Medical Devices and Product Trials	
Summary statement: How does the document support patient care?	Clinicians may wish to trial and evaluate medical devices either when reviewing options for replacing equipment and products, or to take advantage of new technology. This policy establishes a safe system of trial and procurement to protect patients and the Trust as well as ensuring products are suitable for their intended purpose, safe to use and cost effective.
Staff/stakeholders involved in development: *Job titles only*	Clinical Procurement Specialist/ Clinical Engineering / Commercial Director
Division:	Finance – Commercial Directorate
Department:	Procurement Department
Responsible Person:	Clinical Procurement Specialist
Author:	Clinical Procurement Specialist
For use by:	All staff/ Directorate General Managers
Purpose:	*The policy sets out governance of any medical or surgical equipment trials carried out in the Trust for patient care are suitable for their intended purpose, safe to use and are cost effective.*
This document supports: *Standards and legislation*	Medicines Healthcare Product Regulatory Agency (MHRA) The NHS Terms and Conditions for the Supply of Goods and the Provision of Services
Key related documents:	Receipt of Hospitality, Gifts and Inducements Policy (UHSTW004), Managing Conflicts of Interest Policy (UHSTW003) Bribery Act 2010 Declaration of Interests, Gifts and Sponsorship documents, Loans and Consignment Stock documents, Anti-fraud, bribery & corruption policy (UHSFN008) Supplier Representative Policy (UHSF011) Medical Equipment Management Group – Terms of Reference
Approved by:	Commercial Director & Procurement Leadership Team
Approval date:	July 2023
Ratified by Board of Directors/ Committee of the Board of Directors	TMC
Ratification Date:	July 2023

Review date:	July 2026
If you require this document in another format such as Braille, large print, audio or another language please contact the Trust's Communications Team	
Reference Number:	UHSFN010

Version	date	Author	Status	Comment
1.0	April 2021	Clinical Procurement Specialist	Archived	Reviewed and amended for ratification
2.0	July 2023	Clinical Procurement Specialist	LIVE	Reviewed and amended
3.0				

Contents

1. Introduction

University Hospitals Sussex NHS Foundation Trust (UHSussex) has a responsibility to ensure that medical and surgical products used by the Trust for patient care are suitable for their intended purpose, safe use and are cost effective.

Directorates and Clinicians may wish to trial and evaluate medical devices either when reviewing options for replacing equipment and products, or to take advantage of new technology.

There are a number of essential control checks in the Trust. By following the guidance of this policy, unnecessary delays can be avoided and a safe system of trial and procurement established to protect patients and the Trust. This policy applies to all staff that wish to purchase or introduce new medical equipment, medical devices, or consumable products into the Trust.

All medical equipment and devices must be trialled prior to purchase. The aim of this policy is to ensure that all trials are valid, managed in a safe manner and the Trust has a record of these.
Staff must not accept samples of any products for the clinical treatment of patients within the Trust other than through the mechanisms outlined in this policy.

This policy applies for trials of all medical devices and consumables in the Trust.

2. Purpose

2.1 To identify the lines of responsibility for the selection and purchase of products, the application of which is not restricted to a particular ward or department.

2.2 To ensure that users are able to participate in decisions on product selection, whilst maintaining Trust standards.

2.3 To confirm that existing and new products are safe to use, cost effective and meet the Trusts' quality requirements to administer patient care before use.

2.4 By following the guidance contained in this Policy, unnecessary delays in obtaining equipment and consumables may be avoided and a safe system established to protect both the user and the patient.

2.5 To minimise potential litigation against the Trust.

3. Scope

The policy applies to all UHSussex staff initiating or undertaking trials and/or evaluations of medical devices. Such devices must be CE / UKCA marked.

4. Definitions and abbreviations

Medical Device	Any instrument, apparatus, appliance, material or health-care product, used for a patient or client for the purpose of investigation, diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap.
UHSussex	University Hospitals Sussex NHS Foundation Trust

I-PROC	Trust Ordering System
IT	Information Technology
MEMG	Medical Equipment Management Group
MHRA	Medicines Healthcare Product Regulatory Agency.
PSG	Product Selection Group

5. Responsibilities, Accountabilities and Duties

5.1 Responsibilities of the Trust

To comply with relevant medical devices legislation, local and national procurement and clinical policies and guidelines.

