Medical Equipment and Product Trials	
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Department:	
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1.0				
2.0				
3.0				
4.0				

CONTENTS

1.0 Introduction

1.1 University Hospitals Sussex NHS Foundation Trust (UHSFT) 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 wishes 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, pharmaceuticals and information technology in the Trust.

Procurement governance and requirements

The following table explains the tendering requirements and governance route that must be applied to every procurement exercise within the corresponding value bands**.**

Group	Whole contract Value Brand	Governance Authority	Tender/Quote	Requirements	Minimum Time scale
1	£1 – £10,000	AS under delegated authority of the Band 9 or above director, at Peer Group Review	At least One Written Quote	Select Contractor from an approved source	0 – 3 months
	£10,000 – £29.999		At least Two Written Quote		
	£30,000 - £49.999		At least Three Written Quote		3 – 6 months
2	£50,000 up to EU Threshold or £150,000, whichever is the lowest for all categories of expenditure	Band 9 or above director on recommendation of AR at Peer Group Review	You must be able to evidence that you have sought to obtain at least 3 tenders. See Note 1 Below Compliance with EU regulations if appropriate	Place tender on e- portal	

Group	Whole contract Value Brand	Governance Authority	Tender/Quote	Requirements	Minimum Time scale
3	Above EU Threshold or in excess of £150,000, whichever is the lowest, for all categories. £1.5M (up to £300,000 for consultancy agreements)	Executive Director on recommendation of Gate Review Panel	You must be able to evidence that you have sought to obtain at least 4 tenders EU requirements. (The number of tenders may change depending on what procurement route is selected).	Advertise on Trust Website and Supply2Gov Website. Advertise in OJEU. *	12 – 18 months
	£1.5M and Over (or over £300,000 for consultancy agreement)	The Board via Executive Director on recommendation of Gate Review Panel	At least 4 tenders EU requirements. (The number of tenders may change depending on what route is selected	Advertise on Trust Website and Supply2Gov Advertise in OJEU.	
	Key Decisions	Board on advice of Executive Director, or CPO in accordance with the definition in the SFI's	Procurement route appropriate to value *		

* If the advertising routes described are unlikely to generate enough interest and there is specific budget allocation, then you may consider advertising in an industry publication

Please Note:

Quotations - Can be an email/screen print or written quotation.

Tenders – All requirements over £50K threshold will need to be tendered.

2.0 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.

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. Litigation against the Trust will therefore be both managed and minimised.

3.0 Scope

The policy applies to all USHFT staff that initiates or undertakes trials and evaluations of medical devices that are CE marked and currently in the market place.

4.0 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.

Loan equipment - Consignment equipment –

T	University Hospitals Sussex NHS Foundation Trust		
EBME	Electrical Biomedical Equipment Department	I-Proc	Internet Procurement
IT	Information Technology		
MDMG	Medical Device Management Group		
MHRA	Medicines Healthcare Product Regulatory Agency.	PSG	Product Selection Group

5.0 Responsibilities, Accountabilities and Duties

5.1 Responsibilities of the Trust

To comply with any local and national procurement and clinical policies and guidelines which exist e.g. NICE, MHRA 2013, USHFT Procurement Strategy 2013. Whilst ultimate responsibility is vested in the Trust Board, executive responsibility is delegated to the Chief Executive for managing health and safety. The Chief Executive has overall responsibility for ensuring that effective systems are in place for learning from poor implementation of national 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 prior to commencing any trials or purchase, Procurement are contacted to inform them of any proposed purchase and to check if there is a tender in process, as this may lead to a legal challenge from companies and suppliers.

5.2.3 To inform the Information Technology (IT) team if any IT 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 who is taking the overarching responsibility of the trial, from beginning to end, including evaluation and feeding back to procurement

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 they keep a record of all staff who participate in product trials.

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

trialled.

5.3.5 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.

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 Complete appropriate training if they are using I-Proc and ordering stock for wards and departments.

5.4.3 Complete appropriate training prior to using any equipment and/or products that are being trialled.

5.5 Responsibilities of EBME

- To ensure that all patient connected medical devices approved for loans/trials are appropriately checked and tested.
- EBME will check supplier's indemnity.
- To hold records of testing, including all relevant documentation (to be attached to records).
- Assign a unique identifier which will be archived after the loan period.
- Apply a unique ID number to the device showing the start and end date of the loan period.

