Policy Directive

The Safe Introduction of New Interventional Procedures and Clinical Innovations into Clinical Practice

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Functional Sub-Group:	Clinical Governance Corporate Governance
Summary:	The policy defines a process so that patients, clinicians and managers may be confident that new interventional procedures and clinical innovations are supported by evidence of efficacy, safety and effective resource utilisation. It also ensures that there is an agreed process for monitoring the outcomes of the new intervention and clinical innovations.
Approved by:	Director Clinical Governance and Risk
Consultation:	Clinical Quality Council
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Previous Review Dates:	Nil

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- Addition of reference to NSW Health Policy Directive NSW Framework for New Health Technologies and Specialised Services (GL2017_004)
- Addition of section 4, 'Emerging Technologies'.
- Additional reference added to section 7 to GL2017_004

Note: Sydney Local Health District* (SLHD) was established on 1 July 2011 following amendments to the Health Services Act 1997 which included renaming the former Sydney Local Health Network (SLHN). The former SLHN was established 1 January 2011, with the dissolution of the former Sydney South West Area Health Service (SSWAHS).

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1. Introduction

Sydney Local Health District (SLHD) invests significantly in supporting innovation across its facilities and health services and is dedicated to achieving positive patient outcomes through original changes and maximising service improvement.

Effective oversight is essential to ensure agreed processes are in place to monitor the outcomes of the new interventions and or clinical innovation.

The decision to undertake a new intervention or practice should take into consideration the structural requirements and clinical support systems required for safe implementation as outlined in the NSW Health (2002) *Guide to Role Delineation of Health Services*, and NSW Health (2002) *,* and the Australian Commission on Safety and Quality in Health Care Standard for Credentialing and Defining the Scope of Clinical Practice January 23, 2012.

In addition, the introduction of new devices for procedures requires prior evaluation and approval by the Therapeutic Goods Administration (Commonwealth Department of Health & Aged Care).

1.1 The Aim of this Policy

The aim of this policy is to ensure that patients, clinicians and managers have confidence that when clinicians and teams introduce new interventional procedures and clinical innovations to SLHD facilities that they are:

a) Supported by evidence of efficacy, safety and effective resource utilisation;
b) Capable of being supported technically and financially by the health service; and
c) Subject to an agreed process for monitoring outcomes.

1.2 The Risks addressed by this Policy

This policy aims mitigates the risk that new procedures or innovation is introduced at SLHD without the necessary oversight to ensure efficacy, benefit, and viability.

1.3 Exclusions

This policy does not cover those procedures involving changes to instrumentation or medical devices where no additional training is required or procedures that are undergoing experimentation or research.

Experimental or research procedures will need to have Research Ethics Committee approval prior to commencement and will have to fulfil the conditions laid down by the Ethics Committee.

2. General Principles

Regardless of the type of new interventional procedure or clinical innovation to be introduced or by whom, the following principles apply:

2.1 Health and Safety Considerations

The primary motivating concern of the actions described in this policy is the health and safety of consumers, clinicians, and the community.

2.2 Risk Management

This policy emphasises a risk management approach. The aim is to have a defined process for the introduction of new interventions and clinical innovations into clinical practice, and thereby reduce the risk of adverse outcomes. Systems for support during the early stages of the introduction of the procedure should be given consideration.

2.3 Ethical considerations

2.3.1 Ethics
Information regarding the safety, efficacy, current universal level of application and outcome results needs to be included with the application in accordance with the flowchart. All applications will be forwarded to the Ethics of Clinical Practice sub-committee for consideration of risks and benefits, and approval of information and consent documents.

2.3.2 Evidence Based Practice
Most techniques will have been evaluated or at least implemented elsewhere. When assessing a procedure the quality of any evaluation should be considered, as well as the particular conditions in which the procedure is being introduced. Where there is no evidence, a well-reasoned scientifically based argument in support of the proposed innovation is required.

Detailed references for supporting literature, including three high quality published studies evaluating this procedure or clinical innovation, where available, should be provided.

2.3.3 Conflicts of Interest
Conflicts of interest must be disclosed. There must be full disclosure of any relationship between the clinician and supplier concerned or other significant party or involvement in prior assessment of the procedure or clinical innovation and of any financial involvement that could result in a conflict of interest.

2.3.4 Patient Information and Informed Consent
Patient information and consent forms need to be developed at the time of application outlining the potential risks as accurately as possible and including any areas of uncertainty. The criteria for selection of patients for these procedures or clinical innovation should also be included in the information and consent.

