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

**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](mailto:SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au).

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

1. **Applicant details**

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

1. **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? |  |

1. **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?* * *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 Administration (TGA)? | **Yes  No**  **If YES, provide details, including any conditions placed on the use of the modality** |
| 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? | **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**    **If NO, provide details of the research/trial setting** |
| Provide details of any previous briefs, risk assessments or minutes which have referenced or discussed this intervention. | **N/A** |

1. **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** |

1. **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** |

1. **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** |

1. **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](https://www.seslhd.health.nsw.gov.au/sites/default/files/2019-02/NIAP%20Business%20Case%20Template%202019.docx) 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** |

1. **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** |

1. **Additional comments**

|  |  |
| --- | --- |
| Provide any additional information/comments relevant to your application |  |

1. **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-](mailto:SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au) [ClinicalGovernanceandMedicalServices@health.nsw.gov.au](mailto: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-](mailto:SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au) [ClinicalGovernanceandMedicalServices@health.nsw.gov.au](mailto:SESLHD-ClinicalGovernanceandMedicalServices@health.nsw.gov.au)

1. **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:* |

1. **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:  First  Second  Third | Due | Received |
| Date:  Date:  Date: | Date:  Date:  Date: |