SESLHD POLICY COVER SHEET

NAME OF DOCUMENT	New or altered interventional procedures, technologies including devices, implants, point of care (POC) diagnostic machines and treatments – safe introduction into clinical practice
TYPE OF DOCUMENT	Policy
DOCUMENT NUMBER	SESLHDPD/286
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LEVEL OF EVIDENCE	National Standards and Quality Health Services Standards: Standard 1 – Clinical Governance NSW Ministry of Health Guideline GL2022_012 – New Health Technologies and Specialised Services
REVIEW DATE	March 2027
FORMER REFERENCE(S)	SESIAHS Area Policy Directive PD 007: Interventional procedures – safe introduction into clinical practice NSW Health Policy Directive PD2005_333 Clinical Practice – Model Policy for Safe Introduction of New Interventional Procedures (rescinded 2014)
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director, Clinical Governance and Medical Services
AUTHOR	Director, Clinical Governance and Medical Services
FUNCTIONAL GROUP(S)	Clinical Governance
POSITION RESPONSIBLE FOR THE DOCUMENT	Director, Clinical Governance and Medical Services SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au
KEY TERMS	New interventions, altered interventions, new interventional procedures, altered interventional procedures, new pathology tests, new technologies, devices and implants, point of care (POC) diagnostic machines, altered technologies, new treatments, altered treatments; safe introduction into clinical practice.

SESLHD POLICY COVER SHEET

SUMMARY	This procedure provides a systematic approach to gaining approval for the implementation of new/altered interventional procedures, technologies including devices, implants, point of care (POC) diagnostic machines and treatments An application form (link) is to be completed by the applicant clinician with required attachments. Applicants may also be requested to complete progress reports, and a final report after 12 months for approval for ongoing use. These templates are also located in the above link. Refer to: Appendix A for the New Intervention Assessment Form Appendix B for the New Intervention Assessment Process Urgent requests for approval will **ONLY be actioned in cases of genuine clinical urgency** from the CQC/CE out of session.

1. POLICY STATEMENT

South Eastern Sydney Local Health District (SESLHD) must ensure that all new or altered interventions, diagnostic machines, pathology tests, interventional procedures, technologies and treatments are subject to appropriate assessment prior to their introduction into clinical practice.

The review and assessment process will take into account a range of issues relating to patient safety and quality of care, scientific evidence, cost and resource implications.

2. PURPOSE AND SCOPE

The purpose of this policy is to assist clinicians introduce new and/or altered interventional procedures, diagnostics machines, pathology tests, technologies and treatments (hereafter 'new interventions') by providing a standard process for assessment and approval, to ensure that patients, clinicians and managers can be confident that new interventions are supported by evidence of efficacy, patient safety and effective resource utilisation.

2.1 This policy applies to:

2.1.1 New interventions which are TGA-approved and proposed for introduction into clinical practice in a SESLHD facility – i.e. the intervention has not previously been used anywhere within SESLHD.

2.1.2. New interventions that already occur in one SESLHD facility, but where approval is sought to expand the intervention to other SESLHD facilities.

2.1.3. New interventions with alterations that will result in *significant variation* to an existing clinical procedure, technology or treatment already conducted within an SESLHD facility, such that the variation is likely to adversely impact on efficacy, safety or cost effectiveness, or the impact on efficacy, safety or cost is unknown, and needs to be formally evaluated.

2.1.4. New interventions which are NOT approved by TGA AND which meet the following requirements:

- A comparable overseas agency (in Europe or North America e.g. the FDA) has approved the intervention
- There is enough literature supporting its safety and effectiveness compared to existing approved interventions
- Approval has been obtained from the TGA under the Special Access Scheme (SAS).

2.1.5 The introduction of any new pathology tests or POC pathology testing machines. This includes: any machines in a location that has previously not had a POC machine and any machines that provide an additional test to what has previously been available in a location.

2.2 This policy does not apply to the following:

2.2.1 New interventions that require state-wide or national planning approval (for example, low volume, high-cost interventional procedures or treatments that require concentrated clinical expertise, or which require significant capital investment). These interventions remain under the jurisdiction of the Ministry of Health.