5.2 Responsibilities of Directorate Management Teams

5.2.1 To ensure that the Directorate or Division for which they are responsible, complies with this policy.

5.2.2 To ensure that any trial is fully justified with regards to Divisional business need and any impact on existing procedures/process is fully considered before commencing any trial.

5.2.3 To ensure that prior to commencing any trials or purchase, approval is received from the Procurement Department.

5.2.4 To inform the Information Technology (IT) team if any network support is required for any equipment on trial e.g. patient monitors, networked image data.

5.3 Responsibilities of Ward Managers, Department Managers and Consultant Managers

5.3.1 To ensure there is a named lead for the relevant service who is responsible for the trial, from beginning to end, including evaluation and feeding back to the Procurement Department

5.3.2 To ensure that all staff who conduct product trials receive training in the use of products and/or equipment and are competent to do so.

5.3.3 To ensure that all staff who conduct product trials keep a record of all staff who participate in product trials.

5.3.4 To ensure that approval is obtained from the Trust's decontamination service regarding the cleaning of any re-useable instrumentation prior to commencing any trial / loan.

5.3.5 To ensure that the financial implications that would result from a successful trial / loan are fully understood and agreed by the Division prior to commencement of any trial / loan.

5.3.6 To ensure all staff have the knowledge and skills for the safe use of any product that is being trialled.

5.3.7 To ensure any company representatives who are visiting their department have an appointment to do so and have informed Procurement that they are visiting the Trust. Refer to Supplier Representative Policy (UHSF011).

5.4 Responsibilities of individual staff members

5.4.1 To undertake their role in trials in a manner that will minimise the risk to patients and users whilst maximising the full potential of the equipment, both in utilisation and clinical effectiveness.

5.4.2 To complete appropriate training prior to using any equipment and/or products that are being trialled.

5.4.3 Ensure that no commitment to purchase any items is provided to suppliers. Commitment can only be provided by the Procurement Department.

5.5 Responsibilities of Clinical Engineering

5.5.1 To ensure that all patient connected medical devices approved for loans/trials are appropriately checked and tested.

5.5.2 To check supplier's indemnity – the Procurement Department may do this.

5.5.3 To hold records of testing, including all relevant documentation (to be attached to records).

5.5.4 To assign a unique identifier which will be archived after the loan period.

5.5.5 To apply a unique ID number to the device showing the start and end date of the loan period.

5.6 Responsibility of the Procurement Department

5.6.1 To co-ordinate all clinical trials of medical devices with clinical staff in the Trust (Clinical Procurement Specialist).

5.6.2 To check indemnity of suppliers, the Clinical Engineering Team may do this.

5.6.3 To hold a central register of all trials of medical devices in the Trust.

5.7 Responsibility of Suppliers to the Trust

5.7.1 To comply with the requirements of this policy with particular note regarding provision of equipment / consumables for evaluation / trial

5.7.2 To ensure that the Trust is provided with all necessary assurances regarding compliance with relevant regulations, e.g., MHRA, prior to commencement of any trial / loan.

6. The Trust shall establish a Product Selection Group that will:

6.0.1 Support the Trusts' strategy for the selection and procurement of medical and surgical products by reviewing existing and new products in accordance with evidence-based practice and national policies.

6.0.2 The groups will take the following roles;

6.0.2.1 To approve trials of new products which are not restricted in their application to a particular ward or department.

6.0.2.2 To receive reports on trials of new products approved by the group and to make decisions about product selection based on quality and value for money.

6.0.2.3 To receive reports comparing costs and features of alternative products and implement standardisation of products where possible.

6.0.2.4 To monitor and review the profile of products used by the Trust ensuring that the Trust continues to receive value for money and maintains high standards and quality in light of any new product development.

Policy

6.1 Management of product trials

6.1.1 All trials of clinical products within the Trust require prior approval by PSG and MEMG (if technically applicable as set out in MEMG terms of reference) and/or Procurement. This is to ensure that trials are robust and transparent, are not being duplicated elsewhere and time is not wasted trialling products that the Trust do not require. All trials will be co-ordinated by Procurement (Please go to Appendix 1 for flowchart of the trials process).