5.6 Responsibilities of Pharmacy

Pharmacy will comply with the guidelines in this policy.

- All educational meetings should be arranged by email with appropriate staff.
- All educational meetings must be recorded and a record held in Pharmacy
- Medical representatives are expected to adhere to the Association of British Pharmaceutical Industry (ABPI) Code of practice.
- All members of the Drugs and Therapeutic Committee will be asked to complete a declaration of Interest form.

5.7 Responsibility of Procurement

5.7.1 Co-ordinate all clinical trials of medical devices with clinical staff in the Trust. (Clinical procurement Manager)

5.7.2 Check indemnity of suppliers/EBME may do this.

5.7.3 Hold a central register of all trials of medical devices in the Trust

5.7.4 Meet with suppliers to negotiate all commercial purchases of medical devices in the Trust.

5.7.5 Assist clinical staff with writing business cases for purchase of medical devices

5.7.6 Discuss all educational literature and information with relevant clinical staff and agree contents prior to approving.

6.0 The role of the Product Selection Group and the Medical Device Management Group (Capital replacement programme)

6.0.1 The 2 groups will lead 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;

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

6.0.4 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.

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

6.0.6 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, MDMG (capital replacement) 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 of any trials that are occurring. Equipment must not be left on Trust premises without prior approval by Procurement and EBME.

6.1.3 A central register of all trials will be kept by Procurement.

6.1.4 Staff trialling products must complete the 'Product trials request' form and return this to the Clinical Procurement Manager. (This can be found in Appendix 3). 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 Department Head or Budget Holder

6.1.5 Any equipment brought into the Trust without approval will be removed.

6.1.6 EBME and Procurement will ensure that an indemnity form is completed before a trial proceeds (Please see Appendix 2).

6.1.7 All electro-mechanical equipment must comply with current safety regulations and be CE marked. This equipment must be safety tested by EBME before use. All suppliers will complete an EBME notification form prior to bringing equipment into the department to be checked (Please see Appendix 4). Please note that EBME require 2 weeks' notice prior to bringing any equipment into the Trust.

6.1.8 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.

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

representatives are not permitted to leave free samples of products in clinical areas without prior agreement with Procurement. If they do not comply with this policy, the trial will cease.

6.1.10 If the trial is not free, an understanding of the financial implications should be evident at the start of the trial. Approval for additional expenditure must be agreed with the budget holder and Procurement prior to the trial commencing.

6.1.11 It should be possible to return all unused products to the supplier with no financial penalty.

6.1.12 A trial and evaluation report form should be completed by the trials co- ordinator and the Procurement buyer (please see appendix 5). This should cover clinical issues and any training impacts on staff as well as, technical and financial implications/cost savings.

6.1.13 All trial results should be presented to the PSG, MDMG and/or Procurement for approval.

6.1.14 Decisions about trial evaluation and approval to proceed to introduce a product into the Trust will be awarded on the basis of a product attaining a percentage agreed prior to trials commencing.

6.1.15 Procurement and implementation will be co-ordinated by Procurement and relevant clinical staff. Clinical staff must not commit to purchase of any trial item.

6.1.16 Irrespective of the outcome of the trial the Trust must follow the standing financial instructions of Public Contractors Regulations (PCR 2015).

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

7.0 Loan Equipment

- Terms and conditions relating to the loan should be agreed with Procurement
- EBME will mark equipment with a unique identifier number and record on a database which allows for storage of data on purchase date, maintenance, service and breakdown history and replacement due date
- Suitable details will be taken for indemnity purposes (IFA Number).
- Appropriate electrical safety and performance tests are to be verified before use.
- Prescribed in accordance with this policy.
- Equipment will be appropriately decontaminated by the issuing department or supplier prior to delivery to the end user.
- All equipment will be accompanied by appropriate information and training instructions
- Clear instructions for the return of equipment will be issued to end users.
- Non-electrical devices should be visually checked for signs of wear, tear or damage on return.