2.2.2. New or altered interventions (not approved by the TGA) that are experimental in nature and require introduction in a research (clinical trial) setting with approval by an appropriately constituted Human Research Ethics Committee (HREC).

2.2.3. New interventions considered by an attending clinician to be required urgently to prevent or minimise harm to a patient.

2.2.4. New medications, as these fall under the jurisdiction of the SESLHD Drug and Quality Use of Medicines Committee.

2.2.2 Other devices or prostheses that while not classified as a new intervention or procedure are a new model or type of device/prosthesis not currently in use in the hospital. Under these circumstances, a facility-based assessment of the utility of implementing the new device or prosthesis should be made. This may require referral to local committees or application to the General Manager.

2.3. Personalised Medical Devices & Custom made prostheses

Whether a personalised or custom-made prosthesis requires a NIAP application depends on a number of factors. Appendix One (1) sets out the TGA decision tree for personalised medical devices and should be used to determine whether a device may be a patient matched or custom-made device.

Patient matched medical devices do not require a NIAP application where the generic device is currently in use in the hospital. If not in use, a NIAP application should be made;

Custom made medical devices that are not made via 3D printer do require a NIAP application;

Custom prostheses made with 3-D printers. As a general principle, these should be approved for use only as part of a clinical trial which has been approved by a Human Research Ethics Committee. However, where there is no off-the-shelf prosthesis available in Australia, AND where the anticipated number of cases in

SESLHD per year is less than 3 patients only, AND where the use of a 3-D printer prosthesis is likely to result in an improved functional outcome for the patient, an application under this procedure may be considered on a case-by-case basis.

If a clinician, manager, or director is unsure whether an intervention falls within the scope of this policy, advice should be sought from the facility DMS.

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3. TARGET AUDIENCE

This procedure applies to clinical staff who are proposing a new or altered clinical intervention or diagnostic machine and any staff involved in the implementation of new interventions. All staff have an obligation to ensure that any new or altered intervention in which they are involved has been appropriately authorised.

4. PRINCIPLES

The following are principles that will be taken into account for each application.
The overarching consideration of this Policy is to ensure the health and safety of patients, clinicians and health service staff.

Conflicts of interest	Any conflicts of interest must be disclosed. There must be full disclosure of any relationship between the clinician and supplier(s) concerned, or other significant party involved in the procedure. Any involvement in a prior assessment of the intervention or any financial association that could result in a conflict of interest must be disclosed.
Costs and benefits	The introduction of a new/altered intervention, pathology test or diagnostic machine may have an opportunity cost. A new intervention that will use resources must be evaluated against the benefits of performing the intervention, and the effect of taking these resources from existing services.
Equipment and supplies	New equipment and supplies which may be required for the new intervention must be approved by the appropriate facility-authority.

Ethics	Information regarding the current use of the intervention and the results of trials and other research findings should be provided as part of the application. If the new intervention is approved by the Therapeutic Goods Administration (TAG) the application can proceed as above. If the new intervention is not TGA approved, a research application must be made to a relevant Human Research and Ethics Committee (HREC) for approval. If the new intervention is in a grey area and not subject to TGA regulation (e.g. 3D printer applications), a research application must be made to an appropriate HREC for approval.
Evidence based practice	Most techniques will have been evaluated or implemented elsewhere, and the assessment of the procedure needs to consider the quality of the evidence provided.
Monitoring	Any new/altered intervention and diagnostic machine must be monitored after its introduction. Systems to collect data should be established prior to introduction and assessed as part of the application.
Patient information and informed consent	Patient information and consent forms may need to be developed at the time of the application outlining as accurately as possible any potential risks, including any areas of uncertainty. The criteria for selection of patients for the interventions should also be included in the information and consent documentation.
Risk management	This Procedure emphasises a risk management approach. The aim is to have a clearly defined process for the introduction of new/altered interventions into clinical practice, and thereby reduce the risk of any incident occurring. Systems for support during the early stages of introduction of the intervention should be given consideration.
Training	Training needs to take into consideration all professionals who will be involved in the new/altered intervention. This includes junior medical staff, nursing staff, allied health as well as biomedical and support staff who may be involved in sterilising, maintaining, or setting up any new equipment.

New interventions must be appropriate to the role delineation of the facility for which approval is sought, and consistent with the current SESLHD Health Care Services and Strategic Plans.

