

Title:	Policy for the introduction of new Interventional Procedure		
Policy Author(s)	[REDACTED] Deputy Medical Director, Risk and Governance Tel: [REDACTED]		
Responsible Director:	[REDACTED], Medical Director		
Policy Type: (tick as appropriate)	*Directorate Specific ☐	Clinical Trust Wide ☒	Non Clinical Trust Wide ☐
If policy type is confirmed as *Directorate Specific please list the name and date of the local Committee/Group that policy was approved			
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Date	Version	Policy Author	Comments
21/02/2008	2.0	[REDACTED]	To Policy Committee
30/07/2012	2.1	[REDACTED]	New template, non-approval process 4.5.5
02/08/2012	2.2	[REDACTED]	Training and experience required – Form
07/08/2012	2.3	[REDACTED]	Appeals process – flowchart, 4.5.5; Roles
15/07/2013	3.1	[REDACTED]	GC&LC /170/11 case: Conflicts of interest
11/12/2013	3.1	[REDACTED]	Approved at S&G Committee. I Young to take to Ethics Committee
October 2014	4	[REDACTED]	Approved and online
June 2016	4.1	[REDACTED]	Minor amendment to form to include co-chair of S&G Committee and change to front page of policy
October 2016	5	[REDACTED]	Through Committees for intranet.
August 2022	5.1	[REDACTED]	Policy review dates updated and moved to new policy format.
October 2022	6		Final version

1.0 INTRODUCTION / SUMMARY OF POLICY

1.1 Background

Since January 2007, Northern Ireland participates in the National Institute for Health and Clinical Excellence (NICE) Interventional Procedures (IP) Programme. [ppmd_nice_1-07.pdf](#)

The NICE IP Programme assesses the efficacy and safety of IPs, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately.

New arrangements for HPSS healthcare professionals intending to undertake new IPs are outlined below.

1.2 Purpose

This policy describes the steps that need to be taken when there is a request to perform an IP not used before in the Trust.

1.3 Objectives

To describe the steps to be taken by a clinician before performing a new IP.

To describe the steps to be taken by the Policy and External Guidance Assurance Committee (Formally known as Standards and Guidelines Committee) before a new IP is performed.

2.0 SCOPE OF THE POLICY

This policy will apply throughout the BHSCT.

2.1 Exceptions to above procedure

Where the procedure is being used within a research protocol which has been approved by an HPSS/NHS Research Ethics Committee, notification to NICE is not required.

There may be a need to use a new procedure in a clinical emergency. In such circumstances, they must inform the Policy and External Guidance Assurance Committee within 72 hours.

The Committee should then consider approval of the procedure for future use as above and notify NICE of the procedure.

NICE guidance on a new IP does not override the individual responsibility of clinicians to make appropriate decisions in the circumstances of the individual patient or carer, always putting the best interests of their patient foremost.

3.0 ROLES AND RESPONSIBILITIES

3.1 Medical Director

The Medical Director is responsible for the correct implementation of the IP programme. Management of this programme has been delegated to the Policy and External Guidance Assurance Committee, its Co-chairs and Senior Manager.

3.2 Directors, Chairs of Divisions, Clinical Directors

Directors, Chairs of Division and their Clinical Directors are responsible for disseminating the IP programme, as set out in this policy, to all staff in their Directorate.

They are to ensure that clinicians in their Directorate are aware of and comply with the programme. If they become aware that a clinician wishes to perform a new IP or are concerned about the safety or efficacy of an established procedure, they must refer the relevant clinician to the Policy and External Guidance Assurance Committee Co-chair.

Once aware that a new IP is approved, Divisional Chairs and Clinical Directors must work with the relevant clinician to assess (on behalf of the Medical Director) what training, mentoring, supervision, audit and good governance might be required when that new procedure is introduced in their specialty or Directorate.

3.3 Co-Chairs Policy and External Guidance Assurance Committee

The Policy and External Guidance Assurance Committee, its Co-chairs and Senior Manager of Risk and Governance, Medical Director's Office have been delegated as the BHSCCT Committee with responsibility for clinical governance issues relating to the IP programme.

On receipt of an approval request from a clinician, the Committee Chair should check the NICE website to find out what guidance, if any, has been issued or whether the procedure is listed as having already been notified to NICE.

If the procedure is the subject of NICE guidance, the Committee should consider whether the clinician's proposed use of the procedure complies with the guidance before giving its approval.

