**Introduction of New Therapeutic Intervention or Medical Device Request Form**

*Health Service Establishments Act 2006*

###### **Form 3** Version 1.0 October 2022

## Innovations in both technologies and treatments can enable establishments to build clinical services to meet changing consumer demand and improve the effectiveness and efficiency of care delivery.

## The introduction of new Therapeutic Interventions or Medical Devices to a licensed private Health Service Establishment (HSE) must first be approved by the Department of Health.

## [Please click here to see Advisory Notice 4/20 for further information](https://doh.health.tas.gov.au/__data/assets/pdf_file/0020/400673/Advisory_04_2020_Introduction_to_Medical_Devices_050320_V0.3.pdf).

# Instructions

1. Please complete the entire form. If a question is not applicable, write N/A
2. It is recommended that the form is completed electronically and must include a signature.
3. Return the completed form, with supporting documentation, to hselicensing@health.tas.gov.au

# Assessment process

The Regulation, Licensing and Accreditation (RLA) Unit aim to process all New Therapeutic Intervention or Medical Device requests within 28 working days of receipt of the request form. However, this is very much dependent on the complexity of the new intervention or medical device and the supporting documentation/evidence provided.

Please ensure you provide the necessary relevant information to allow your request to be accurately assessed in a timely manner.

All requests are first assessed by the Regulation, Licensing and Accreditation Unit. The final decision on whether the therapeutic intervention or medical device can be implemented is given by the Chief Medical Officer, Department of Health.

# Questions

If you have any questions, please contact the Regulation, Licensing and Accreditation Unit on