5. CREDENTIALING AND SCOPE OF PRACTICE

Credentialing of and scope of practice for senior medical staff for the use of new technologies, will be overseen by the Director, Clinical Governance and Medical Services (DCG&MS) and the Credentials sub-committee of the SESLHD Medical and Dental Appointments Advisory Committee (MDAAC).

6. PROCEDURE

Proposals for new or altered interventional procedures, technologies or treatments (refer sections 2.1 and 2.2 above) link to form below: http://seslhnweb/Forms_and_Templates/Forms/default.asp should be assessed initially through the relevant Facility Department/ Clinical Program/Service Line where a decision is made together with the Facility DCS, regarding what level of endorsement/approval is required:

6.1 Facility level (General Manager)

6.1.1 If the required decision relates to a minor alteration of an existing procedure, technology or treatment of proven safety and effectiveness that is manageable within existing resources, the Facility General Manager may approve the application and is not required to seek LHD approval. The GM may seek a facility business case and/or further advice from the CSMC and may limit the number of procedures or period of time the application is approved for.

6.2 LHD level (Chief Executive)

6.2.1 If the intervention requires Chief Executive approval (refer to section 2.2) the facility DCS sends the application to Clinical Governance Medical Services Directorate SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au before the GM signs off.

6.2.2 Clinical Governance and Medical Services Directorate will distribute to the relevant clinical streams for clinical review and to the Director, Clinical Governance and Medical Services to review for credentialing and scope of practice requirements. Advice will be returned to the GM.

6.2.3 If the GM supports the application, the signed application is sent to Clinical Governance and Medical Services Directorate and checked for completeness before it is sent with agenda papers to the SESLHD Clinical and Quality Council for

discussion and **approval (by the Chief Executive).**

6.2.4 Clinical Governance and Medical Services will ensure that the CQC decision is communicated to the applicant and to the Facility.

6.2.5 Once an intervention/procedure has been approved, the applicant will be required to provide regular progress updates on the experience with the new intervention. Progress reports should be forwarded to Clinical Governance & Medical Services Directorate, using the templates located; and sent to: SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au The frequency and duration of the reporting period, and the specific reporting requirements will be determined by the CQC. After a 12-month period a final report must be completed to be considered by the CQC for ongoing use of the intervention/procedure as business as usual.

7. RESPONSIBILILITIES

New interventions, tests and diagnostic machines will be introduced into SESLHD according to a defined process, which considers safety, efficacy and cost effectiveness.

A register of applications and approved procedures will be maintained by Clinical Governance and Medical Services Directorate.

The CQC will be responsible for ensuring that the review of all new applications considers the principles outlined in Section 4 above. Should additional information be required to make a determination, external advice may be sought as part of the review/assessment process.

The monitoring requirements for the introduction of new/altered procedures will be outlined in the approval letters issued on behalf of the Chief Executive.

Staff will be delineated clinical privileges for the introduction of a new interventional procedure only following the approval of the intervention at a District level.

8. DEFINITIONS

New intervention: any interventional procedure, technology or treatment (including the use of medical devices, POC diagnostic machines, implants and processes of clinical management) which is entirely novel, substantially different, has not been available previously, requires training or new process/es development from the alternative (which may or may not already being conducted in an SESLHD facility), and which has the potential to impact upon patient safety, efficacy and/or cost effectiveness.