When approving a new IP, the Policy and External Guidance Assurance Committee Co-chair must seek assurance that the relevant Chair of Division and Clinical Director have ensured that the correct checks for training, mentoring, supervision, audit and good governance are performed.

3.4 Clinician

For any clinician using a new procedure, normal good practice includes:

- ❖ Informing the clinical and hospital management,

- ❖ Informing patients clearly and
- ❖ Auditing outcomes thoroughly.

These principles are translated into IP guidance as recommendations that clinicians wishing to use a new procedure with inadequate or uncertain evidence should do the following:

1. Inform their Clinical Director, Divisional Chair and the Co-Chair of the Policy and External Guidance Assurance Committee
2. Inform Clinical Director so that they can ensure that the correct checks for training, mentoring, supervision, audit and good governance are performed.
3. Lead on notifying the new procedure to NICE where appropriate along with the Senior Manager of Risk and Governance, Medical Director's Office.
4. Make special arrangements for consent i.e. informing patients about the newness of the procedure, the clinician's own experience with it, and any particular uncertainties. Special arrangements for consent should include giving patients thorough written information.
5. Make special arrangements to audit and review of their results. This means keeping detailed and accurate records of all patients who have the procedure, including all adverse events and outcome measures of efficacy. These data should be reviewed at appropriate intervals and practice should be changed if the results suggest a need to do so. The directorate must ensure these audits are reviewed and presented within their Quality Management System Data.

4.0 CONSULTATION

The primary sources for this document are the DHSSPSNI documentation and similar information from NICE.

Policy and External Guidance Assurance Committee, Service Directorate, Medical Director and the Ethics Committee approval were obtained.

5.0 POLICY STATEMENT/IMPLEMENTATION

5.1 Key Policy Principles

IP guidance issued by NICE is concerned only with safety and efficacy; there is no consideration of cost or cost-effectiveness. Cost effectiveness can occur if the Interventional Procedures Advisory Committee (IPAC) on Topic selection selects a Technology Appraisal (TA) evaluation

However in the absence of a TA the introduction of a new procedure in the Trust may incur costs and these need to be addressed within the Service Directorate through the appropriate process.

All IPs to be considered by the Policy and External Guidance Assurance Committee must have prior approval from the Service Director's Directors/Managers.

5.2 Definitions

5.2.1 Interventional Procedure

An interventional procedure is a procedure used for diagnosis or for treatment that involves:

- making a cut or a hole to gain access to the inside of a patient's body e.g. when carrying out an operation or inserting a tube into a blood vessel, or
 - gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body e.g. examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth, or
 - using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) e.g. using a laser to treat eye problems.
- [NICE interventional procedures guidance](#) | [NICE guidance](#) | [Our programmes](#) | [What we do](#) | [About](#) | [NICE](#)

To fall within the NICE Programme's scope, a notified procedure must:

- involve an incision or a puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy, and
- be available within the NHS or about to be used for the first time in the NHS, outside formal research, and
- either not yet be generally considered standard clinical practice

Safety concerns can be shared with NICE and also any new information in relationship to an IP. NICE can also be updated with any new information which may alter the decision of the advisory committee (IPAC).

5.2.2 Definition of 'New'

An interventional procedure should be considered **new** if it is not in regular use **and** a clinician, not in a training post, is using it for the first time in their HPSS clinical practice.

Reference to the "The Interventional Procedures Programme process guide" indicates that procedures should be notified to NICE if they are:

- entirely novel, with an unknown or uncertain efficacy and/or safety profile; or
- a variation of an established procedure which is likely to have a different efficacy and/or safety profile from that of the established procedure.

<http://www.nice.org.uk/media/1E0/17/IPProgrammeProcessGuideJan09.pdf>

This policy is primarily designed to deal with IPs which are new to the Trust rather than solely being new to the clinician.

While the Programme is concerned largely with new procedures, it may also assess established procedures if there is concern about their safety and/or efficacy.

5.3 Policy Principles

This policy will summarise what:

- a clinician needs to do before performing a new IP = Notification
- the Trust then needs to do = Approval.

5.4 Notification - Clinician's responsibilities before performing a new IP

If a clinician identifies and wants to use a new IP they should:

- Inform their Chair of Division and Clinical Director and discuss with them.
- Check the NICE Interventional procedures website to identify that there is not already NICE guidance on this procedure

<http://guidance.nice.org.uk/IP/Published>

or

- whether NICE has been notified and guidance is being developed.