Any adverse events are to be reported and the causes reviewed at the local level. These should be entered into the IIMS program. This includes any problem that occurs with any equipment, medical device or clinical product that is part of the new interventional procedure or clinical innovation.

2.4 Credentialing

The safe and effective introduction of new technology requires that skills, resources and infrastructure be aligned to ensure safety, effectiveness and efficiency for individual patients, care teams and the broader health service.

As well as assessing new procedures to ensure they are safe and that there are appropriate resources to support them, it is necessary to determine that individual clinicians and the clinical teams who will perform them are competent to do so, and properly supported. This is achieved through the District's credentialing systems. For medical staff, this is overseen by the Medical and Dental Appointments Advisory Committee ("MDAAC").

2.5 Resource Considerations

2.5.1 Training
Training needs to take into consideration all professionals who will be involved in the new procedure or clinical innovation. This includes junior medical staff, nursing staff, allied health, biomedical and support staff who may be involved in sterilising, maintaining or setting up the equipment.

2.5.2 Equipment and Supplies
New equipment and supplies which may be required for the procedure or clinical innovation are to be approved through the appropriate committees/channels. Systems to obtain and maintain the equipment and supplies are also to be defined.

2.5.3 Costs and Benefits
The introduction of a new procedure may have an opportunity cost. A new procedure or clinical innovation that will consume resources must be evaluated against the benefits of performing the procedure or clinical innovation and the effect of taking these resources from existing services.

Requirements in relation to resources (financial, space, equipment and staff) should be addressed as per the flowchart.

Proposals should be within the role delineation of a facility and considered within the context of the LHD Clinical Service Plan.

The financial implications regarding costs of a new procedure or clinical innovation will need to be seriously considered.

2.6 Monitoring

Any new procedures or clinical innovations need to be monitored after their introduction. Systems to collect data should be established prior to introduction and then reviewed by peer groups as well as an independent group.

3. The Process

All new interventional procedures and clinical innovations or new applications of current procedures must be formally approved as outlined below. Where a clinician is unsure whether a procedure or clinical innovation falls within the scope of this policy, advice should be sought from the clinical directorate and / or facility management in the first instance.

3.1 Applications should be discussed within the local department and facility stream. The Stream Director must be aware of any proposal and give support to proceed. Discussion with the facility Director of Medical Services is also recommended at this stage.

3.2 A business case must then be developed. The business case should include:

- a completed application form (Attachment One),
- costing details including one off and recurrent costs and
- other relevant information such as whether the proposal could have any impact on Theatre scheduling, staff rostering or the business of other units.

3.3 The Business case must be submitted to the relevant facility General Manager for consideration.

3.4 The General Manager at this stage will either give approval in principle to support the proposal or reject the proposal. Please note that as well as initial approval, General Managers must also give final approval which will only be provided pending satisfactory ethics and credentialing outcomes.

3.5 If approval in principle is given the application must then be submitted by the applicant to the Ethics of Clinical Practice subcommittee for review.

3.6 At the same time the applicant must liaise with the Director of Medical Services and, if it is considered to be necessary, submit a request to MDAAC for credentialing of those involved. Clinical privileges supported by MDAAC, and approved by the CE, are contingent on the device/procedure being granted Ethics and final General Manager approvals.

3.7 Once the application has been considered by the Ethics of Clinical Practice Sub-committee correspondence from them will be sent to the applicant and in addition to the General Manager.

3.8 Once the General Manager has received supportive advice from the Ethics of Clinical Practice sub-committee and MDAAC they will provide final approval for the proposal to progress.

3.9 It is recognised that in emergency situations a Health Professional may have a duty of care to provide a service for which the clinician has undergone training but is not yet formally credentialed. If this is the case then immediately following the procedure the clinician should notify administration and initiate the credentialing procedure if not already done so.

3.10 If a problem occurs with a medical device then a Medical Device Incident Report, must be submitted to the LHD Clinical Practice Sub Committee of the Ethics Committee, the TGA notified and the incident logged in IIMS.