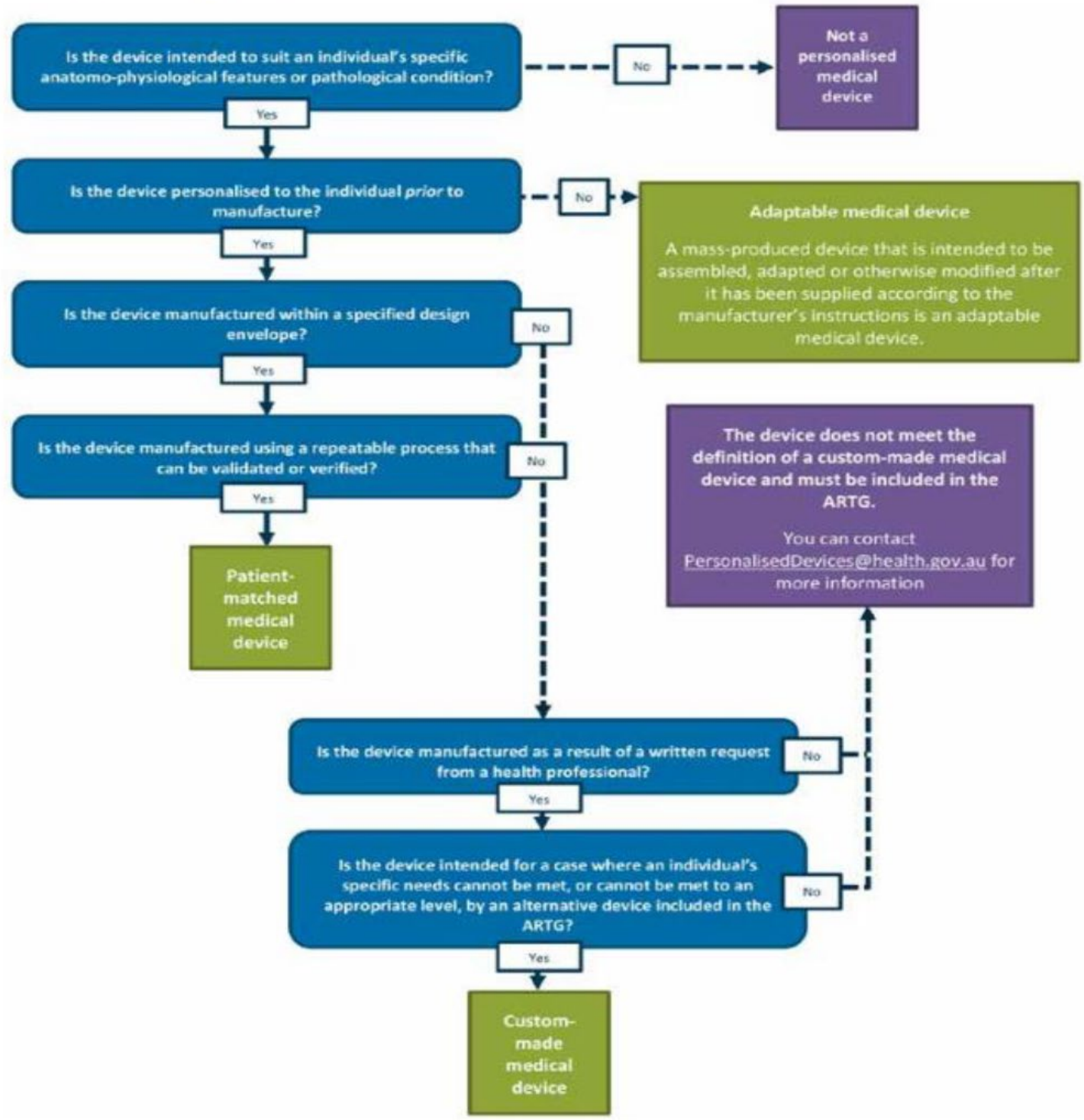
9. REFERENCES

- National Institute for Health and Clinical Excellence (2009). Interventional Procedures Programme: process guide. London, NICE.
- NSW Ministry of Health Policy Directive PD2020_047 - Incident Management Policy
- NSW Ministry of Health Guideline GL2022_012 - New Health Technologies and Specialised Services

10. VERSION & APPROVAL HISTORY

Date	Version No.	Author and approval notes
July 2015	0	Vanessa Paterson, Clinical Governance Unit
April 2015	1	Changes endorsed by Executive Sponsor
October 2017	2	Changes made by Author endorsed by Executive Sponsor
Dec 2017	3	Changes in 6. Procedure – Added a new point (10) by Author
Feb 2019	4	Update by George Rubin and Sarah-Jane Messum – streamlining the procedure and rendering consistent with the NSW Health GL2018-023.
July 2019	5	Updated by Jo Karnaghan and George Rubin – included an additional clause Custom-made prosthesis. Approved by CQC 10 July 2019
October 2019	6	Replaced Medical Executive Directorate with Clinical Governance and Medical Services Directorate and District, Director Medical Services to Director, Clinical Governance and Medical Services
June 2021	7	Minor review. New paragraph 2.2.5 added to clarify definition of items that don't require approval under this procedure. Approved by Executive Sponsor.
April 2022	8	Minor review: the removal of reference to Clinical Stream Management Committee due to it be discontinued; and updating of hyperlinks. Approved by Executive Sponsor
May 2022	8	Formatted and published by SESLHD Policy.
6 March 2024	8.1	Minor review. Updated definition in 2.3 Personalised Medical Devices & Custom-made prostheses and included a personalised medical devices decision tree.