6.1.2 The introduction of new equipment into the Trust is strictly controlled and Procurement should be notified prior to any trials commencing. Equipment must not be left on Trust premises without prior approval by the Procurement Department and Clinical Engineering.

6.1.3 Staff trialling products must complete the 'Product trials request' form and return this to the Clinical Procurement Specialist. (This can be found in Appendix 3).

6.1.3.1 This allows Procurement to check the register to see if a trial of the same or similar item has previously been carried out and to check that the trial has been authorised by the Budget Holder. A copy of this form should be kept by the Departmental Head or Budget Holder

6.1.4 Any equipment brought into the Trust without approval must not be used and will be removed.

6.1.5 The Clinical Engineering Lead and Procurement will ensure that an indemnity form is completed before a trial proceeds (Please see Appendix 2).

6.1.6 All electro-mechanical equipment must comply with current safety regulations and be CE/UKCA marked.

6.1.6.1 All electro-mechanical equipment must be safety tested by Clinical Engineering before use.

6.1.6.2 All suppliers must complete a Clinical Engineering notification form prior to bringing equipment into the department to be checked (Please see Appendix 4). Please note that Clinical Engineering require 2 weeks' notice prior to bringing any equipment into the Trust.

6.1.7 All goods and equipment brought into the Trust must be clean and appropriately decontaminated in accordance with the Trusts' policy. If this is not the case, equipment will be removed from the Trust.

6.1.8 If the trial is by use of free samples, the Procurement Department will ensure that there are no hidden costs of using the samples and the Trust is not committed to the supplier concerned.

6.1.9 Supplier representatives are not permitted to leave free samples of products in clinical areas without prior agreement from the Procurement Department. If representatives do not comply with this policy, the products must be removed from the Trust and any evaluation / trial will be

considered null and void.

6.1.10 If the trial does not involve free samples, an understanding of the financial implications must be evidenced prior to the start of the trial. Approval for additional expenditure must be agreed with the budget holder and the Procurement Department prior to the trial commencing.

6.1.11 At any stage during a trial / evaluation it must be possible to return all unused products to the supplier with no financial penalty. This must be established prior to the commencement of the trial as part of section 6.1.8 above.

6.1.12 A trial and evaluation report form must be completed by the trials co-ordinator and the Procurement lead using the form in appendix 5.

6.1.13 All trial results must be presented to the PSG, MEMG and/or Procurement for approval. Equipment / consumables associated with the trial must not be ordered until such approval is obtained.

6.1.14 Implementation of any change as a result of the approved trial, will be co-ordinated by the Procurement lead and relevant clinical staff.

6.1.15 Irrespective of the outcome of the trial the Trust must follow the Standing Financial Instructions of Public Contractors Regulations (The Public Contracts (Amendment) Regulations 2022 (legislation.gov.uk).

6.1.16 All appropriate staff will be informed of any changes/implications prior to any change implementation.

7. Loan Equipment

Before any equipment for loan or trial is provided:

7.0.1 Terms and conditions relating to the loan must be agreed by the Procurement Department.

7.0.2 The equipment must be marked with a unique identifier by Clinical Engineering who will log this identifier with other key data on a suitable system. Suitable details will be taken for indemnity purposes (IFA Number).

7.0.3 Appropriate electrical safety and performance tests for the equipment must be verified by Clinical Engineering.

7.0.4 Equipment will be appropriately decontaminated by the issuing department or supplier prior to delivery to the end user.

7.0.5 All equipment will be accompanied by appropriate information and training instructions.

7.0.6 Clear instructions for the return of equipment must be provided to the Procurement Department, Clinical Engineering and end users.

7.0.7 All equipment must be visually checked for signs of wear, tear or damage on return.

Training Implications

7.1 Procurement must be informed of any education, training or promotional activity which is being undertaken at the Trust by supplier representatives in advance to ensure that existing Trust policies are not compromised.

7.2 Training must be completed before equipment is used on patients.

7.3 All training must be free of charge to the Trust.

7.4 Leaflets and posters produced by suppliers must be approved by clinical staff and/or Procurement prior to distribution or display.