8.0 Training Implications

8.1 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.

8.2 Training should be completed before equipment is used on patients

8.3 All training should be free of charge to the trust

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

9.0 Monitoring Arrangements

Measurable Policy Objective	Monitoring / Audit Method	Frequency	Responsibility for performing monitoring	Where is monitoring reported
Monitoring compliance to policy	PSG and MDMG	Annually	PSG and MDMG Chair	Chief Nurse, Medical Director, Department Heads, Ward Managers

10.0 Equality Impact Assessment Screening

As an NHS organisation, USHFT is under a statutory duty to set out arrangements to assess and consult on whether their policy and function impact on equality with regard to race, ethnic origin, nationality, gender, gender identity, culture, religion or belief, sexual orientation, age, marriage and civil partnership status, pregnancy and maternity status and disability.

Links to other Trust policies Decontamination policy
Supplier Representative Policy

Medical Device Management policy

11.0 Associated documentation

This policy is available on the Procurement website Medical and Health Regulatory Agency (MHRA) 2013

12.0 References

USHFT. 2013. Procurement Strategy

HMSO 2006. Public procurement, England and wales. Public procurement, Northern Ireland. The Public Contract Regulations. 1-88; The Stationary Office Limited. HMSO. UK.

MHRA 2014. Managing Medical Devices. Guidance for healthcare and social services organisations. MHRA. London.

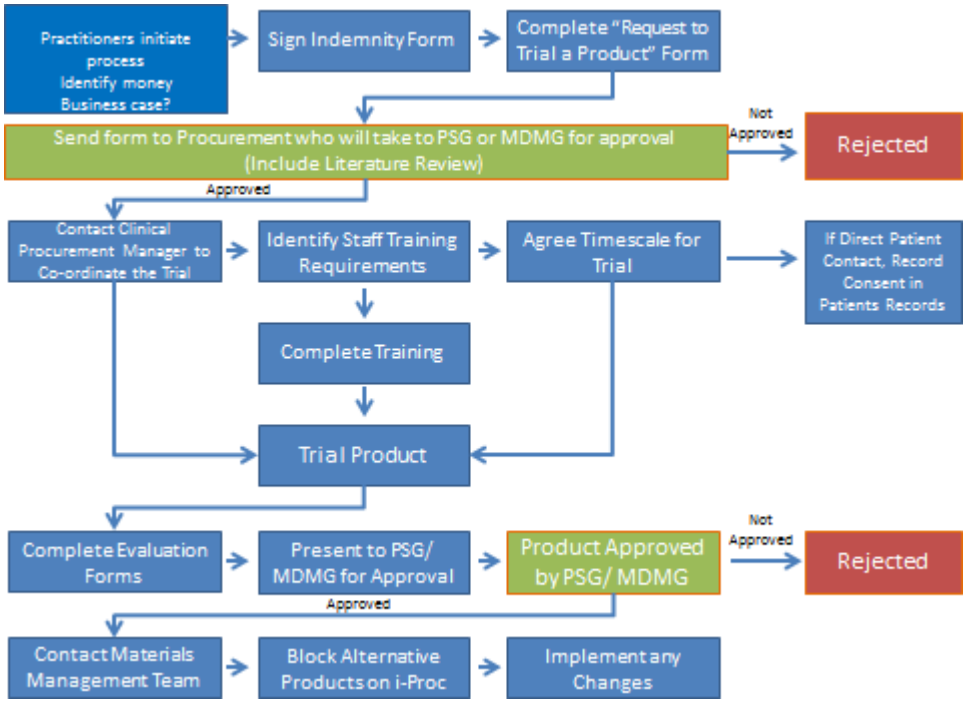
National Institute for Health and Care Excellence (NICE) 2013. NICE launches new Framework Agreement for purchasing information resources

https://www.nice.org.uk/news/article/nice-launches-new-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.

Appendix 1.

Process flowchart



Appendix 2.

NATIONAL HEALTH SERVICE

EQUIPMENT ON LOAN

STANDARD FORM OF INDEMNITY

AN AGREEMENT made the…….day of .....20 ..... BETWEEN

University Hospitals Sussex NHS Foundation Trust ..... ("The Trust") and

..... ("The Supplier")

WHEREAS

1) The Supplier is the owner of the equipment described in the schedule ("the equipment")

2) The Supplier wishes the Trust to use the equipment for the benefit of the Supplier for the purpose of evaluation, testing, research, design, investigation or trial demonstration.

