Policy Document

Reference: C30

University Hospitals of North Midlands NHS Trust

Consultants Using New Interventional Procedures or Undertaking Major Modifications to Existing Techniques

Version:	**6**
Date Ratified:	**June 2019 by Trust Executive Committee (TEC)**
Date of Next Review:	**June 2022**
Expiry Date:	**June 2023**
Policy Author:	**Deputy Head of Quality, Safety and Compliance**
Executive Lead:	**Medical Director**

Version Control Schedule

Version	Issue Date	Comments
1	August 2004	
2	June 2005	
3	May 2008	
4	April 2012	
5	April 2015	
6	June 2019	Changes to roles and responsibilities.

Statement on Trust Policies

The latest version of 'Statement on Trust Policies' applies to this policy and can be accessed here

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1. INTRODUCTION

The Trust will provide support and encouragement to the introduction of new techniques in response to local or national objectives or demand. Since November 2003 it has been the remit of NICE to make recommendations on new interventional procedures.

The purpose of the NICE Interventional Procedures Programme is to assess the safety and efficacy of mainly new interventional procedures. The programme's aims are to protect the safety of patients and to support Consultants, other clinicians, Clinical Governance Forums, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly. The Trust places equal weight on removal/replacement of redundant interventional procedures and the introduction of new interventional procedures.

A key function of the NICE programme is to gather further information on safety and efficacy where uncertainty exists. The necessity for notification to NICE should be judged on whether the new procedure is likely to have a different safety and/or efficacy profile from that of the original procedure. In circumstances where it is uncertain whether notification to NICE should take place the Clinical Director and Medical Director should be consulted. The purpose of this policy is both to protect patient safety and support Consultants the process of introducing new procedures.

From November 2003, medical practitioners planning to undertake new interventional procedures must seek approval from the Trust's Quality and Safety Forum before doing so. If the proposal is approved by the Quality and Safety Forum, the **Medical Director** will notify the procedure to the Interventional Procedures Programme at NICE.

This policy will ensure that any new clinical procedure is considered and approved prior to implementation and that safety, governance, training, experience and reassurance have been considered. In order to achieve this, the policy will outline the process by which new clinical procedures are considered prior to implementation.

2. SCOPE

The Trust is committed to providing effective and up to date treatment. All professional staff are encouraged to explore, develop, and implement new techniques in order to accomplish this.

This policy sets out the process for the introduction of new procedures and techniques.

In general terms, new procedures and techniques will only be considered if:

- The technique/procedure is in line with the Trust and Commissioner's strategy for local healthcare delivery.
- The clinician has met externally set standards of training.
- Clear funding or income streams have been identified.
- The technique/procedure has been agreed for use by the Clinical Director and has been incorporated into divisional business planning if necessary.
- The Management of Medical Equipment Policy has been followed for the procurement of any associated equipment.
- Rigorous arrangements for consent are in place if necessary.
- Arrangements for clinical audit are sound and will capture data on clinical outcomes that will be used to review continued use of the procedure.

The only exception to the above process is when the technique or procedure is being used within a protocol approved by a Research Ethics Committee (REC). In this case notification is not required, because patients are protected by the REC's scrutiny.

Therefore in the case of original interventional procedures, these must be considered as a research study and the Trust Policy on Research Governance must be followed. The Local Research Ethics Committee

(LREC) have been made aware of the need notify the Trust Quality and Safety Forum of any studies approved which involve new interventional procedures.

Colleagues should use their judgement as to whether a development is a genuine innovation requiring approval or a simple modification of an existing technique, which does not. However if there is any doubt this policy should be followed.

Please note: This policy applies to NHS and non-NHS patients of the Trust.

3. DEFINITIONS

An interventional procedure defined by National Institute for Health and Clinical Excellence (NICE) is one used for diagnosis or treatment that involves one of the following:

- Making a cut or hole to gain access to the inside of a patient's body
- Gaining access to a body cavity without cutting into the body,
- Using electromagnetic radiation (including x-rays, lasers, gamma-rays and ultraviolet light).

