**Canberra Health Services**

**Policy**

**Introduction of New Health Technology**

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| Purpose |

Canberra Health Services (CHS) must ensure all new health technologies are subject to appropriate assessment prior to their introduction into clinical practice in accordance with the *Therapeutics Goods Act 1989* (the Act)*.*

**Health Technologies** are defined in the Act and the *Therapeutic Goods (Medical Devices) Regulations 2002*. Refer to the **Definition of Terms** section for the full definition.

The purpose of this policy is to establish a process for the introduction of new health technologies in a CHS facility. The process will take into consideration a range of issues relating to patient safety and quality of care, as well as scientific evidence.

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| Section 1 – Scope |

This policy applies to clinical staff who are proposing a new health technology in a CHS facility, as well as any staff involved in the implementation of a new health technology.

* 1. **This policy applies to:**
		1. New health technologies which are Therapeutic Goods Administration (TGA) approved and proposed for introduction into clinical practice in a CHS facility (i.e., the technology has not been used anywhere else within CHS).
		2. New health technologies with modification and/or upgrades that will result in significant variation to an existing clinical procedure, technology or treatment already conducted within a CHS facility, such that the variation is likely to adversely impact on safety and efficacy, or the impact on safety and efficacy is unknown, and needs to be formally assessed.
		3. New health technologies which are **NOT** approved by the TGA **AND** approval has been obtained from the TGA under the Special Access Scheme (SAS).
	2. **This policy DOES NOT apply to:**
		1. New or altered health technologies (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. New health technologies considered by an attending clinician to be required urgently to prevent or minimise harm to a patient.
		3. New medications, as these fall under the jurisdiction of the CHS Drugs and Therapeutics Committee.
		4. Other devices or prostheses that while not classified as a new health technology 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.
		5. ACT Pathology, as there are already strict and rigorous governance processes embedded to meet regulatory requirements. This includes the development, use and implementation of health and in-vitro diagnostic technologies.

If a clinician, manager or director is unsure whether a health technology falls within the scope of this policy, advice may be sought from the Director of Healthcare Technology Management on **(02) 5124 8360** or via email at HTACSecretariat@act.gov.au.

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| Section 2 – Target Audience |

This policy applies to clinical staff who are proposing a new health technology in a CHS facility, as well as any staff involved in the implementation of a new health technology.

All CHS staff have an obligation to ensure that any new health technology in which they are involved has been appropriately authorised.

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| Section 3 – Decision making process |

The CHS Health Technology Advisory Committee (HTAC) coordinates the adoption of health technologies that are new to CHS. It also coordinates the adoption of modifications to, and upgrades of, existing health technologies where the modification and/or upgrade will result in significant variation and therefore deemed as new to CHS.

For the health technology to be considered by HTAC, it must have already:

* Completed the Medical Services Advisory Committee (MSAC) assessment and approval process or is subject to the in-principal approval of the MSAC; and
* Been registered with the TGA.

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| Section 4 – Roles and Responsibilities |

**4.1 Chair of HTAC**

* Ensure that HTAC functions are compliant with the HTAC Terms of Reference (refer to Attachment A).
* Ensure the HTAC Secretariat maintains complete records of the *Introduction of New Health Technology Application* process for each submission and ensures those records are available for auditing purposes.
* Ensure HTAC members conduct their responsibilities to a high standard and in a timely manner. Meetings of HTAC should be conducted on at least a monthly basis.
* The Chair may convene an executive meeting where, in the opinion of the Chair, a matter should not reasonably wait for the next scheduled meeting of HTAC.

**4.2 HTAC Members**

* Provide advice in accordance with the HTAC Terms of Reference.

**4.3 HTAC**

* Oversees the coordination and adoption of health technologies that are new to CHS, including modifications to, and upgrades of, existing technologies where the modification and/or upgrade will result in significant variation and therefore deemed as new to CHS.
* HTAC has accountability for ensuring it reviews comprehensive documentation and seeks relevant third-party advice regarding each HTAC application for the introduction of new health technology in a CHS facility.
* HTAC will not consider incomplete applications or make a recommendation about a new health technology while it is waiting for further information.

**4.4 HTAC Sub-Committee**

* Conduct extraordinary (unplanned) out of session review of an *Introduction of New Health Technology Application* (refer to *Section 7 – HTAC Sub-Committee*).