IT IS HEREBY AGREED that the Supplier shall lend and the Trust shall borrow and use free of charge the equipment for the period specified in the schedule in the premises specified in the Schedule ("the premises") on the terms set out below.

1. The loan of the equipment shall be deemed to be a contract for the hire of goods defined by Section 6 of the Supply of Goods and Services Act 1982.

2. The Supplier shall be liable for and shall indemnify the Trust and the Secretary of State for Social Services against all liability in respect of personal injury to or the death of any person, loss of or damage to property, and any loss or expense in consequence of or in any way arising out of the installation, presence, use or removal of the equipment on or from the premises provided that this indemnity shall not extend to liability resulting from the negligence of the Trust's own servants or agents.

3. a) The Supplier shall insure against its full liability under condition 2

b) The insurance covers shall be a minimum sum of £1 million in respect of any one incident.
c) The Supplier upon request shall produce to the Trust documentary evidence that the insurance is properly maintained

4. The Supplier shall provide the Trust with written evidence on the safety of the equipment, drawing attention to any failures to comply with relevant British Standards or DHSS specification or aspects of safety that have not been fully tested. Restrictions on the use of the equipment necessary to ensure the safety of patients or staff shall be pointed out to the

Trust.

5. A delivery note shall accompany the delivery of the equipment, identifying the equipment by serial number or otherwise.

6. Detailed instructions in the use of the equipment shall be given to the Trust's nominated staff by a qualified agent of the Supplier and detailed instructional manuals, where available, shall be supplied to the Trust.

7. The equipment will not be modified or interfered with by the Trust without the agreement of the Supplier.

8. The Trust shall not be liable for any charge for maintenance, repair, consumable materials and accessories required for the operation of the equipment during the period of the loan or for any carriage or installation charges except by prior notification to and the issue of an official purchase order by the Trust

a) On receipt of a written request at any time from the Trust the Supplier shall remove the equipment from the premises with all practicable speed free of charge and at that time provide the Trust with a receipt for the equipment.

b) The Trust shall permit the Supplier to remove the equipment from the premises on receipt of reasonable notice in writing.

c) The Supplier will be responsible for the cost of reinstating the premises, including the service therein, to the satisfaction of the Trust.

10. The equipment shall remain continuously at the Supplier's risk during and after the period of the loan.

SIGNED on behalf of the Trust.....

SIGNED on behalf of the Supplier.....

THE SCHEDULE

1. The Equipment

Description:

Model No: .....

Serial No: .....

Value: .....

2. Period of Loan

..... Months / weeks / days commencing the..... day of

..... 20.....

3. The Premises

.....

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:**
Lead person for trial			
Trial Area/department			
What does product replace during trial?			
Suppliers rep. contact details:			
Number of units for trial			
Training requirements			
Describe the purpose of proposed purchase and explain how it will assist the Trust to; **Meet corporate objectives** **Improve quality of care** **Improve service efficiency** **Reduce length of stay.**			

Appendix 4

EBME notification form

Start Date of Trial:		**Finish Date of Trial**	
Name of product	**Make:**	**Model:**	**Product Code:**
Lead person for trial			
Trial Area/department			
What does product replace during trial?			
Suppliers rep. contact details:			
Number of units for trial			
Date approved by EBME			
Approver Name			

Please complete this form and return to EBME 2 weeks prior to any equipment trial.

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:
Lead person for trial			
Trial Area/department			
What does product replace during trial?			
Suppliers rep. contact details:			
Number of units for trial			
EVALUATION			
Did it work better than the product currently in use?			
Does it suit the patients' needs?			
Did the product save time?			
Would you recommend the product to others?			