03 6166 3856 or hselicesning@health.tas.gov.au

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| **Health Service Establishment Details** |
| 1.1 | Facility name: | Click or tap here to enter text. |
| 1.2 | Facility address: | Click or tap here to enter text. |
| 1.3 | Licensee name: | Click or tap here to enter text. |
| **New Therapeutic Intervention / Medical Device details** |
| 2.1 | What is the name of the new Therapeutic Intervention / Medical Device you wish to provide? | Click or tap here to enter text. |
| 2.2 | What is the rationale for introduction of new Therapeutic Intervention / Medical Device? | Click or tap here to enter text. |
| 2.3 | For medical devices, what is the manufacturers information and contact?Please provide information on the registration of the device with the Australian Register of Therapeutic Goods (ARTG) | Click or tap here to enter text. |
| 2.4 | Type of patientsWho will be treated? Adults, children or both? If children are to be treated, include the age range. | Click or tap here to enter text. |
| 2.5 | Who is the lead specialist medical practitioner involved in implementing the new Therapeutic Intervention / Medical Device? | Click or tap here to enter text. |
| 2.6Paperclip with solid fill | What is the date you propose to commence?As soon as possible is not an acceptable answer.Attach the implementation plan that includes assessment of potential risks associated with implementation of the new Therapeutic Intervention / Medical Device and ongoing services | Click or tap here to enter text. |
| 2.7 | What is the number of patients to be treated?* Per session?
* Per day?
* Which days?
 | Click or tap here to enter text. |
| 2.8Paperclip with solid fill | What are the specific admission and discharge criteria for patients accessing this service?This should include identification of diversity and high-risk groups. Attach documented policy/procedure | Click or tap here to enter text. |
| 2.9 | Is the same/similar service involving the new therapeutic intervention/medical device provided in the public health system?If yes, where?Provide evidence of consultation with other providers, both interstate and international.Provide evidence of Health Technical Assessment (ie best practice guidelines, clinical pathways, decision support tools).Provide evidence of incorporation of ACSQHC’s clinical standards into policy documents and practice. | Click or tap here to enter text. |
| **Equipment** |
| 3.1 | Is additional equipment required for the service?If so, what type? | Click or tap here to enter text. |
| 3.2Paperclip with solid fill | What area/space will be used for storing the equipment?Highlight on a building plan and attach | Click or tap here to enter text. |
| 3.3Paperclip with solid fill | Do the medical personnel involved in the implementation already have qualifications/training in the use of the equipment or require training?Provide training details and/or training completion certificates and logbooks with caseload data.  | Click or tap here to enter text. |
| 3.4Paperclip with solid fill | Do other staff require training in using or implementing the equipment required?If yes, provide details of which staff have completed the training, the content of the training course and completion certificates.If no, provide a detailed plan of how the training needs will be addressed for various staff groups. | Click or tap here to enter text. |
| 3.5 | Is there any additional cleaning associated with the equipment?If yes, provide details of the cleaning scheduleIf no, provide details of the assessment to verify there are no additional requirements | Click or tap here to enter text. |
| **Instruments** |
| 4.1 | Are additional instruments required for the service?If yes, which ones? | Click or tap here to enter text. |
| 4.2 | Is there capacity within the current CSSD to reprocess the additional instruments?Provide details of the assessment to verify whether there is capacity. | Click or tap here to enter text. |
| 4.3Paperclip with solid fill | Is validation of the instruments required?Provide details of the assessment to verify whether validation required.If validation is required, attach the validation report. | Click or tap here to enter text. |
| 4.4 | Where will the additional instruments be stored? | Click or tap here to enter text. |
| **Consumables** |
| 5.1 | Are additional consumables (sterile and non-sterile) required for the service?If yes, provide details of consumables required | Click or tap here to enter text. |
| 5.2 | Where will the consumables be stored? | Click or tap here to enter text. |
| **Staffing** |
| 6.1 | Provide names of the medical practitioners and their credentials, who will be involved in provision of the new Therapeutic Intervention / Medical Device or service? | Click or tap here to enter text. |
| 6.2Paperclip with solid fill | Are additional training/competencies required for these medical practitioners?If yes, what training? Attach evidence of training/education attendance recordsWhat ongoing competency requirements are there?What is the frequency of this requirement?  | Click or tap here to enter text. |
| 6.3 | Will additional staff be required?If so, identify category and numbers required to support this new service e.g. RNs, ENs etc and any specific new roles. | Click or tap here to enter text. |
| 6.4Paperclip with solid fill | What additional/speciality qualifications / training / competencies are required for other staff?Attach evidence of training/education attendance recordsWhat ongoing competency requirements are there?What is the frequency of this requirement? | Click or tap here to enter text. |
| **Impact on other services** |
| 7.1 | Does the additional service require support from speciality clinical services (eg ICU, CCU and HDU)? If yes, describe | Click or tap here to enter text. |
| 7.2 | Does the additional service require support from other services in the facility? (eg radiology, pharmacy, pathology etc). If yes, describe | Click or tap here to enter text. |
| 7.3 | Have cleaning, waste management and maintenance requirements been assessed and planned for?If yes, provide the details. If no, provide details of how this will be assessed. | Click or tap here to enter text. |
| **Patient related** |
| 8.1 | Are there any clinical requirements that impact on patients? (eg adult/child patient separation)If yes, is there enough staff and physical space for this to occur? | Click or tap here to enter text. |
| 8.2 | Are there any environmental matters that impact on patient flow (e.g. parking, waiting area or post procedure recovery?) | Click or tap here to enter text. |
| 8.3Paperclip with solid fill | Attach a copy of patient information in relation to new service, including discharge information | Click or tap here to enter text. |
| 8.4Paperclip with solid fill | Attach a copy of the PROMS audit tool in relation to new service | Click or tap here to enter text. |
| 8.5Paperclip with solid fill | Attach feedback process in relation to new service | Click or tap here to enter text. |
| **Management / Governance** |
| 9.1Paperclip with solid fill | What are the risks associated with implementing the new service?Attach a copy of the Risk Assessment | Click or tap here to enter text. |
| 9.2Paperclip with solid fill | Has the additional service been approved by the Medical Advisory Committee?Attach meeting minutes where approval was granted | Click or tap here to enter text. |
| 9.3Paperclip with solid fill | Attach evidence of credentialing of clinicians specific to the new service | Click or tap here to enter text. |
| 9.4 | Has the additional service been reviewed by the Infection Control (IC) Committee? Where any recommendations made and have these been implemented?If the additional service has not been reviewed by the IC Committee, please provide rationale on why this is not necessary | Click or tap here to enter text. |
| 9.5 | What specific policies and/or procedures will impact this additional service? | Click or tap here to enter text. |
| 9.6Paperclip with solid fill | Have policies and /or procedures been drafted or updated to reflect the additional service?Attach draft policies, and/or updated policies/procedures (with changes highlighted) | Click or tap here to enter text. |
| **Licence** |
| 10.1 | Does your licence have any conditions that this may affect? | Click or tap here to enter text. |
| 10.2 | Will the maximum number of patients that may be treated at any one-time increase? | Click or tap here to enter text. |
| 10.3 | Will the maximum number of beds increase? | Click or tap here to enter text. |
| **Audit** |
| 11.1Paperclip with solid fill | Formal audit is required for every new therapeutic intervention/medical device implemented until such time that the new service is fully implemented.Provide evidence on inclusion of audit programme and audit tool.Please note the RLA Unit will also require periodic reporting and the timeframe will be advised once a full assessment of request has been completed. | Click or tap here to enter text. |
| **Other** |
| 12.1 | Any other relevant information? | Click or tap here to enter text. |

Indicates attachment required

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| **Declaration**  |
| I declare that all the information I have given on this request form is true to the best of my knowledge and belief. I understand this request, and information provided with it, may be distributed to relevant agencies for review and comment to assist with assessment of the request. |
| Print name:Click or tap here to enter text. | Position:Click or tap here to enter text. |
| Signature: Click or tap here to enter text. | Date:Click or tap to enter a date. |