An interventional procedure will be considered *new* if a fully trained clinician is considering the use of the procedure/techniques for the first time **in the NHS** outside a Research Ethics Committee approved protocol.

However this policy also applies to:

The intention to introduce a planned **Major** modification or **substantial degree of difference** (technical or conceptual) of an existing procedure which could result in changed outcomes in terms of efficacy or safety.

While comprehensive and accurate registers of current interventional procedures and indeed the expected standards to be achieved in their delivery and outcome remain unavailable, the Trust recognises that it will need to be guided by local clinicians, expert within the field in question as to what constitutes a new technique or major modification.

The Trust recognises that the majority of therapeutic techniques are generic in nature and subject to variation in their delivery by different clinicians. Variations and modifications of such techniques are commonly required due to variations in clinical presentation. **These constitute minor modifications and are not subject to this policy.**

(For more information see Health Service Circular HSC 2003/011: The Interventional Procedures Programme; working with the National Institute for Clinical Excellence to promote safe clinical innovation).

4. ROLES AND RESPONSIBILITIES

4.1 Consultants

Before decisions are made to adopt new techniques Consultants must take into account any relevant evidence and guidance relating to the proposed development e.g. NICE guidance, guidance from Royal College or learned Societies.

The following questions should also be considered:

- What is the new procedure/technique?
- Why is the procedure/technique being considered for adoption?
- What is the background to the implementation of the procedure/technique?
- What will be the patient selection criteria?
- What are the indications and contra – indications?
- What are the complications and safety issues?
- What will be the impact on service (positive and negative)?
- Will there be an impact on other service areas e.g. pathology, radiology
- What evidence is available that demonstrates the clinical effectiveness of technique/procedure?

- What will be the arrangements for audit?

The Consultant must consult the NICE New Interventional Procedures List to identify whether the proposed intervention is already listed and follow the appropriate pathway (as referenced in the appendices)
http://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance

If the technique does appear on the NICE New Interventional Procedures List refer to Appendix 2 for approval.

If the technique does not appear on the NICE New Interventional Procedures List refer to Appendix 3 for approval.

Copies of the C30 forms can be obtained on request by contacting the Quality, Safety and Compliance Department on extension [redacted].

The Consultant is responsible for liaising with the relevant clinicians and Forums/ Groups to ensure appropriate support, assurance, approval is obtained and demonstrate clinical competence in that procedure, prior to implementation. The Consultant is responsible for ensuring the C30 form is completed prior to commencement of the procedure.

The Consultant will be responsible for ensuring implementation. It is also the responsibility of the consultant to ensure systems are in place to allow ongoing monitoring/audit of performance including the consideration of benchmarked data where appropriate.

Consultants should supply information requested by NICE on every patient undergoing the procedure. The collection of data from patients will be governed by the Data Protection Act, Freedom of Information Act and Caldicott Principles.

In the event of an adverse incident or near miss event occurring, this must be reported through the Trust Adverse Incident Reporting System.

Use of the Procedure in Emergency Situations
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 a patient at serious risk. If a Consultant has performed a new interventional procedure in such circumstances he/she must inform the Medical Director/Associate Medical Director, within 72 hours. The Quality and Safety Forum will consider approval of the procedure for future use.

Consent
The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensive information about their condition and about possible treatments/investigations and their risks and benefits. Refer to C43 Trust Policy and Procedure for Obtaining Consent.

The patient must also be informed of circumstances where a new interventional procedure is proposed and in particular that the risks and benefits are uncertain. NICE have produced a patient information leaflet to support this process.

Audit Arrangements
The Consultant must confirm that arrangements have been made to audit the new technique after an appropriate interval. The Consultant needs to liaise with the Clinical Audit & Effectiveness Team to ensure the audit is logged on the clinical audit register.

4.2 Clinical Director

The Clinical Director (CD) will facilitate relevant learning opportunities and create the conditions in which safe and effective practice can be achieved.