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 MDMG	Yes / No	Date:

EQUALITY IMPACT ASSESSMENT (EIA)

PURPOSE OF EQUALITY IMPACT ASSESSMENT

The EIA should:
Inform the Trust if any groups are, or could be, disadvantaged by a policy, service change or reconfiguration and if so clarify / propose action to mitigate that impact
Enable the Trust to identify where policy changes may be needed to actively promote equality / inclusivity and eliminate inequality
Remind all involved in delivering services of the determination to promote equality
If advice is required in completing the EIA please contact an HR Advisor

Section 1 – About the Policy, Service, Function, Proposal, Strategy or Consultation

1.1 Name of Policy, Service, Function, Proposal, Strategy or Consultation	
1.2 Name of person completing this assessment (and role / department)	
1.3 Brief description of the aims of the policy, service, function, proposal, strategy or consultation? **(include details of who is affected by, involved in and / or benefits from it)**	
1.4 Which department owns the policy, service, function, proposal, strategy or consultation?	
1.5 Is responsibility for implementation of this policy, service, function, proposal, strategy or consultation shared with another agency / department?	**Yes** **No** **(If yes describe their involvement in this process, if a partner has conducted an EIA, please attach this information)**
1.6 Does the policy, service, function, proposal, strategy or consultation have direct	**Yes** **No**

consequences or implications for service users and / or staff?	**(If no then it is not relevant to Equality Duties. Please complete statement in section 3 and send the completed form for approval to the Care Group Manager / Head of Service to sign off as shown. If yes, please also complete section 2)**

Section 2 – Equality Impacts

2.1 Have you made sure that the views of stakeholders, including key people likely to face exclusion have been influential in the development of the policy, service, function, proposal, strategy? (please indicate which)

External		Partners		Internal	
Service user interviews		Care Quality Commission		Staff event	
Focus Groups		Multi Agency event		Staff interviews	
Public events		Joint Working group		Staff workshop/focus groups	
Patient experience surveys		Regional Minority network		Management Board	
Voluntary organizations		Regional equality forum		Trust Executive Committee	
Minority group events/forums		GP Practice groups		Diversity Matters Group	
Carer Forum		Local/County Council		Staff side reps	
LINks		Equality and Human Rights Commission (EHRC)		Staff minority forums (e.g disability, BME, sexual orientation, religion/beliefs) (please state)	
HOSC		Other NHS Trust (please identify below)		Trust Board	
On line forums				Staff survey results	
Local media				Annual General Meeting	
Published research into minority needs				Other (please state)	
Census data or other external demographic reports					

Comments:

Section 3 – Equality Analysis Template

To be used to analyse the effect of your policy or service on the protected groups in equality law, resulting in either:

1. *removing or minimizing disadvantages suffered by people due to their protected group characteristics (i.e. age, race/ethnicity, disability, gender reassignment, sex, sexual orientation, marriage & civil partnership, pregnancy, maternity/paternity, religion/ belief, human rights)*
2. *taking steps to meet the needs of people from protected groups where these are different from the needs of other people*
3. *no further action required*

Equality law protects people on the following grounds:	Is your policy or service relevant to this area of equality or human rights?		If relevant, is the effect positive or negative		Evidence of the effect (e.g. statistics, research, surveys, results of engagement, etc)	Is further action required?	
	Yes	No	Positive effect	Negative effect		*Yes	No
Age		X					
Race / Ethnicity		X					
Disability		X					
Gender Reassignment		X					
Sex		X					
Sexual orientation		X					
Marriage and Civil Partnership		X					
Pregnancy, Maternity / Paternity		X					
Religion / Belief		X					
Human Rights		X					

* Complete the following Equality Analysis Action Plan only for the equality grounds marked: *Yes further action required.

Equality Analysis Action Plan								
Equality grounds ticked *yes requiring further action:	**Does your policy or service:**			**Any action taken to date**	**Action to be taken**	**Target date**	**Responsible Person(s)**	**Expected Outcome (including monitoring arrangements)**
	Discriminate?	**Eliminate discrimination or promote equality?**	**Promote good relations between groups?**					
Age								
Race / Ethnicity								
Disability								
Gender Reassignment								
Sex								
Sexual orientation								
Marriage and Civil Partnership								
Pregnancy, Maternity/Paternity								
Religion / Belief								
Human Rights								
Equality Analysis: Care Group Manager / Head of Service to sign off								
Signed				**Date**				