Appendix 1: Personalised medical devices decision tree



Appendix A: SESLHD New Intervention Application Form

Instructions for completing the New Intervention Application Form:

1. Save this template and complete all fields, providing as much detail as possible (use as much space as required to address the questions). If a field is not relevant, please note as being 'N/A'.
2. Ensure all relevant parties are consulted in the development of your application.
3. Attach all relevant supporting documentation when submitting your application
4. Ensure that the appropriate approvals (See Appendix A for the process flowchart including approvals) are obtained before submitting your application (electronic approvals / scanned signatures will be accepted.

For further advice on the application procedure, please contact Clinical Governance and Medical Services Directorate on 9540 8822 or via email: SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au

1. Details of the new or altered procedure, diagnostic, technology or treatment ('the intervention')

Title of the intervention:	
Date of application:	
Proposed site(s) of introduction:	

2. Applicant details

Name:	
Position:	
Department or Service:	
Contact Telephone:	
Email: ***Email will be the primary mode of communication unless otherwise indicated.***	

3. Description of the Service/Department/Location

Provide a brief statement regarding your service/ specialty, and why you wish to introduce this intervention	
What are the organisational benefits associated with the new intervention?	
How does performing this intervention fit with the recognised scope of the service and the designated level of service of the facility?	
What are the proposed governance arrangements for the intervention? ***Include the name and position of the person(s) responsible for managing/overseeing the intervention***	
Is the item on a NSW State contract or SESLHD local tender?	
Has the item been implicated in TGA Recalls?	

4. Description of the intervention

Provide a detailed overview of the intervention ***Ensure that you address any surgical and rehabilitation processes, additional equipment that is required, and any other relevant information. Attach the clinical protocol if one has been developed***	*For example: (delete the guideline information before submitting)* • *the process for patient selection (e.g. MDT, criteria led screening)* • *How will the patient enter the organisation (day surgery, clinic, DTW)?* • *Will the intervention be likely to have an impact on Emergency Department presentations?*

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	• *Is it expected that the patient will be an outpatient or inpatient?* • *Where is the procedure expected to be performed (OPD, procedure room, operating theatre, cath lab etc.)?* • *What is the expected LOS for the patient?* • *What is the expected disposition of the patient post procedure (PACU, ward, OPD, home)?* • *Will the patient require post intervention follow-up?* • *Is there an expectation that the activity undertaken by the new intervention will supersede current activities being undertaken?*
What is the expected number of interventions that will be performed each year?	*Please identify the number of patients, number of treatments and expected frequency of intervention e.g. 3 patients completed in a half day operating list every 2 months for a total of 18 patients per year.*
Has the proposed new intervention been submitted as a research project to a Human Research Ethics Committee (HREC)?	**Yes** **No** **If YES, please provide the name of HREC that has reviewed the project** ☐ ☐ ***Please attach a copy of all HREC and research governance documents (e.g. HREC Approval letter, National Ethics Application Form, Site Specific Assessment Form, and all documents approved by the HREC, curriculum vitaes of study personnel, and documentation of training and credentialing)***
Has the new intervention been reviewed by the Health Insurance Commission (HIC), Medical Services Assessment Committee (MSCA) or the Therapeutic Goods	**Yes** **No** **If YES, provide details, including any conditions placed on the use of the modality** ☐ ☐ ☐

Administration (TGA)? If the intervention involves use of a device, is the device listed on the Australian Register of Therapeutic Goods (ARTG) for use in the proposed	**Intervention does not involve a device (go to next Section)** **Yes – listed on ARTG** **No – not listed on ARTG** **If YES, provide details from the ARTG**

intervention? Provide details of any previous briefs, risk assessments or minutes which have referenced or discussed this intervention.	**If NO, provide details of the research/trial setting** **N/A** ☐