**4.5 Credentialing and Scope of Practice**

* Credentialing of and scope of practice for senior medical staff for the use of new health technologies will be overseen by the Executive Director of Medical Services and the CHS Medical and Dental Appointments Advisory Committee (MDAAC) – refer to the *Credentialing and Defining the Scope of Clinical Practice for Senior Medical and Dental Practitioners Procedure.*

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| Section 5 – Principles |

The overarching consideration of this policy is to ensure the health and safety of patients, clinicians and health service staff. The following are principles that will be taken into consideration for each *Introduction of New Health Technology Application*.

**5.1 Conflicts of Interest**

* Any conflicts of interest must be disclosed via the CHS Conflict of Interest Declaration Form in line with the Conflict of Interest Procedure.
* All Conflict of Interest Declaration Forms are to be emailed to CHS.SERBIR@act.gov.au **PRIOR** to submitting an application.
* There must be full disclosure of any relationship between the clinician and supplier(s)/sponsor(s) concerned, or other significant parties involved in the health technology.
* Any involvement in a prior assessment of the health technology and/or any financial association that could result in a conflict of interest must be disclosed.

**5.2 Ethics**

* Information regarding the current use of the health technology and the results of the trials and other research findings should be provided as part of the application.
* If the new health technology is approved by the TGA the application can proceed as above.
* If the new health technology is not TGA approved, approval must be obtained from the TGA under the SAS **PRIOR** to submitting an application.

**5.3 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.
* Best practices and guidelines should be developed to ensure appropriate use, training and ongoing monitoring of the new health technology.

**5.4 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 health technology should also be included in the information and consent documentation.

**5.5 Risk Management and Monitoring**

* This policy emphasises a risk management approach.
* The aim is to have a clearly defined process for the introduction of new health technology into clinical practice, and thereby reduce the risk of any incident occurring.
* Systems for support during the early stages of introduction of the health technology should be given consideration (i.e., changes to infrastructure, power and data requirements, additional and/or special staff or training to support introduction at early stages such as Laser Safety or MRI Safety, etc.)
* Any new health technology must be monitored after its introduction.
* Systems to collect data should also be established prior to introduction and assessed as part of the application process, if applicable.
* Additional information, including tools and templates, is available on the [Risk Management HealthHub](https://actgovernment.sharepoint.com/sites/Intranet-CHS/SitePages/Risk-management.aspx) page. Support may also be sought from the Risk Management team on **(02) 5124 9551**.

**5.6 Education and Training**

* Training needs to take into consideration all professionals who will be involved in the new health technology.
* 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.
* Continuous professional development opportunities should also be considered for staff to stay updated with the evolving technology and its application.

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| Section 6 – Introducing New Health Technology process |

New health technologies will be introduced into CHS facilities according to a defined process, which considers safety and efficacy.

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

Overview of the application process:



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| Section 7 – HTAC Sub-Committee |

A HTAC Sub-Committee can be formed to make recommendations in relation to the introduction of a new health technology in response to an urgent need prior to the next HTAC meeting. This **ONLY** applies in cases of genuine clinical urgency.

The HTAC Sub-Committee must consist of the following HTAC members:

* Executive Director, Medical Services – Canberra Hospital
* Executive Director, Medical Services – North Canberra Hospital
* Medical Director, Quality, Safety, Innovation and Improvement
* Director, Healthcare Technology Management
* Executive Director and/or senior clinician from Division responsible for application.

Approvals must be tabled at the next HTAC meeting for the purposes of governance and notification to the Committee.

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| Evaluation |

**Outcome**

Introduction of new health technologies at CHS facilities will occur in accordance with this policy and the *Introduction of New Health Technology Application* process.

**Measures**

Regular reporting to the CHS Operational Clinical Executive Meeting for cross divisional awareness.

Annual review of all the HTAC *Introduction of New Health Technology Application Forms* and documented approval process.

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| Related Policies, Procedures, Guidelines and Legislation |

**Policies**

* Work Health and Safety
* Informed Consent (Clinical)
* Asset Management

**Procedures**

* Infection Prevention and Control
* Review of Credentials and Defining of Scope of Clinical Practice prior to the Introduction of New Health Technologies
* Managing a Conflict of Interest

**Legislation**

* *Therapeutic Goods Act 1989*
* *Health Records (Privacy and Access) Act 1997*
* *Human Rights Act 2004*
* *Work Health and Safety Act 2011*
* *Carers Recognition Act 2021*

**Other**

* Australian Charter of Healthcare Rights
* National Safety and Quality Health Service (NSQHS) Standards
* National Safety and Quality Digital Mental Health (NSQDMH) Standards