<http://guidance.nice.org.uk/Type/IP/Search>

If there is guidance and the clinician is wishing to personally perform it for the first time in this Trust, then he/she should notify the Policy and External Guidance Assurance Committee by submitting a “Notification of New Interventional Procedure” form filled in appropriately. The process will now involve ascertaining the experience, training and facilities needed by the clinician as well as the consent and audit arrangements.

IPs that have been notified to NICE will progress through their system. The major steps taken may involve the following:

- not in remit
- notification, listing and in progress,
- overview document produced,
- consultation document issued,
- guidance issued.

If there is no guidance, the clinician should notify the Policy and External Guidelines Assurance Committee by submitting a “Notification of New Interventional Procedure” form filled in appropriately. The process will then involve the notification of NICE and the DHSSPSNI and then ascertaining the experience, training and facilities needed by the clinician as well as the consent and audit arrangements.

Although clinicians most frequently notify procedures, anyone may make a notification. This may include device manufacturers, the National Horizon Scanning Centre, Specialist Advisors and Specialist Societies.

5.5 Approval - Trust's responsibilities.

When informed by a "Notification of Interventional Procedure" form, the Policy and External Guidelines service manager will check on the NICE website to see:

- Whether the procedure is listed as already having been notified to NICE or
- Any guidance has been issued.

Where guidance has already been issued, the Policy and External Guidance Assurance Committee should consider whether the clinician's proposed use of the procedure complies with the NICE guidance prior to giving approval. This will, for example, take heed of the experience, training and facilities needed by the clinician as well as the consent and audit arrangements.

If approved, the Policy and External Guidance Assurance Committee Co-chair must seek assurance that the Chair of Division and the Clinical Director have the correct checks for training, mentoring, supervision, audit and good governance are performed.

Where the procedure is not listed by NICE, the Standards and Guidelines Service manager should inform the Chairs of the Policy and External Guidance Assurance Committee and also co-produce with the relevant clinicians the notification to NICE via the NICE website and informed the DHSSPSNI via e-mail:

squ-niceguidance@dhsspsni.gov.uk

Where a procedure is not listed by NICE or where it is listed but guidance has not been developed, the Committee should only approve the procedure in the interim if:

- The clinician has met externally set standards of training.
- The Committee is satisfied the proposed arrangements for consent and clinical audit are sound and will capture data on clinical outcomes that will be used to review continued use of the procedure. NICE issues audit criteria for certain specific pieces of guidance that may be used for this purpose.
- The Committee is satisfied adequate clinical and social care governance arrangements are in place to ensure appropriate management of risks, complaints, negligence and redress.

5.6 Conflict of Interest/Appeals

Where there may be a perceived or possible conflict of interest within the Policy and External Guidelines Committee and approval or non-approval of a new IP by the Co-chair, he/she should inform the Medical Director who will appoint a substitute to ensure satisfactory arrangements are established for such circumstances.

In circumstances when a clinician objects to non-approval of their application, for whatever reason, adjudication will be provided through the Office of the Medical Director who may appoint a group to consider the application.

Although not a member of this decision making group, the Co-chair of the Policy and External Guidance Assurance Committee will be expected to table their reasons for non-approval and the clinician may be invited to state their case for approval. The decision of the group appointed by the Medical Director will be final.

5.7 Post Trust Approval

5.7.1 Consent

Consent, in the context of a procedure new to the BHSCT and/or a clinician, must ensure that the patient is aware that it is a 'new' procedure. Therefore, all patients offered the procedure should be made aware of the:

- lack of experience of its use and that the professional is early in their learning
- uncertainty (if any) around its safety and efficacy.
- anticipated benefits,
- possible adverse effects of the procedure,
- alternatives (including no treatment).

This should be done as part of the consent process and should be clearly recorded.

It is understood that when a trainee is about to perform a procedure that is new or relatively new to them, they do not necessarily have to inform the patient; it would be accepted that they will be under supervision by their Consultant or senior medical colleague.

It would not be expected in an emergency situation to provide all of these details to the patient although it may be wise to inform them that a new procedure is proposed and the reasons why, without necessarily explaining all the potential hazards, uncertainties and lack of experience.

During the consent process, the patient should be offered the opportunity to ask any pertinent questions e.g:

- numbers of times that the clinician has performed the procedure in question.
- details regarding results
- details regarding problems, side effects, etc.

