Clinical Product Evaluation Policy

1. Background

The use of clinical products can result in clinical, financial and operational risks. This policy outlines the process for the evaluation of clinical products, prior to introduction into a clinical area, to minimise these risks. Clinical products for the purpose of this policy include medical equipment and consumables.

2. Policy Statement

New clinical products are required to go through an evaluation process as described in this policy. This process involves consideration of safety, quality, value for money, service and maintenance costs, compatibility and environmental impact.

It is to be noted that the evaluation process is dependent on the clinical product type and risk assessment and may not always involve a trial. It is each region's Product Evaluation and Standardisation Committee (PESC) responsibility to determine the most appropriate course for clinical products presented.

Clinical products that are available to purchase from a contract are exempt from this policy. However, at the discretion of the Regional PESC, these clinical products may be submitted to the evaluation process described in this policy.

Clinical products that have been subjected to a Metropolitan PESC evaluation process can be approved for use at the discretion of the Regional PESC.

The scope of this policy **excludes** the following:

- Telehealth applications, services and technology unless it has a component that could be deemed a clinical product
- Radiological equipment/ items requiring licensing under the *Radiation Safety Act 1975* (WA) should be referred to Area Chief Medical Imaging Technologist
- Point of Care Testing devices are to be referred to Point of Care Department PathWest
- Cleaning equipment must be referred to the Regional Infection Control and prevention and Patient Support Services
- Facilities / plant equipment must be referred to the Regional Facilities Manager
- Scheduled drugs, impregnated medical devices and drug delivery systems must be referred to the Regional Pharmacist
- Prosthetics / implantable devices must be referred to the Regional Medical Director

Clinical products related to the introduction of a new clinical procedure (which is not currently performed by WACHS) may need to be referred to the Credentialing and Scope of Practice (CASOP) Committee in accordance with the Medical Credentialing and Compliance Requirements Guideline. Where the value exceeds $1 million the proposal is to be managed in accordance with Health Technology Governance Policy.

The following scenarios provide strong evidence to undertake a clinical product evaluation.

- Proposed product is superior the current one in use
- Unmet/ new clinical requirement/ quality improvement initiative
- Savings opportunity
- Consolidation of multiple products
- Contract compliance

Clinical product evaluations must not be progressed on the following scenarios.

- Pressure from company representatives.
- Additional funding has not been approved
- The product does not have TGA (Therapeutic Goods Administration) registration

2.1 Process

Section 1 - Product Presentation
A designated senior nurse or senior clinician must be identified as the 'Clinical Sponsor' who is to be responsible for the implementation, coordination and compliance with policy during the clinical product evaluation process. To initiate the process a Clinical Product Evaluation Form must be completed and reviewed by the Product Liaison Officer (PLO) prior to submission to the relevant Regional PESC. An overview can be seen of Product Evaluation Process Flowsheet appendix 1.

Section 2 - Initial PESC Review
The request is tabled and discussed at the regional PESC meeting. Section 2 of form is completed and signed by regional PESC Chair to reflect one of the following potential outcomes of initial PESC review.

- Endorsed* for use subject to procurement and funding approval as per Authorisations Schedule
- Not endorsed*, no further evaluation required
- Further evaluation required via specialist review from Infection Control, Biomedical Engineering (BME), Occupational Safety and Health as appropriate.
- Further evaluation required via a trial of product.

* Process complete for these scenarios.

Section 3 - Specialist Review
The nominated specialists are to review the item and record their assessment on Section 3 of the Clinical Product Evaluation Form and return to the PESC Chair.
If a specialist deems the product ‘not fit for purpose’ any plan to trial must be postponed and referred to PESC.