Prior to approval the Clinical Director will seek assurance from the consultant that the development of a new technique meets local or national objectives in addition to personal and professional goals.

The Clinical Director will support the Consultant in the approval process and subsequent implementation and review of the technique.

Where a new technique has been approved the Clinical Director should utilise the appraisal system to monitor performance against the results of clinical audit and benchmarked data.

4.3 Directorate Management Team

The Directorate Management Team will consider and **support** the introduction of a new interventional procedure.

Consideration should be given to:

- financial implications
- quality implications
- resource requirements
- staffing implications and training needs
- monitoring and review

4.4 Directorate/ Divisional Clinical Governance Group

The Directorate/Divisional Clinical Governance Groups will review the completed proforma, seeking **assurance** that the Directorate Management Team support the principle and that any quality issues have been addressed.

Consideration should be given to;

- consent arrangements
- patient information
- Risks and benefits
- Training and competency of the clinical team
- Monitoring and review

4.5 Medical Director

The Medical Director will provide **advice** and **Executive support** on the introduction of new procedures.

In the case of procedures which do not appear on the NICE new interventional procedures list, the Medical Director will notify NICE and inform the Chief Executive if the procedure is to be carried out in the period between notification and the issuing of guidance from NICE.

In circumstances where the interventional procedure does not appear on the NICE List but is believed by colleagues to be an effective and established procedure, the Medical Director will consult with NICE to agree a resolution.

In the event of dispute the Medical Director will arbitrate between the Consultant and the Directorate/Divisional Management Team.

4.6 Trust Quality and Safety Forum

The Quality and Safety Forum will **approve** the introduction of the interventional procedure:

- Where the Consultant has met externally set standards of training or can provide evidence of training deemed acceptable by their Clinical Director or colleague within the same specialty.
- Where procedures are in place for ensuring patients are made aware of the special status of the procedure (including patient information leaflet) and the lack of experience of its use. This will be done as part of the consent process and be clearly recorded in the patient's health record.
- Where assurance has been provided that all operational implications have been considered and the Directorate Management Team are supportive of its introduction.

- Arrangements for clinical audit are in place.

4.7 Trust NICE & External Publications Group

The Trust NICE & External Publications Group will **monitor** all newly published interventional procedure guidance (G14 Trust Policy on the Implementation of NICE Guidance). Where the lead clinician has identified the possibility of introducing new guidance in the future, the NICE & External Publications will initiate regular communication with the clinical lead and advise them of their responsibilities, as outlined in this policy.

When the NICE & External Publications Group has received notification of approval of a C30 form, the Group will seek assurance of its implementation via the audit process.

4.8 Quality Assurance Manager

The Quality Assurance Manager will;

- Liaise with the Consultant ensuring appropriate support and assurance has been sought prior to approval at the Quality and Safety Forum.
- **Maintain** a register of new interventional procedures/major modifications, once approved at the Quality and Safety Forum.
- Support the Medical Director in ensuring appropriate communication has taken place with NICE.
- Liaise with the Trust NICE & External Publications Group to ensure review of audit activity.

4.9 Research Ethics Committee (REC)

This applies when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC). In this case, notification to NICE is not needed, as patients are protected by the REC's scrutiny. However, RECs should notify the Trust Quality and Safety Forum when they approve a protocol involving a new interventional procedure. Use outside the protocol should only occur after approval from the Quality and Safety Forum as set out in this document. Such studies are subject to the Trust Research Governance Policy.

5. EDUCATION/TRAINING AND PLAN OF IMPLEMENTATION

Consultants undertaking new procedures need to obtain/have documented evidence that they have attended approved training sessions, or have personal data to show their competence. This can be held within their personal file (CPD/CME/appraisal/revalidation). The recognition and uptake of such training should be formally acknowledged at appraisal.

6. MONITORING AND REVIEW ARRANGEMENTS

A register of new interventional procedures will be maintained.
A summary of the NICE & External Publications Group will be forwarded to the Quality and Safety Forum.
Audit activity will be monitored via the NICE & External Publications Group.