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| Definition of Terms  |

**Health Technology**

*‘A* ***medical device*** *is:*

1. *Any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:*
	1. *Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;*
	2. *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;*
	3. *Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;*
	4. *Control or support of conception;*
	5. *In vitro examination of a specimen derived from the human body for specific medical purpose*

*And that does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or*

*(aa) any instrument, apparatus, appliance, software, implant, reagent, material or other article specified under subsection (2A); or*

*(ab) any instrument, apparatus, appliance, software, implant, reagents, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or*

1. *An accessory to an instrument, apparatus, appliance, software, implant, reagent, material or other article covered by paragraph (a), (aa) or (ab).*
2. *A system or procedure pack’*

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| Search Terms |

Technology, Introduction of New Technology, Health Technology Advisory Committee, HTAC

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| Attachments |

Attachment A: HTAC Terms of Reference

Attachment B: Introduction of New Health Technology Application Form

**Disclaimer**: *This document has been developed by Canberra Health Services specifically for its own use. Use of this document and any reliance on the information contained therein by any third party is at his or her own risk and Canberra Health Services assumes no responsibility whatsoever.*

*Policy Team ONLY to complete the following:*

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| --- | --- | --- | --- |
| *Date Amended* | *Section Amended* | *Divisional Approval* | *Final Approval*  |
| *16/10/2023* | *New Document* | *Medical Services Group* | *CHS Committee* |
|  |  |  |  |

*This document supersedes the following:*

|  |  |
| --- | --- |
| *Document Number* | *Document Name* |
| *CHS21/456* | *Introduction of New Health Technology* |
|  |  |

Attachment A: HTAC Terms of Reference

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| **TERMS OF REFERENCE**Health Technology Advisory Committee |
| **Purpose** | This document sets out the Terms of Reference (TOR) for the Canberra Health Services (CHS) Health Technology Advisory Committee (HTAC), established to coordinate the territory-wide adoption of health technologies that are new to CHS. The Committee also coordinates the territory-wide adoption of modifications to, and/or upgrades of, existing health technologies at CHS. **Health Technologies** are defined in the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Devices) Regulations 2002*.  |
| **Reporting mechanism** | HTAC reports recommendations to the ACT Medical and Dental Appointment Advisory Committee (MDAAC) on a monthly basis. MDAAC reviews and ensures credentialing of stall involved in using the health technology prior to approval being given to the applicant in the HTAC process.  |
| **Functions** | The Committee will review applications for new health technologies and assess them based on:* Safety and efficacy
* Credentialling and training requirements
* Operational capability to support the Digital Health Record (if applicable)

HTAC Chair to provide all recommendations to MDAAC on a monthly basis. MDAAC will review and ensure credentialing of staff involved in use a new health technology. HTAC Secretariat will be emailed confirmation of credentialing prior to the approval for new health technologies is provided to the applicant.It is an expectation that HTAC seeks feedback on the use of new health technologies. Details of feedback required will be detailed in the provisional approval letter that is sent out once credentialing is confirmed. At the end of the agreed period, there will be a final sign off that is monitored and assured by the HTAC Secretariat.  |
| **Membership** | HTAC comprises of the following:* Executive Director, Medical Services – Canberra Hospital (CHAIR)
* Executive Director, Medical Services – North Canberra Hospital (DEPUTY CHAIR)
* Chief Operating Officer
* Chief Finance Officer
* Chief Information Officer
* Medical Director, Quality, Safety, Innovation and Improvement
* Director, Healthcare Technology Management
* Representative, Clinical Trials (where required)
* Representative, Clinical Consumables (where required)
* Consumer Representative, Health Care Consumer Association

**Supplementary Membership (as invited when discussing relevant submissions)*** Executive Director, Nursing & Midwifery and Patient Support Services
* Executive Director, Allied Health
* Chief Medical Physicist
* Executive Director and/or senior clinician from Division responsible for application.
* Other attendees at the discretion of the Chair or Deputy Chair

An interstate specialist may be consulted for independent expert advice, as required.  |
| **Quorum** | 50% + 1 of membership (excluding Secretariat)In the case of absence, a proxy may be nominated.  |
| **Secretariat** | The provision of secretariat support will be provided by the Quality Support Officer, Healthcare Technology Management – HTACSecretariat@act.gov.au. The Secretariat will support the Chair and Deputy Chair in the smooth operations of the meeting. The secretariat is to receive requests for agenda items and associated papers for collation with other meeting papers no later than one week prior to the scheduled meeting.                    The secretariat will distribute minutes and action items within three (3) working days post the scheduled meeting.  |
| **Meeting Frequency / Duration** | Meetings will be held monthly.Where necessary, the Committee may choose to make out-of-session determinations and decisions via electronic means (i.e., email or teleconference). **HTAC Sub-Committee**A HTAC Sub-Committee can also be formed to make recommendations in relation to the introduction of a new health technology in response to an urgent need prior to the next scheduled HTAC meeting. **This only applies to critical patient need as a one off.**The HTAC Sub-Committee must comprise of the following HTAC members:* Executive Director, Medical Services – Canberra Hospital
* Executive Director, Medical Services – North Canberra Hospital
* Medical Director, Quality, Safety, Innovation and Improvement
* Director, Healthcare Technology Management
* Executive Director and/or senior clinician from Division responsible for application.