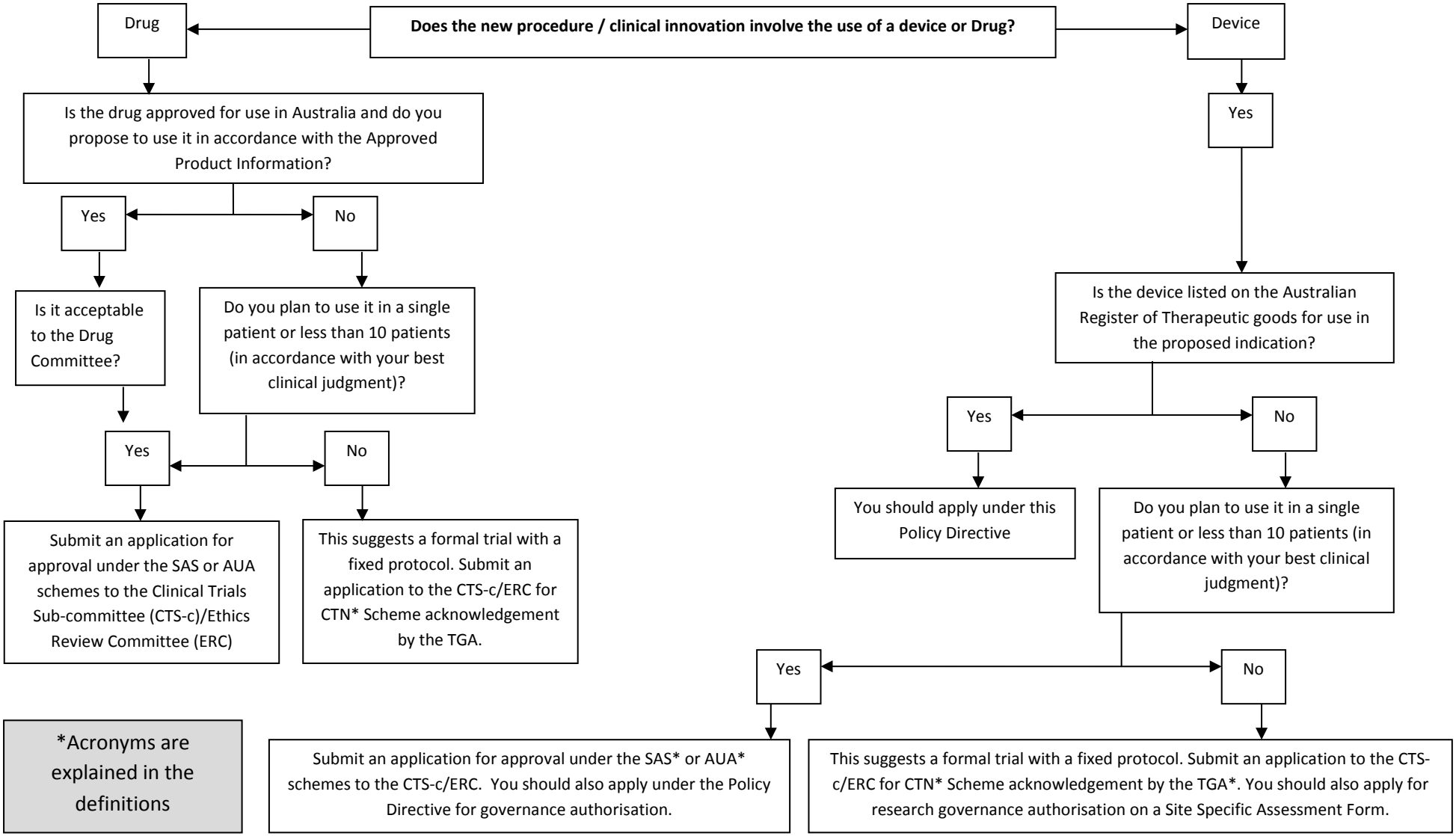
3.11 Progress reports are to be submitted to the Facility Director of Medical Services and Director of Clinical Governance at quarterly intervals.

3.12 A copy of applications and approved procedures is to be kept by the District and also at the relevant facility Executive Unit.