Review

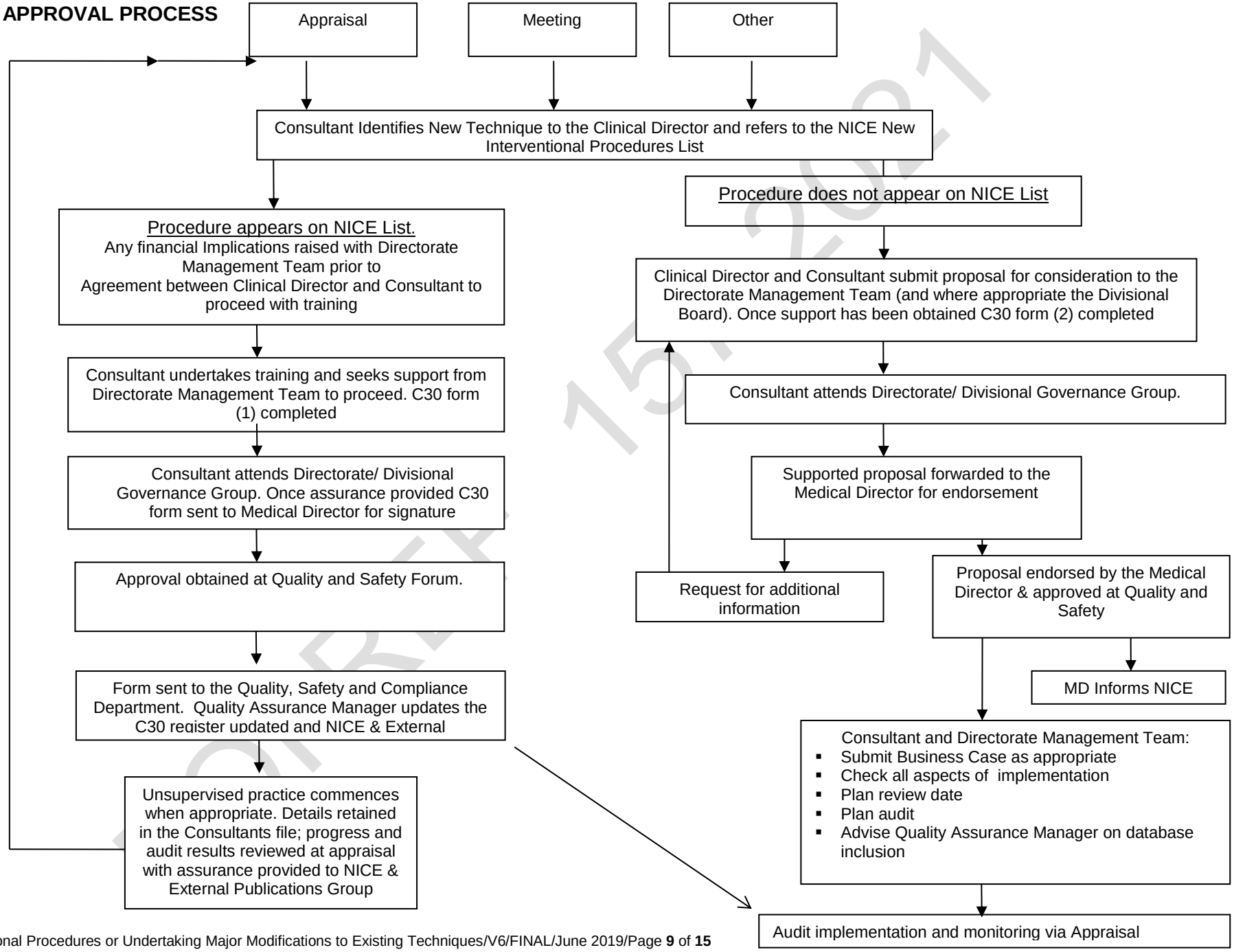
This policy will be reviewed at least every three years post ratification, unless changes in national legislation override this or there has been a specific request to review sooner.