8. Monitoring Arrangements

Measurable Policy Objective	Monitoring / Audit Method	Frequency	Responsibility for performing monitoring	Where is monitoring reported
Monitoring Number of trials carried out	Reviewing up-dated trial data	Annually	Clinical Procurement Specialist	**Heads of category PSG Chair**

9. Due Regard Assessment Screening

University Hospitals Sussex NHS Foundation Trust has a statutory duty to assess and consult on whether planning, policies and processes impact service users, staff and other stakeholders with regard to age, disability, gender (sex), gender identity, marriage or civil partnership, pregnancy and maternity, race (ethnicity, nationality, colour), religion or belief and sexual orientation. It recognises that some people may face multiple discrimination based on their identity. A review of the assessed impact of this policy against these criteria can be seen (Appendix 17).

10. Associated documentation

This policy is available on the Procurement website Medical and Health Regulatory Agency (MHRA2021).

11. References

UHSussex. (2021). Procurement Strategy

Procurement Bill 2022-23 https://researchbriefings.files.parliament.uk/documents/CBP-9402/CBP-9402.pdf (online)

MHRA (2021). Managing Medical Devices. Guidance for healthcare and social services organisations. MHRA. London.

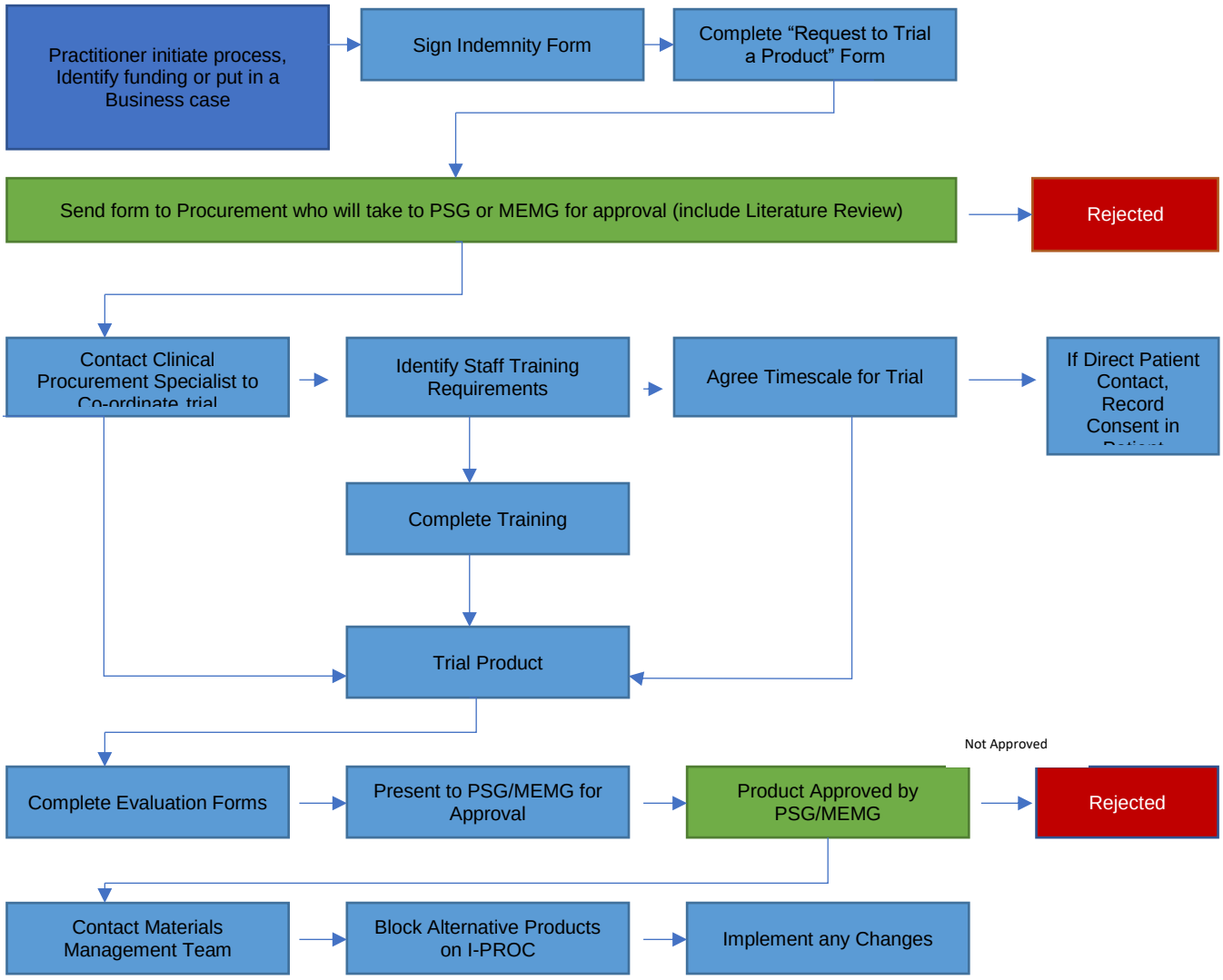
National Institute for Health and Care Excellence (NICE 2013). NICE launches new Framework Agreement for purchasing information resources. https://www.nice.org.uk/search?q=Framework+Agreement+for+purchasing+information+resources (online)

