – Registration Form

Title of Procedure:		
Details of Procedure: Please outline key features, how it differs from current practice and which group of patients will benefit		
Tick Appropriate Category (see 'Summary' section in the 'Policy for the Introduction of New Interventional Procedures' for details)		
(a) Technique/Procedure never before undertaken anywhere		
(b) Technique/Procedure in use elsewhere, but not in RCHT		
(c) An established procedure extended to a new condition		
(d) A New Technique/Procedure that is emerging in the Trust elsewhere		
(e) A significant variation in technique or development of an established procedure		
Supporting information		
Is the interventional procedure listed on NICE's website?	**Yes** IPG number	**No**
List any other evidence-based information/evidence. (Support for carrying out an evidence search can be provided by Library Services: https://www.cornwallhealthlibrary.nhs.uk/journals/request-a-literature-search/):		

Staff Involved		
Names	**Training Received (place, dates and who provided training)**	**Evidence of Competence**
Arrangements for skills/competency maintenance and update:		
Risk Assessment: Refer to Risk Strategy on the Documents Library and Risk Team intranet page for guidance on scoring a risk.		
Risk assessment completed: **date and score**		**Identified risks placed on relevant risk register:** **date and ref number**
Resource Implications:		
Has this procedure been commissioned?	**Yes**	**No**
Business case developed and approved:	(date and details)	
If this procedure is replacing a previous one are there any issues or consequences of stopping the previous procedure?		

Arrangements for ongoing monitoring/audit of outcomes/competency assessment (initially monitoring should be continuous to assure patient safety):		
Care Group agreement to proceed:		
Date:	**Title**:	**Signature**
Trust agreement from Chief Medical Officer/Clinical Effectiveness Group:		
Date:	**Signature:**	
Any additional supporting information or comment:		

Once Care Group approval has been received the form is to be sent to:

Clinical Effectiveness Team, 2nd Floor Knowledge Spa

rcht.clinicaleffectiveness@nhs.net

Paperwork will be passed to the Chief Medical Officers office for final approval or consideration at Clinical Effectiveness Group

Appendix 4: NICE IGP tool

Printable data collection sheet:

Patient reference		
Baseline measure	**Date**	**Score**
Baseline measure, for example quality of life score		
Baseline measure, for example condition specific measurement score		
Other outcome measure of benefit		
Other outcome measure of benefit		
Other outcome measure of benefit		
Other outcome measure of benefit		
Additional comments		
Outcome measures of benefit	**Date**	**Score**
Outcome measure, for example condition specific measurement score, measured at a follow-up timepoint.		
Outcome measure, for example condition specific measurement score, measured at a follow-up timepoint.		
Other outcome measure of benefit, measured at a follow-up timepoint.		
Other outcome measure of benefit, measured at a follow-up timepoint.		
Other outcome measure of benefit, measured at a follow-up timepoint.		
Other outcome measure of benefit, measured at a follow-up timepoint.		
Other outcome measure of benefit		
Additional comments		
Adverse outcomes	**Date**	**Yes/No**
Adverse outcome, measured at a follow-up timepoint		
Adverse outcome, measured at a follow-up timepoint		
Adverse outcome, measured at a follow-up timepoint		
Adverse outcome, measured at a follow-up timepoint		
Adverse outcome, measured at a follow-up timepoint		
Adverse outcome, measured at a follow-up timepoint		
Adverse outcome, measured at a follow-up timepoint		
Other adverse outcome		
Additional comments (including assessment date of any adverse outcomes recorded)		