7. REFERENCES

This policy should be read in conjunction with:

RM01	Risk Management and Assurance Policy and Strategy
RM07	Reporting and Management of Untoward Incidents Including Serious Incidents
C43	Policy and Procedure for Obtaining Consent
G14	Implementation of NICE Guidance
G15	Clinical Audit

APPENDIX 1: APPROVAL PROCESS



APPENDIX 2

Procedures APPEARING on the National Institute for Clinical Excellence (NICE) list of New Interventional Procedures, but is new to the Consultant not in training.

It is the responsibility of the Consultant to recognise their individual training needs in liaison with their Clinical Director, to identify and organise relevant and appropriate training opportunities.

If the proposed procedure appears on the NICE website but is new to a Consultant, the Clinical Director should be consulted. Any relevant financial implications need to be raised with the Directorate Management Team prior to agreement between the Clinical Director and the Consultant to proceed with training. Where appropriate the Medical Director should be informed.

On successful completion of training and introduction of unsupervised practice the consultant will complete ***C30 Form 1*** and seek support from the Directorate Management Team to proceed. Once support has been gained the Clinical Director will sign C30 Form 1.

The consultant should attend the Directorate and/or the Divisional Governance Group to provide assurance that all appropriate aspects of the technique have been addressed. Once support has been gained the consultant will liaise with the Clinical Director to forward a copy of this form to the Medical Director.

Once the form has been signed the Consultant will liaise with the Quality Assurance Manager for approval at the Quality and Safety Forum. Once approved the Quality Assurance Manager will add to the C30 register and notify the Trust NICE & External Publications Group and the Directorate/ Division.

The consultant will be responsible for implementation and ensuring appropriate audit arrangements are in place.

(C30) FORM 1
FOR USE IN CONJUNCTION WITH POLICY (C30) TRUST POLICY FOR CONSULTANTS USING NEW INTERVENTIONAL PROCEDURES or UNDERTAKING MAJOR MODIFICATIONS TO EXISTING TECHNIQUES

To be completed for procedures appearing on the National Institute for Clinical Excellence (NICE) list of New Interventional Procedures but new to the Consultant not in training.

NAME OF PROCEDURE:
BRIEF DESCRIPTION OF WHAT IS INVOLVED DURING THE PROCEDURE:
DATE THAT YOU CHECKED THE NICE LIST OF NEW INTERVENTIONAL PROCEDURES:
BRIEF DESCRIPTION OF TRAINING RECEIVED INCLUDING DETAILS OF ATTENDANCE AT RELEVANT TRAINING EVENTS (PLEASE ATTACH APPROPRIATE DOCUMENTATION):
PLAN FOR IMPLEMENTATION
Financial Implications
Outline any financial issues and how these have been addressed (example medical equipment costs, consumables, funding or income streams)
Operational Implications
Outline any operational issues and how these have been addressed (example clinic activity, wait times, patient selection criteria, indications and contra-indications, impact on support services)
Quality Implications
Outline any quality issues to include consent arrangements, Patient information (attach a copy of the patient information leaflet), medical equipment checks prior to installation, complications
HR Implications
Outline any HR implications (example staffing costs)
PLAN FOR AUDIT & MONITORING
Outline of audit activity

APPROVAL:			
Consultant (using technique):	**Signature:**		**GMC Number:**
	Print Name:		**Date:**
Clinical Director:	**Signature:**		**Date:**
	Print Name:		
Medical Director	**Signature:**		**Date:**
	Print Name		

When complete contact the Quality Assurance Manager

APPENDIX 3

Procedures which DO NOT APPEAR on NICE New Interventional Procedures List

The introduction of the new interventional procedure requires endorsement by the Clinical Director.

The Clinical Director and Consultant concerned should submit a proposal for consideration to the Directorate Management Team (and where appropriate the Divisional Board). The Directorate Management Team should reach a decision following evaluation of the evidence, statement of need and related Business Planning Proforma. Where there are concerns this should be escalated to the Divisional Board. Once support has been gained the Clinical Director will sign C30 Form 2.