These approvals must be tabled at the next HTAC meeting for the purposes of governance and notification to the Committee.  |
| **TOR Review Frequency** | TOR will be reviewed by the Committee annually, or sooner if required by legislative changes or changes to organisational arrangements.  |

Attachment B: HTAC Introduction of New Health Technology Application Form

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| Introduction of New Health Technology Application Form  |

***Instructions for completing the HTAC Introduction of New Health Technology Application Form:***

1. Save this template and complete all fields, providing as much detail as possible. If a field is not relevant, please note as being ‘Not applicable’.
2. Ensure all relevant parties are consulted in the development of your application.
3. Attach all relevant supporting documentations when submitting your application.
4. Ensure the appropriate approvals (refer to *Section 6 – Introducing New Health Technology process*) are obtained **PRIOR** to submitting your application.
5. Submit completed application to CHS.HTACSecretariat@act.gov.au.

For further advice on the application process, please contact the HTAC Secretariat on **(02) 5124 8360** or via email at CHS.HTACSecretariat@act.gov.au.

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| 1. Application Details
 |
| Title of the health technology: |  |
| Application Reference Number: | *HTAC USE ONLY* |
| Date of application: | *HTAC USE ONLY* |
| Proposed site(s) of the health technology:*\*Please provide the physical location* |  |
| 1. Applicant Details
 |
| Name: |  |
| Position / Title: |  |
| Department / Unit: |  |
| Contact Telephone: |  |
| Email: |  |
| *\*Please note, email will be the primary mode of communication unless otherwise indicated.* |
| 1. Description of Department / Service / Location
 |
| Provide a brief statement regarding your service / specialty, and why you wish to introduce this health technology. |  |
| What are the organisational benefits associated with the health technology? |  |
| How does performing this health technology fit with the recognised scope of the service and the designated level of service of the CHS facility? |  |
| What are the proposed governance arrangements for the health technology?*Include the name and position title of the person(s) responsible for managing/overseeing the technology* |  |
| 1. Description of the Technology
 |
| Provide a detailed overview of the health technology.*Ensure that you address any surgical and rehabilitation processes, additional equipment that is required, and any other relevant information.* *If a clinical protocol has been developed, please attach as an appendix.* |  |
| 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., three patients completed in a half day operating list every two months for a total of 18 patients per year).* |  |
| Has the proposed health technology been submitted as a research project to a Human Research Ethics Committee (HREC)? *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 approval by the HREC, the curriculum vitaes of study personnel, and documentation of training and credentialing).* | Yes No If YES, please provide the name of HREC that has reviewed the project.  |
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| Has the health technology been reviewed by MSAC or TGA?  | Yes No If YES, provide details, including any conditions / indications placed on the use of the modality.  |
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| If the health technology involves use of a device, is the device listed on the Australian Register of Therapeutic Goods (ARTG) for use in the technology?  |  Health technology does not involve a device - (Go to Step 5)  |
| listed on ARTG Yes No If **YES**, provide details from the ARTG or Special Access Scheme approval. 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 health technology |  |
| 1. Processes
 |
| Will the health technology replace, or be used in conjunction with, an existing procedure, technology or treatment? | Yes No If YES, provide details of the advantages the health technology may have over current procedures, as well as information regarding the existing procedure, technology or treatment it would be replacing. |
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| Has the health technology been used elsewhere? *Information / details may also be attached as an appendix.* | Yes No If YES, provide details of where this has been used – either at another CHS site, within ACT, Australia or internationally |
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| Have there been any reviews of the health technology by independent national bodies (e.g., 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, provide details. |
|  |
| Have any systematic reviews of the health technology been undertaken? | Yes No If YES, provide details. |
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| Are there any other reviews and/or observational studies or clinical series reports relating to the health technology?*Information / details may also be attached as an appendix.* | Yes No If YES, provide details. |
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| 1. Risks and Benefits
 |
| What are the expected benefits from the health technology? 1. *For patients*
2. *For clinicians*
3. *For the organisation*
4. *For the service*
5. *Clinical progression and prognosis*
 |  |