When a clinician (and their CD/Chair of Division) considers that they have:

- performed a reasonable number of procedures, considered sufficient
 - by their peers or a
 - body such as a Royal College

- become proficient

and as long as the efficacy and safety of a new IP is deemed suitable by NICE, it would then be reasonable for the clinician to:

- observe the normal arrangements for governance, consent and audit and to revert to providing the standard safety and risk information when obtaining consent.
- follow and apply NICE guidance to meet the needs of individual patients.

5.7.2 The clinician must ensure review of the IP is performed at an agreed pre-defined end-point – initially at 6 months, a year and presented to the Clinical Director/ Chair of Division and/or suitable governance forum. Also, proposed audits are to be completed and reported.

5.7.3 The Policy and External Guidance Assurance Committee will grant or refuse approval in the form of notification to the:

- Clinician
- Relevant Service Directorate and/ or Clinical Director/ Chair of Division.

The Policy and External Guidance Assurance Committee may stipulate certain conditions or contingencies.

The Service Directorate will also still need to supply approval for certain areas e.g. financial impact on the BHSCT.

5.7.4 When the Policy and External Guidance Assurance Committee do not approve an application, the Senior Manager from Risk and Governance will ensure that they will inform the:

- Clinician
- Relevant Service Directorate and/or Clinical Director/ Chair of Division.
- Medical Director.

5.8 Dissemination

Clinicians in Northern Ireland are encouraged to register an interest on the NICE website in order to receive updates on the development of IP guidance relevant to their HPSS practice.

5.9 Resources

None

5.10 Exceptions

None.

6.0 **MONITORING AND REVIEW**

Periodic audits of the governance process for approved IP applications will be part of the Standards, Quality and Audit department workplan.

7.0 **EVIDENCE BASE/REFERENCES**

For a detailed description of the required steps when introducing a new IP consult the following documentation:

- NICE Interventional Procedures programme in pdf format
- NICE Interventional Programme Manual
[Http://www.nice.org.uk/page.aspx?O=ipprogrammemanual](http://www.nice.org.uk/page.aspx?O=ipprogrammemanual)

8.0 **APPENDICES**

Appendix 1 Protocol Flowchart

Appendix 2 Notification of NEW Interventional Procedure Form

9.0 **NURSING AND MIDWIFERY STUDENTS**

Nursing and/or Midwifery students on pre-registration education programmes, approved under relevant 2018/2019 NMC education standards, must be given the opportunity to have experience of and become proficient in the **Policy for introduction of new Interventional Procedure**, where required by the student's programme. This experience must be under the appropriate supervision of a registered nurse, registered midwife or registered health and social care professional who is adequately experienced in this skill and who will be accountable for determining the required level of direct or indirect supervision and responsible for signing/countersigning documentation.

Direct and indirect supervision

- Direct supervision means that the supervising registered nurse, registered midwife or registered health and social care professional is actually present and works alongside the student when they are undertaking a delegated role or activity.
- Indirect supervision occurs when the registered nurse, registered midwife or registered health and social care professional does not directly observe the student undertaking a delegated role or activity. (NIPEC, 2020)

This policy has been developed in accordance with the above statement. Wording within this section must not be removed.

10.0 **EQUALITY IMPACT ASSESSMENT**

The Trust has legal responsibilities in terms of equality (Section 75 of the Northern Ireland Act 1998), disability discrimination and human rights to undertake a screening exercise to ascertain if the policy has potential impact and if it must be subject to a full impact assessment. The process is the responsibility of the Policy Author. The template to be complete by the Policy Author and guidance are available on the Trust Intranet or via this [link](#).

All policies (apart from those regionally adopted) must complete the template and submit with a copy of the policy to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the equality screening for the policy is:

Major impact	☐
Minor impact	☐
No impact	☐

Wording within this section must not be removed

11.0 **DATA PROTECTION IMPACT ASSESSMENT**

New activities involving collecting and using personal data can result in privacy risks. In line with requirements of the General Data Protection Regulation and the Data Protection Act 2018 the Trust considers the impact on the privacy of individuals and ways to mitigate against any risks. A screening exercise must be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this [link](#).

If a full impact assessment is required, the Policy Author must carry out the process. They can contact colleagues in the Information Governance Department for advice on Tel: 028 950 46576

Completed Data Protection Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the Data Protection Impact Assessment screening for the policy is:

Not necessary – no personal data involved	☐
A full data protection impact assessment is required	☐
A full data protection impact assessment is not required	☐

Wording within this section must not be removed.