The Consultant should attend the Directorate and/or the Divisional Governance Group to provide assurance that all appropriate aspects of the technique have been addressed. Once support has been gained the consultant will liaise with the Clinical Director to forward a copy of this form to the Medical Director for endorsement.

Once all appropriate signatures have been obtained the consultant will liaise with the Quality Assurance Manager for approval at the Quality and Safety Forum. Once approved the Quality Assurance Manager will include on the C30 register and notify the Trust NICE & External Publications Group and the Division.

Once approved the Medical Director should notify the procedure to NICE via the website and confirm this action to the Clinical Director and Quality Assurance Manager.

http://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance/ip-notification-form

The consultant will be responsible for implementation and ensuring appropriate audit arrangements are in place:

- Consultants should supply information requested by NICE on every patient undergoing the procedure. The collection of data from patients will be governed by the Data Protection Act, Freedom of Information Act and Caldicott Principles.
- It is also the responsibility of the consultant to ensure systems are in place to allow ongoing monitoring/audit of performance including the consideration of benchmarked data where appropriate.
- In the event of an adverse incident or near miss event occurring, this must be reported through the Trust Adverse Incident Reporting System which will subsequently be reported to the National Patient Safety Agency via the national reporting and learning system for adverse events.

Once NICE is notified of the intention to introduce a new interventional procedure:

- NICE will prepare a brief overview of the evidence on the procedure's safety and efficacy and consult its Specialist Advisors.
- The independent Interventional Procedures Advisory Committee (IPAC) will decide either to issue guidance on the procedure or to seek more information before doing so.
- NICE may commission a systematic review of research on the procedure, or set up a national register to collect data about patients who have been treated with it.
- NICE consults publicly on all its guidance and its advisory committee will consider responses to consultation before guidance on any procedure is issued.

(C30) FORM 2
FOR USE IN CONJUNCTION WITH POLICY (C30) TRUST POLICY FOR CONSULTANTS USING NEW INTERVENTIONAL PROCEDURES or UNDERTAKING MAJOR MODIFICATIONS TO EXISTING TECHNIQUES

To be completed for procedures which <u>do not appear</u> on the National Institute Clinical Excellence (NICE) New Interventional Procedures List.

NAME OF PROCEDURE:
IS THE PROCEDURE SIMILAR TO ESTABLISHED PROCEDURES, A NEW TYPE OF PROCEDURE OR A MAJOR MODIFICATION?
WHICH EXISTING PROCEDURES MIGHT THIS REPLACE?
BRIEF DESCRIPTION OF WHAT IS INVOLVED IN THE PROCEDURE:
WHAT IS THE INTENDED HEALTH GAIN OF THE PROCEDURE?
PATIENTS LIKELY TO BENEFIT (POTENTIAL IMPACT, NUMBERS WHERE POSSIBLE):
ARE THERE ANY POTENTIAL ADVERSE EFFECTS (INDICATING LEVELS OF RISK WHERE POSSIBLE)
CAN YOU PROVIDE ANY EVIDENCE ON THE EFFICACNY OF THE TECHNIQUE?
PLAN FOR IMPLEMENTATION
Financial Implications
Outline any financial issues and how these have been addressed (example medical equipment costs, consumables, funding or income streams)
Operational Implications
Outline any operational issues and how these have been addressed (example clinic activity, wait times, patient selection criteria, indications and contra-indications, impact on support services)

Quality Implications
Outline any quality issues to include consent arrangements, Patient information (attach a copy of the patient information leaflet), medical equipment checks prior to installation, complications
HR Implications
Outline any HR implications (example staffing costs)
PLAN FOR AUDIT & MONITORING
Outline of audit activity

APPROVAL:			
Consultant (using technique):	**Signature:**		**GMC Number:**
	Print Name:		**Date:**
Clinical Director:	**Signature:**		**Date:**
	Print Name:		
Medical Director	**Signature:**		**Date:**
	Print Name:		

When complete contact the Quality Assurance Manager