4. Emerging Technologies

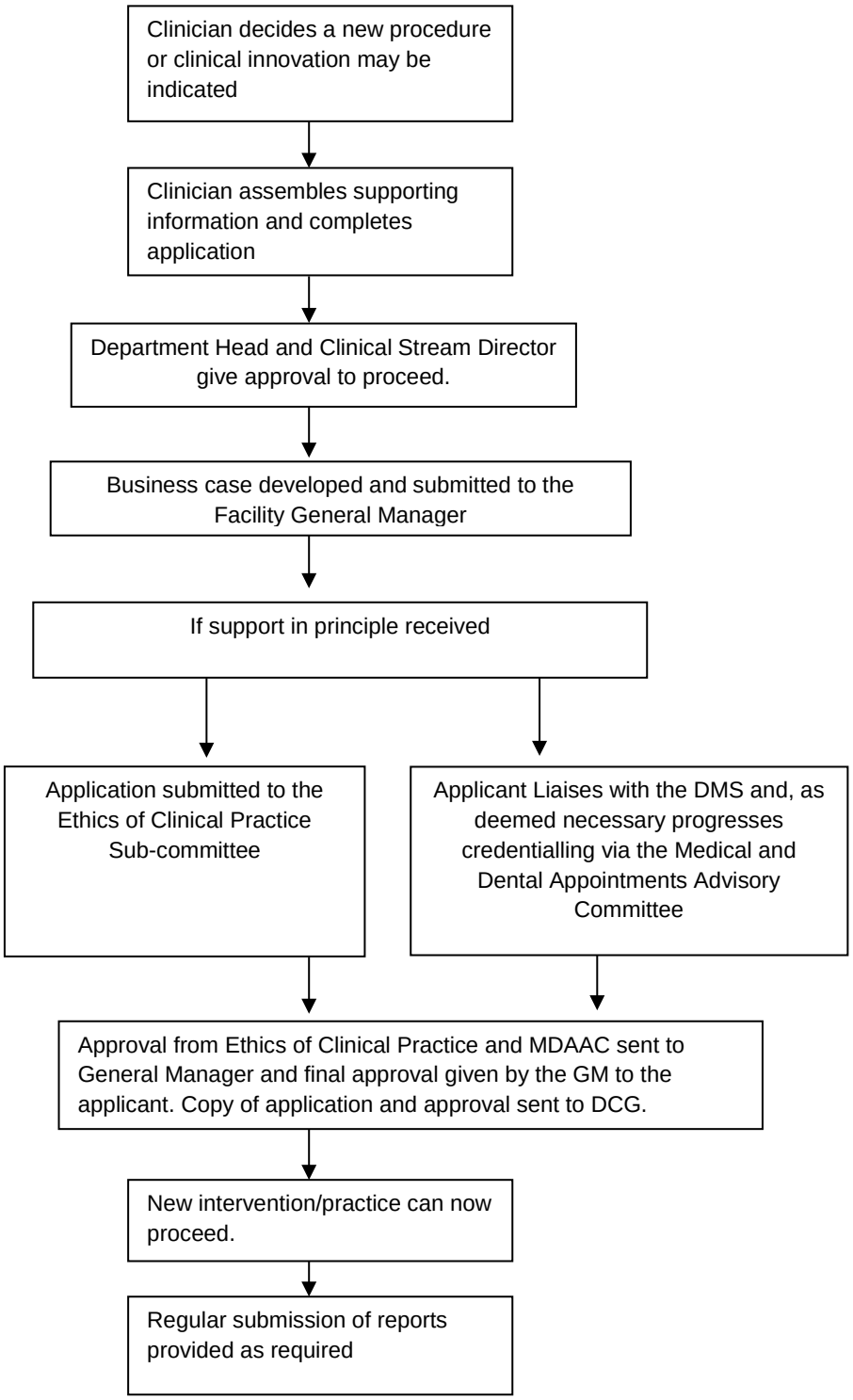
In accordance with NSW Framework for New Health Technologies and Specialised Services (GL2017_004), SLHD notes that there is a NSW process for state approval for emerging technologies whereby the NSW Ministry of Health will invite the submission of nomination forms annually for consideration by the NSW Ministry of Health's Health Technology and Specialised Services Strategic Forum. All emerging technology updates and nominations to the NSW Ministry of Health should be approved by the Chief Executive. Nominations will not be accepted from individual hospitals or clinicians.

- For more information and relevant forms, refer to the Policy Directive: NSW Framework for New Health Technologies and Specialised Services (GL2017_004)



*Acronyms are explained in the definitions

Flowchart for the Approval Process for New Interventional Procedures or Clinical Innovations



5. Definitions

Adverse Event – an unintended injury or complication resulting in disability and / or death and / or extended length of stay that is caused by the health care intervention and not by the patient's disease.

AUA – Authorised User Access

Clinician – a health clinician or health service provider (whether or not the person is registered under a health registration act) for example, nurses, medical clinicians, allied health clinicians, social workers etc.

Clinical Innovation- A clinical practice (therapeutic intervention, diagnostic procedure, new product, model of care or practice change) that is new to Sydney Local Health District, that improves patient care, and that:

- Is not research
- Is considered by a reasonable body of medical opinion to be significantly different from existing clinical practice
- Has associated potential risks that are not fully defined,
- Has credentialing, training or supervisory implications.

CTN – Clinical Trial Notification

CTS-c - Clinical Trials Sub-committee

ERC - Ethics Review Committee

Interventional Procedure – a procedure involving any invasive contact with the patient. Examples include surgical operations, endoscopy, certain radiological procedures, chemical or other therapies.