12.0 RURAL NEEDS IMPACT ASSESSMENT

The Trust has a legal responsibility to have due regard to rural needs when developing, adopting, implementing or revising policies, and when designing and delivering public services. A screening exercise should be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this [link](#).

If a full assessment is required the Policy Author must complete the shortened rural needs assessment template on the Trust Intranet. Each Directorate has a Rural Needs Champion who can provide support/assistance.

Completed Rural Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

Wording within this section must not be removed.

13.0 REASONABLE ADJUSTMENT ASSESSMENT

Under the Disability Discrimination Act 1995 (as amended) (DDA), all staff/ service providers have a duty to make Reasonable Adjustments to any barrier a person with a disability faces when accessing or using goods, facilities and services, in order to remove or reduce such barriers. E.g. physical access, communicating with people who have a disability, producing information such as leaflets or letters in accessible alternative formats. E.g. easy read, braille, or audio or being flexible regarding appointments. This is a non-delegable duty.

The policy has been developed in accordance with the Trust's legal duty to consider the need to make reasonable adjustments under the DDA.

Wording within this section must not be removed.

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

28/02/2024

Policy Author

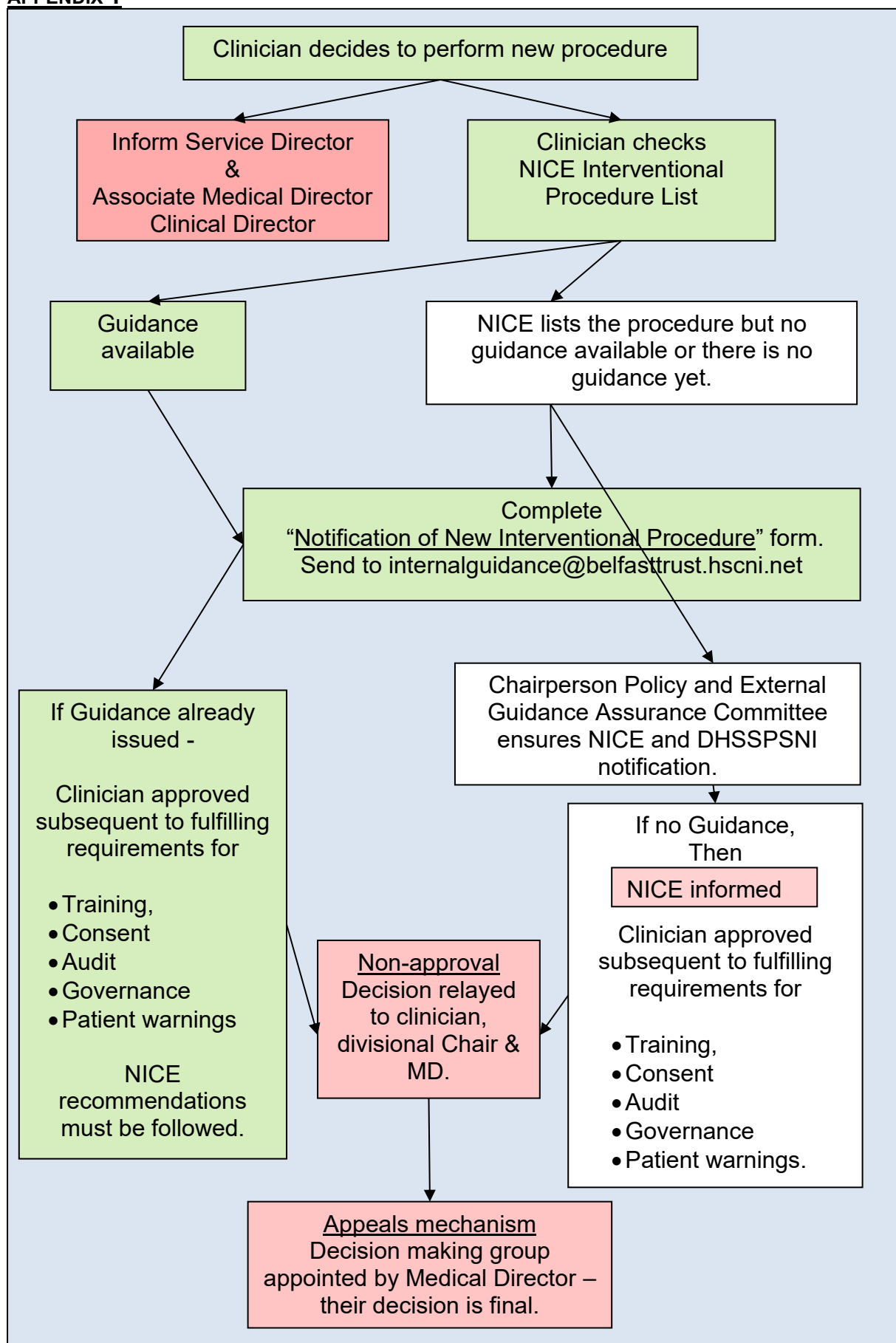
Date: _____

28/02/2024

Director

Date: _____

APPENDIX 1



Appendix 2 Notification of NEW Interventional Procedure Form

Notification of NEW Interventional Procedure	
TO BE COMPLETED BY CLINICIAN INTENDING TO USE PROCEDURE.	
Name	"[Click here and type]"
Job Title	"[Click here and type]"
Speciality	"[Click here and type]"
Service Directorate	"[Click here and type]"

1	How did you hear about the procedure?
	"[Click here and type]"
2	Is this procedure listed by NICE? <i>Provide details of any guidance.</i>
	"[Click here and type]"
3	Insert NICE IP number <i>if available.</i>
	"[Click here and type]"
4	Indicate stage of process within NICE. <i>If notified to NICE.</i>
	not in remit
	notification, listing and in progress,
	overview document produced
	consultation document issued,
	guidance issued.
5	Is this procedure new to you as a practicing clinician?
	"[Click here and type]"
6	Outline the experience, training and facilities needed by the clinician to perform this procedure and any perceived gaps.
	"[Click here and type]"
7	Is this procedure new to the BHSCT?
	"[Click here and type]"
8	What is the procedure called? <i>Please also include any synonyms.</i>
	"[Click here and type]"
9	The procedure details.
	"[Click here and type]"