5. Processes

Will the new intervention replace an existing procedure, technology or treatment?	☐ **Yes** ☐ **No** **If YES, what advantages does the new intervention have over current procedures? Provide details**
Has the proposed new intervention been used elsewhere? ***Information/details regarding the intervention may also be attached as an appendix***	☐ **Yes** ☐ **No** **If YES, provide details of where this has been used – either at another SESLHD site, within NSW, Australia or internationally.**
Have there been any reviews of the intervention by independent national bodies eg. ASERNIP'S, MSAC, NICE (United Kingdom), FDA (USA), National Institute of Clinical Studies. ***Information/details may also be attached as an appendix***	☐ **Yes** ☐ **No** **If YES, please provide details below**
Have any systematic reviews of the intervention been undertaken?	☐ **Yes** ☐ **No** **If YES, please provide details below**
Are there any other reviews and/or observational studies or clinical series reports relating to the intervention?	☐ **Yes** ☐ **No** **If YES, please provide details below**

6. Risks and Benefits

What are the expected benefits from the new intervention?	**For patients?**
	For the facility?
	For clinicians?
	For finances?
Are there any side effects or complications related to the new intervention? ***Consider how the new intervention compares to existing procedure(s) – if applicable.***	☐ **Yes** ☐ **No** **If YES, list all side effects or negative consequences**
Are there any potential risks to patients and/or staff, including infection, chemical or radiation safety issues? ***Consider occupational health and safety factors***	☐ **Yes** ☐ **No** **If YES, how will these factors (including OH&S) be addressed?**
Has a patient information sheet been developed to inform patients about risks/potential risks?	☐ **Yes** ☐ **No** **If YES, attach a copy** **Attachment number**

7. Quality and safety

Outline the plan for monitoring and evaluation of the new intervention?	
If the proposed new interventional procedure, diagnostic, technology or treatment carries with it a risk of adverse events, are there criteria for reviewing outcomes before any further procedures are performed?	☐ **Yes** ☐ **No** **If YES, please describe the process for review**

8. Staffing, resources and costs

Are there any expected costs associated with the new intervention? - Staffing - Education and or training of staff - Consumables / prosthesis / high cost disposables - Equipment / machines - Space	☐ **Yes** ☐ **No** **If YES, provide a business case for any initial and ongoing costs, and any expected savings.** The NIAP Business Case template can be located here. This is a standard business case noting that each facility may require additional information. Attachment number:
Have all staff groups which will be affected by the new intervention been consulted? ***For example, operating theatre staff, nursing, allied health, etc.*** ***Provide information on any consultations that have occurred***	☐ **Yes** ☐ **No**
Which specialists in your department have experience performing the	

intervention? ***Include information regarding appropriate credentialing and training for medical, nursing, allied health and technical staff. Provide any specific qualifications and credentials as an attachment if applicable***	
Do you have a specialist recognised for the teaching of the new intervention? ***Provide details of any specialists that are accredited to proctor (teach) other staff in the intervention/equipment. Provide any qualifications as an attachment if applicable***	☐ **Yes** ☐ **No** ☐ **N/A**
Outline the plan for developing the skills required for the new intervention for the clinical nursing and allied health staff. Is there an established credentialing process? ***Include details of timeframes, staff involved and the training process. Post-procedure care of the patient should also be considered***	☐ **Yes** ☐ **No** ☐ **N/A**

9. Conflict of interest

Do you have any relationship with the supplier of the device/intervention, or other significant party identified in this application?	☐ **Yes** ☐ **No** **If YES, provide details**
Have you been involved in any prior assessment of the device/intervention?	**Yes** **No** ☐ ☐ **If YES, provide details**

Do you (or a member of your immediate family) have any financial interest in the device/intervention supplier or manufacturer?	**Yes** **No** **If YES, provide details** ☐ ☐
Have you, or the organisation, received any financial incentive to use the proposed device/intervention?	**Yes** **No** **If YES, provide details**
Have you benefited by receiving any training, travel or accommodation related to the proposed device/intervention?	☐ **Yes** ☐ **No** **If YES, provide details**