Medical and Dental Appointments Advisory Committee ("MDAAC") – A formal committee of the SLHD Governing Council charged with the oversight of senior medical staff appointments, credentials and privileges.

New Interventional Procedure – a procedure not previously performed within a Sydney Local Health District facility or one that is performed within a Sydney Local Health District facility and for which approval is sought for its performance at another facility.

SAS – Special Access Scheme

TGA – Therapeutic Goods Administration

6. Acknowledgements

This policy has been based on a model policy developed by Quality and Clinical Policy Branch, NSW Health (now obsolete). SLHD notes that whilst that document is no longer active, that the principles and aims remain relevant.

7. References and Resources

Australian Safety and Efficacy Register of New Interventional Procedures-Surgical ASERNIP-S REPORT NO. 58 July 2007: A review of policies and processes for the introduction of new interventional procedures

NSW Health PD2005_333 January 2005 Clinical Practice - Model Policy for Safe Introduction of New Interventional Procedures (now obsolete)

NSW Health, NSW Framework for New Health Technologies and Specialised Services (GL2017_004)

NSW Health *Guide to Role Delineation of Health Services* July 2002

The Australian Commission on Safety and Quality in Health Care, Standard for Credentialling and Defining the Scope of Clinical Practice January 23, 2012.

National Institute of Clinical Excellence (NICE). NHS The Interventional Procedures Programme – Process Guide, January 2009

Royal Australasian College of Surgeons / ASERNIP-S. (2002) *General Guidelines for Assessing, Approving and Introducing New Procedures into a Hospital or Health Service.* Royal Australasian College of Surgeons, Melbourne

Attachment One

Application Form: New Interventional Procedures and Clinical Innovations: The Safe Introduction of New Interventional Procedures and Clinical Innovations into Clinical Practice

Date:

Name of Individual or Group making application:

Department

Contact details
Tel.
Email

Proposed Operator (if different to Applicant):

Title

Department

Contact details
Tel.
Email.

LHD facility where the new interventional procedures or clinical innovation will be performed

OH&S issues

Conflicts of Interest
Declare any commercial interests that the applicants have in the new interventional procedure or clinical innovation.

New Intervention/ Innovation

Name of procedure:

Give a brief description of what is involved with the new interventional procedure or clinical innovation :

Has this new interventional procedure or clinical innovation been undertaken elsewhere in Australia or overseas? Y/N
If yes ,provide details

What is the scientific rationale for use of this new interventional procedure or clinical innovation?
List key sites nationally and internationally where this procedure is currently in use and any outcome data available

If the new interventional procedure or clinical innovation involves the use of a new medical device, has the device been approved for this purpose by the Therapeutic Goods Administration?

Does this new interventional procedure or clinical innovation replace a current procedure? Y/N
If yes, what advantages does this new interventional procedure or clinical innovation have over current procedures?

What are the financial implications of this new interventional procedure or clinical innovation?

PATIENT GROUP

Which patients are likely to benefit from this new interventional procedure or clinical innovation?

What are the potential benefits of this new interventional procedure or clinical innovation for the patients?
How will the new interventional procedure or clinical innovation change morbidity or mortality compared with other treatment options?

What are the possible adverse effects of this new interventional procedure or clinical innovation?

How will patients be selected for this new interventional procedure or clinical innovation?

Provide details of the proposed selection criteria

Has a Patient Information Sheet and Consent Form been developed?
Please attach

Projected patient use in the next twelve months

TRAINING AND CREDENTIALLING

Which Specialities might perform the new interventional procedure or clinical innovation?

What are the credentialing requirements?
Please list the following for those individuals who wish to be credentialled for this new interventional procedure or clinical innovation:
• the name/s
• qualifications
• evidence of relevant training and courses attended

References for supporting literature
3 high quality published studies evaluating this procedure
NHMRC levels of evidence provides a guide to assessment of the literature

Application Number:

Attachment Two

Progress report: New Interventional Procedures and Clinical Innovations: The Safe Introduction of New Interventional Procedures and Clinical Innovations into Clinical Practice

Date:

Submitted by:

Has the new interventional procedure or clinical innovation been introduced?

If so, how many patients have undergone the new interventional procedure or clinical innovation, for what indications and with what outcomes? (Please report by indication and include data on adverse events relating to the procedure. Attach any relevant data summaries)

Have the outcomes been measured?

Have there been any adverse outcomes or significant problems?
Were the adverse events reported to and discussed at a relevant morbidity or mortality meeting?

Have any clinical, resource or credentialing issues been identified?

Will the new interventional procedure or clinical innovation continue to be employed?

Signature and Date