| Are there any side effects or complications related to the health technology? *Consider how the new technology compares to existing procedure(s), if applicable.* | Yes No If YES, list all side effects or negative consequences. |
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| Are there any potential risks to patients and/or staff, including infection, chemical or radiation safety issues? | Yes No If YES, how will these potential risks be addressed?  |
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| Has a patient information sheet been developed to inform patients about risks / potential risks?  | Yes No N/A If YES, attach a copy as an appendix. |
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| 1. Quality and Safety
 |
| Outline the plan for monitoring and evaluation of the health technology.*These measures are to be reported routinely at the operational level.* *Reports for the Health Technology Advisory Committee may be requested in specific circumstances.* |  |
| If the proposed health technology carries with it a risk of adverse events, are there criteria for reviewing outcomes before any further procedures are performed? | Yes No N/A If YES, describe the process (i.e., patient’s health outcome, service outcome, how will the changes be measured and in what timeframe). |
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| 1. Staffing and Resources
 |
| Are there any expected impacts associated with the health technology?* *Staffing*
* *Education and/or training of staff*
* *Consumables / prosthesis / high-cost disposables*
* *Equipment / machines*
* *Space*
* *IT / network*
 | Yes No If YES, provide details. |
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| Have all staff groups which will be affected by the health technology been consulted? *For example, operating theatre staff, nursing, allied health, etc.* *Provide information on any consultations that have occurred as an appendix.* |  |
| Which specialists in your department have experience in performing the health technology? *Include information regarding appropriate credentialing and training for medical, nursing, allied health and technical staff.* *Provide any specific qualifications and credentials as an appendix (if applicable)* |  |
| Do you have a specialist recognised for the teaching of the health technology?*Provide details of any specialist(s) that are accredited to proctor (teach) other staff in the technology.* *Provide any qualifications as an attachment (if applicable)* |  |
| Outline the plan for developing the skills required for the health technology 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.*  |  |
| 1. Conflicts of Interest
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| Do you have any relationship with the supplier of the health technology, or other significant party identified in this application? | Yes No If YES, provide details. |
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| Have you been involved in any prior assessment of the health technology? | Yes No If YES, provide details. |
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| Do you (or a member of your immediate family) have any financial interest in the health technology supplier or manufacturer? | Yes No If YES, provide details. |
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| Have you, or the organisation, received any financial incentive to use the health technology? | Yes No If YES, provide details. |
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| Have you benefited by receiving any training, travel or accommodation related to the health technology? | Yes No If YES, provide details. |
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| Is there any additional information you wish to provide that may pose a conflict of interest (i.e., donations, equipment loans, subsidies, research sponsorship or gifts of any kind)? | Yes No If YES, provide details. |
| If you have answered ‘Yes’ to any of the above questions, has a Conflict of Interest Declaration Form been submitted to CHS.SERBIR@act.gov.au?  | Yes No  |
| 1. Additional Comments
 |
| Provide any additional information / comments relevant to your application. |  |
| 1. Application Declaration
 |
| Send completed application form and supporting documentation via email to:HTACSecretariat@act.gov.au.  |
| **APPLICANT** | Name: |  | Signature: |
| Date: |  |
| **UNIT DIRECTOR** | Name: |  | Signature: |
| Date: |  |
| Comment(s): |
| **EXECUTIVE DIRECTOR** | Name: |  | Signature: |
| Date: |  |
| Comment(s): |
| Is there a capped number of procedures or restricted period of time the technology can be used? |
| Yes No If YES, provide details. |
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| 1. Advice
 |
| *For completion by the Director, Healthcare Technology Management (Biomedical Engineer)* |
| **Date application received by Director, Healthcare Technology Management:** |
| xx/xx/2023 | Recommended for HTAC Yes No  |
| **Biomedical Engineer Report Attached:** | Yes No  |
| Comment(s): |
| *For completion by MDAAC Chair* |
| Credentialling and specific scope of practice requirements:Yes No  |
| Comment(s): |
| **Name:** |  |
| **Date:** |  |
| **Signature:** |  |
| *For completion by HTAC Secretariat and HTAC Chair:* |
| ApprovedYes No  | Comment(s): |  |
| **Signature of Chair:** | Name: |  |
| Date: |  |
| Date applicant notified of outcome: |  |
| Approval letter provided to applicant: | Yes No  |

*\*Copy of notification to be provided to the Unit and Executive Director.*