10. Additional comments

Provide any additional information/comments relevant to your application	

11. FACILITY APPROVALS

Send completed application form and business case (if required) to the facility General Manager and send a copy to Clinical Governance and Medical Services Directorate SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au

			Signatures:
Applicant	**Name:**		
	Date:		
Department Head:	**Name:**		
	Date:		
	Comments		
Program/ Service Line Director	**Name:**		
	Date:		
	Comments		
Facility Director of Clinical Services	**Name:**		
	Date:		
	Comments:		

Facility General Manager:

GM Comments:

_____

_____

_____

_____

Is there a capped number of procedures or restricted period of time this can be used?
☐ **No** ☐ **Yes, detail:**

_____

Name:	
Date:	
Signature:	

Does this application require Chief Executive approval? ☐ **Yes** ☐ **No**
(refer to 2.2 of the New or altered interventional procedures, technologies including devices, implants, Point of Care (POC) diagnostics and treatments – safe introduction into clinical practice Procedure)

If yes, request applicant send signed form (electronic and/or scanned approvals are acceptable) and any supporting documentation via email to SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au

12. DISTRICT ADVICE

FOR COMPLETION BY DIRECTOR, CLINICAL GOVERANCE AND MEDICAL SERVICES

Credentialing and specific scope of practice requirements: YES ☐ NO ☐	
COMMENTS:	
Name:	
Date:	
Signature:	

FOR COMPLETION BY RELEVANT CLINICAL STREAM/S:

Stream	
Consideration	☐ clinically recommended ☐ clinically not recommended *Comments:*

13. DISTRICT APPROVALS

FOR COMPLETION BY THE CLINICAL GOVERANCE AND MEDICAL SERVICES DIRECTORATE

Date application received by Clinical Governance and Medical Services Directorate: _____

FOR COMPLETION BY CLINICAL AND QUALITY COUNCIL SECRETARIAT:

Clinical and Quality Council consideration	☐ Approved ☐ Not Approved *Comments:*	
Signature of Chairperson	**Name:**	
	Date:	
	Signature:	

FOR COMPLETION BY CLINICAL GOVERANCE AND MEDICAL SERVICES DIRECTORATE

Data applicant notified of outcome**:**_____

Copy of notification to be provided to the Facility General Manager and Director Clinical Services

FOLLOW-UP ACTIONS

Approval letter to applicant	Date:	
Progress reports:	Due	Received
First	Date:	Date:
Second	Date:	Date:
Third	Date:	Date:

Appendix B: SESLHD New Intervention Application Process

Applicant completes the New Intervention Application Form ensuring all relevant consultations have occurred and additional information is attached including clinical evidence and business cases as required. https://www.seslhd.health.nsw.gov.au/services-clinics/directory/seslhd-medical- services/new-interventions-assessment-process-niap

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Facility review and approvals: (section 11 of the form)
The application is reviewed for endorsement at facility level by:
1. The relevant Department Head
2. The Program/Service Line Manager
3. The Director of Clinical Services

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Does the application require Chief Executive Approval? *(refer to 2.2 of the New or altered interventional procedures, technologies including devices, implants, Point of Care (POC) diagnostics and treatments – safe introduction into clinical practice Procedure)*

If no, refer to the facility requirements – approval provided by the GM.

If yes, DCS sends the application to Clinical Governance and Medical Services (CG&MS) SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au

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CG&MS will share the application with the relevant clinical streams for clinical review and the Director, Clinical Governance and Medical Services for scope of practice and credentialing requirements.

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The GM reviews application, attachments and advice for approval.
If rejected, inform applicant.
If approved, inform applicant and request signed form be sent to Clinical Governance and Medical Services (CG&MS) via SESLHD- ClinicalGovernanceandMedicalServices@health.nsw.gov.au

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CG&MS staff check the application for completeness, log it in the NIAP records and forward it to the CQC for approval.

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Applicant notified of date of the expected CQC the application will be tabled at. Application tabled and discussed.
CQC approve or reject application. Clinical Governance and Medical Services Directorate advises the applicant, the Facility GM/s and DCS/s of the outcome, with any feedback and specific reporting requirements.