Section 4 - Product Trial
The Clinical Sponsor must ensure prior to the placement of clinical products within the clinical areas for trial that the following has been pre requisites have been met:

- PESC endorsement.
- Completed deed of agreement by supplier (not required for contracted products)

- Educational resources available to product users.
- Evaluation form developed and available to product users (suppliers forms must not be used)
- Any medical equipment has been checked by BME and has an electrical safety check completed.
- Any costs associated with the trial have been approved

During the trial process, the Clinical Sponsor is to oversee the process, manage any issues and determine the number of evaluation forms required to make an adequate assessment of product. Trials are to be concluded within twelve weeks.
At the conclusion the company representative must be advised and any equipment or unused products returned. Section 4 of Product Evaluation is to be completed summarising the results and submitted to PESC.

Section 5 – Final PESC review
The results are tabled and discussed at the regional PESC meeting. Section 5 of form is completed and signed by regional PESC Chair to reflect one of the following potential outcomes of final PESC review.

- Endorsed for use, fit for purpose
- Not endorsed for use, not fit for purpose.

A summary of the evaluation outcome may be provided to the product company representative from either the Clinical Sponsor or the PLO. Copies of trial documentation are not to be shared to any parties external to WA Health. Suppliers are to be advised that endorsement is not a commitment to purchase.

2.2 Trial Records

All product evaluation documents are to be retained in accordance with the WACHS Records Management Policy. Completed Clinical Product Evaluation Forms must are be forwarded to the PLO for addition to the Product Evaluation Database to facilitate sharing of results with other sites.

2.3 Purchase following product evaluation process

If the trial item is to be purchased, it must be done in accordance with the relevant procurement policies and guidelines.

2.4 Implementation of clinical products

The introduction of any new clinical product must follow a planned implementation process to ensure a safe transition and may include additional training, policy and supply chain changes.

3. Definitions

Product Evaluation Sponsor	The designated senior nurse or clinician who will be responsible for the implementation, coordination and compliance with policy during the clinical product evaluation process.

Clinical Products	Medical devices, equipment or consumables purchased for the purpose of healthcare delivery.
Consumables	Items purchased for either independent use or use with a medical device or equipment that are used and then discarded.

4. Roles and Responsibilities

The **Clinical Sponsor** is responsible for:

- for the implementation, coordination of the clinical product evaluation process as described in this policy.

The **Product Company Representative** is responsible for:

- providing clinical product educational information, including manual /instructions for use and TGA registration certificates
- completing deed of agreement for the provision of medical devices for the purpose of product evaluation when requested
- providing pricing information including any additional costs that may be incurred with product usage over anticipated life

The **Product Liaison Officer** is responsible for:

- providing support and education as required to all stakeholders
- liaising with other WA Health sites to check if product has previously undergone evaluation process and sharing with PESC as appropriate
- maintenance of Clinical Product Evaluation Register

The **Regional Product Evaluation and Standardisation Committee** is responsible for:

- ensuring that all new clinical products introduced into region are compliant with the WACHS Clinical Product Evaluation Policy
- reviewing clinical product evaluations undertaken by other WA Health sites and considering if findings support endorsement of the product for use within the region.

5. Compliance

Failure to comply with this policy document may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to section 26 of the *Health Services Act 2016* (WA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies is mandatory.

6. Evaluation

The evaluation measure is the activity clinical product evaluation undertaken across WACHS regions.

7. Standards

National Safety and Quality Health Service Standards 1.5
Decisions about the procurement of building, plant, consumables and equipment are informed, and that product and services are fit for purpose, comply with relevant standards, and take into consideration safety and quality issues such as multiple chemical sensitivity.

8. References / Links

TGA Website

9. Related Forms

Clinical product evaluation request
Deed of agreement for provision of medical device for purpose of product evaluation

10. Policy Documents

Records Management Policy
Medical Equipment Procurement Policy
Medical Credentialing and Compliance Requirements Guideline
Management of Medical Equipment Policy

11. Related WA Health System Policies

Procurement and Contract Management Policy
Health Technology Governance Policy

12. Policy Framework

Clinical Governance, Safety and Quality

13. Appendices

Appendix 1 – WACHS Clinical Product Evaluation Process Flow sheet

This document can be made available in alternative formats on request for a person with a disability

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WACHS CLINICAL PRODUCT EVALUATION PROCESS FLOW SHEET