NHS England. DOH. 2013. Better Procurement Better Value Better care: A Procurement Development Programme for the NHS. Crown copyright 2013.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/226835/procurement_development_programme_for_NHS.pdf (online)

12. Appendix 1.

Process flowchart



13. Appendix 2.

Master Indemnity Agreement (MIA Call-Off Agreement)

1	Supplier name	
2	Supplier address (including post code)	
3	Contact name	
4	Contact email	
5	Telephone number	
6	Company registration number	
7	Delivery date	(of the Equipment to the Authority)
8	Authority	
9	Authority address (including post code)	
10	Authority contact name	
11	Authority contact email	
12	Authority telephone number	
13	Type of Equipment and its purpose	
14	Model and make	
15	Serial numbers	
16	Value	
17	Personal Data and Data Subjects	Will the MIA Call-Off Agreement involve the Processing of Personal Data? [Please enter "yes" or "no" as appropriate] If yes, Schedule 1 - Information Governance and System Security of the MIA Terms and Conditions shall apply and the Data Protection Protocol (appended below) must be completed by the parties and used
18	IT systems and Security of IT systems	The Authority's IT systems are used to provide essential services If the Equipment is used for the purposes of any essential services **or together with** any of the Authority's IT systems, the extent of this should be detailed here: [enter text as appropriate]
19	Timescales for request to audit for compliance with Data Protection Legislation and Security of IT Systems	[Insert agreed notice period if different to 4 week notice period as set in paragraph 3.10 of the Schedule to the MIA Terms and Conditions]

20	Loan or transfer?	[Please note that where disposable Equipment is provided, this should only be on a transfer basis]
21	Purpose of loan or transfer	
22	Loan time period	[Complete only where the Equipment is to be loaned, not transferred] [Please state number of days, months or years and the date of commencement]
23	Premises and locations at which the Equipment will be kept (including post codes)	
24	In consideration of the Authority taking the Equipment on a loan or transfer basis for the purposes outlined above MIA Indemnity Agreement Terms and Conditions, the Authority and the Supplier confirm that the MIA Terms and Conditions shall apply to the provision of the above Equipment by the Supplier to the Authority (on either a loan or transfer basis as specified above) and that upon signature of this MIA Call-Off Agreement by both the Authority and the Supplier a legally binding agreement on such terms shall come into full force and effect between the parties incorporating such MIA Terms and Conditions. For the avoidance of doubt the MIA Terms and Conditions and any updates are published on the Master Indemnity Agreement website - https://www.supplychain.nhs.uk/mia	

Signed on behalf of the **Supplier**	
Name and position of signatory	
Date	
Signed on behalf of the **Authority**	
Name and position of signatory	
Date	

14. Appendix 3

Product Trial Request Form

Please complete this form and return to Procurement prior to commencement of trial.

Start Date of Trial:		Finish Date of Trial	
Name of product	Make:	Model:	Product Code:
Trial Area/department			
Clinical Lead for the trial			
Procurement Lead			
Suppliers rep. contact details:			
What will the equipment/product replace.			
Number of units for trial			
Training requirements			
Financial Implications - if the trial is successful what would be the financial impact to the Trust over a year. Procurement can assist with this calculation			
Describe the purpose of proposed purchase and explain how it will assist the Trust to; • Meet Trust objectives, e.g. Sustainability • Improve quality of care • Improve service efficiency • Reduce length of stay.			