10	Please give description of category(s) of patient.
	"[Click here and type]"
11	Please list the indications for the procedure <i>(the reasons that the procedure is done).</i>
	"[Click here and type]"

12	Please give a brief description of what the procedure involves.
	"[Click here and type]"
13	What are the intended benefits of performing the procedure?
	"[Click here and type]"
14	What are the main potential adverse effects of the procedure? <i>Please describe likely adverse effects, side effects, complications and any major risks (even if uncommon). If possible, estimate their incidence.</i>
	"[Click here and type]"
15	Does the procedure involve a device? <i>Describe.</i>
	"[Click here and type]"
16	Research and trials. <i>Provide details of trials/registries of this procedure currently in progress?</i>
	"[Click here and type]"
17	Please state any potential conflicts of interest, financial or otherwise, or any involvements in disputes or complaints, relevant to this procedure.
	"[Click here and type]"
18	Please provide the information that will be given to patients who are offered the procedures, ensuring that aspects highlighted in section 4.5.1 of the policy are covered.
	"[Click here and type]"
19	Please outline plans for auditing the procedure.
	"[Click here and type]"
20	Please confirm that the costs of introducing this procedure have / are been addressed within your service area.
	"[Click here and type]"

Signature Applicant	
Printed	
Date	

Signature Director / CD	
Printed	
Date	

Signature Service Mgr	
Printed	
Date	

TO BE COMPLETED BY POLICY AND EXTERNAL GUIDANCE ASSURANCE COMMITTEE

NOTIFICATION OF PROCEDURE

Indicate stage of process within NICE. *If notified to NICE.*

	not in remit
	notification, listing and in progress,
	overview document produced
	consultation document issued,
	guidance issued.

Is NICE Guidance available on this procedure?

"[Click here and type]"

If Yes, then does proposed use of procedure comply with guidance available?

"[Click here and type]"

Is the procedure listed on NICE? *If no guidance.*

"[Click here and type]"

If No, then notify NICE and DHSPSSNI of procedure (see guidelines)

Date NICE notified

"[Click here and type]"

Date Standards & Guidelines Unit, DHSPSSNI notified

"[Click here and type]"

APPROVAL OF PROCEDURE

Does the Clinician meet externally set standards of training?

"[Click here and type]"

Are the arrangements for Clinical Audit sound?

"[Click here and type]"

Are sufficient governance arrangements in place to ensure appropriate management of risk, complaints, negligence and redress?

"[Click here and type]"

Approval for procedure given *(include if dependant on certain criteria or actions)*

1. "[Click here and type]"

Signed by Co-Chair Trust Policy and External Guidance Assurance Committee



Date:

"[Click here and type]"