15. Appendix 4

Clinical Engineering Team notification form

Start Date of Trial:		Finish Date of Trial	
Name of product	Make:	Model:	Product Code:
Trial Area/Department			
Clinical Lead for the trial			
Procurement Category Lead			
Suppliers rep. contact details:			
What will the equipment or product replace?			
Number of units for trial			
Date approved by Clinical Engineering			
Approver Name			

Please complete this form and return to Clinical Engineering Department 2 weeks prior to any equipment trial.

16. Appendix 5.

Medical Product Trial Evaluation Form

Allocated Trial Reference Number:			
Start Date of Trial:		Finish Date of Trial	
Name of product	Make:	Model:	Product Code:
Trial Area/Department			
Clinical Lead for the trial			
Category Lead for the Trial			
Suppliers rep. contact details:			
What will the equipment or product replace?			
Number of units for the trial			
EVALUATION			
Did it work better than the product currently in use?			
Does it suit the needs of the patient?			
Did the product save time?			
Would you recommend the product to others?			

How does this product support the Trust's Environmental strategy?	
Are there any additional or changes to training requirements for staff?	

Please rate the following as acceptable or unacceptable. (Please circle)

Ease of use	Acceptable	Unacceptable
Ease of application	Acceptable	Unacceptable
Ease of removal	Acceptable	Unacceptable
Durability	Acceptable	Unacceptable
Patient comfort	Acceptable	Unacceptable
Overall performance	Acceptable	Unacceptable

Additional information/comments

To be completed by Procurement

Ongoing cost impact		
Ongoing cost of additional equipment/ accessories/consumables		
Ongoing costs of technical support required from EBME		
Is the supplier established in the NHS		
Is the product on national contract or framework		
Indemnity cover confirmed		
Approval by PSG or MEMG	Yes / No	Date:

17. Appendix 6 - Due Regard Assessment Tool

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	Does the document/guidance affect one group less or more favourably than another on the basis of:		
	• Age	No	
	• Disability	No	
	• Gender (Sex)	No	
	• Gender Identity	No	
	• Marriage and civil partnership	No	
	• Pregnancy and maternity	No	
	• Race (ethnicity, nationality, colour)	No	
	• Religion or Belief	No	
	• Sexual orientation, including lesbian, gay and bisexual people	No	
2.	Is there any evidence that some groups are affected differently and what is/are the evidence source(s)?	No	
3.	If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?	No	
4.	Is the impact of the document likely to be negative?	No	
5.	If so, can the impact be avoided?	N/a	
6.	What alternative is there to achieving the intent of the document without the impact?	N/a	
7.	Can we reduce the impact by taking different action and, if not, what, if any, are the reasons why the policy should continue in its current form?	N/a	
8.	Has the document been assessed to ensure service users, staff and other stakeholders are treated in line with Human Rights FREDA principles (fairness, respect, equality, dignity and autonomy)?	N/a	

If you have identified a potential discriminatory impact of this policy, please refer it to [Insert Name], together with any suggestions as to the action required to avoid/reduce this impact. For advice in respect of answering the above questions, please contact uhsussex.equality@nhs.net (01273 664685).

18. Appendix 7 - Dissemination, Implementation and Access Plan

To be completed and attached to any policy when submitted to Corporate Governance for consideration and TMB approval.

	Dissemination Plan	Comments
1.	Identify:	
	Which members of staff or staff groups will be affected by this policy?	All Staff involved in use / trial of medical devices
	How will you confirm that they have received the policy and understood its implications?	Review via Clinical Procurement Specialists in discussions with clinical leads. Also via the Product Selection Group when established
	How have you linked the dissemination of the policy with induction training, continuous professional development and clinical supervision as appropriate?	Policy will be promoted through the CPS regular contacts with clinical leads and will be promoted through the Trust intranet
2.	How and where will staff access the document (at operational level)?	Policy will be accessible via the Trust Intranet and directly through the CPS

		Yes/No	Comments
3.	Have you made any plans to remove old versions of the policy or related documents from circulation?	Yes	Will be removed as part of the establishment of the new intranet page(s)
4.	Have you ensured staff are aware the document is logged on the organisation's register?	Yes	