

## TRUST-WIDE NON-CLINICAL DOCUMENT

# THE RECEIPT, MANAGEMENT AND USE OF PAYMENTS RECEIVED BY TRUST STAFF FOR THEIR INVOLVEMENT IN COMMERCIALY FUNDED RESEARCH PROJECTS

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Lead Author(s):	Research and Development Manager

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2017– Version 3

Quality, recovery and wellbeing at the heart of everything we do

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### Further information about this document:

Document name	<b>Policy and Procedure for the Receipt, Management and Use of Payments Received by Trust Staff for Their Involvement in Commercially Funded Research Projects</b>
Document summary	This Policy has been developed to ensure that payments received by Trust staff from Commercial companies as a result from their involvement in a Commercially Funded research project, are received and managed in accordance with Department of Health and Mersey Care NHS Foundation Trust financial management procedures.
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To be read in conjunction with	
<b>This document can be made available in a range of alternative formats including various languages, large print and braille etc</b>	
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### Version Control:

		Version History:
Version 3	Lead Executive Director	February 2017

## SUPPORTING STATEMENTS

This document should be read in conjunction with the following statements:

### SAFEGUARDING IS EVERYBODY'S BUSINESS

All Mersey Care NHS Foundation Trust employees have a statutory duty to safeguard and promote the welfare of children and vulnerable adults, including:

- being alert to the possibility of child/vulnerable adult abuse and neglect through their observation of abuse, or by professional judgement made as a result of information gathered about the child/vulnerable adult;
- knowing how to deal with a disclosure or allegation of child/adult abuse;
- undertaking training as appropriate for their role and keeping themselves updated;
- being aware of and following the local policies and procedures they need to follow if they have a child/vulnerable adult concern;
- ensuring appropriate advice and support is accessed either from managers, *Safeguarding Ambassadors* or the trust's safeguarding team;
- participating in multi-agency working to safeguard the child or vulnerable adult (if appropriate to your role);
- ensuring contemporaneous records are kept at all times and record keeping is in strict adherence to Mersey Care NHS Foundation Trust policy and procedures and professional guidelines. Roles, responsibilities and accountabilities, will differ depending on the post you hold within the organisation;
- ensuring that all staff and their managers discuss and record any safeguarding issues that arise at each supervision session

### EQUALITY AND HUMAN RIGHTS

Mersey Care NHS Foundation Trust recognises that some sections of society experience prejudice and discrimination. The Equality Act 2010 specifically recognises the *protected characteristics* of age, disability, gender, race, religion or belief, sexual orientation and transgender. The Equality Act also requires regard to socio-economic factors including pregnancy /maternity and marriage/civil partnership.

The trust is committed to equality of opportunity and anti-discriminatory practice both in the provision of services and in our role as a major employer. The trust believes that all people have the right to be treated with dignity and respect and is committed to the elimination of unfair and unlawful discriminatory practices.

Mersey Care NHS Foundation Trust also is aware of its legal duties under the Human Rights Act 1998. Section 6 of the Human Rights Act requires all public authorities to uphold and promote Human Rights in everything they do. It is unlawful for a public authority to perform any act which contravenes the Human Rights Act.

Mersey Care NHS Foundation Trust is committed to carrying out its functions and service delivery in line with a Human Rights based approach and the FRED A principles of **F**airness, **R**espect, **E**quality **D**ignity, and **A**utonomy

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## 1. PURPOSE AND RATIONALE

1.1 The Department of Health's Research Governance Framework for Health & Social Care published in 2001, with a second edition in April 2005, requires NHS organisations to ensure financial probity in all matters concerning Research and Development Activity. The purpose of this policy is to ensure that any payments received by Trust staff as a result of their involvement in a commercially funded research project, through their position of employment in Mersey Care NHS Foundation Trust, are received, managed and used in accordance with the Department of Health's guidelines concerning financial probity and in full compliance with the law and with the rules set out by H.M. Treasury for the use of public funds. This policy will establish a system that ensures:

- All payments received by Trust staff as a result of their involvement in a research project, in their role within Mersey Care NHS Foundation Trust, will be paid into a Trust held account.
- Mersey Care NHS Foundation Trust will have first claim to any payments received to cover the Trust's overheads and expenses of hosting a project (these costs may be covered in a separate payment to the Trust).
- That in accordance with the recommendations as laid out in the Pharmaceutical Industry Competitiveness Task Force (PICTF) Clinical Research Report 2001, commercial companies who have signed up to the Model Clinical Trials Agreement will be required to make one payment to the Trust which will cover all expenses to the Trust and the fee for the member(s) of Trust staff who has/have been recruited as a local investigator(s).
- That any payments received are managed, accessed and accounted for by the Trust through the R&D Department in collaboration with the respective Trust staff involved in the project and the Finance Department.
- Access to the funds will be in accordance with criteria as contained in this policy.
- That all payments received by Mersey Care NHS Foundation Trust as a result of it's involvement in R&D Activity, are used for funding other R&D based activity (Please see Appendix 1 for the criteria for accessing funds).

## 2. OUTCOME FOCUSED AIMS AND OBJECTIVES

2.1 This policy is to ensure that all payments received by Trust staff are managed in accordance with Trust wide, standard, stringent and transparent systems, in full accordance with the requirements of the Department of Health and H.M. Treasury.

### 3. SCOPE

- 3.1 This policy applies in the event of any current or former member of Trust staff being offered payment by a commercial company for recruiting participants or taking part in a research project of any kind, as a result of their employment in Mersey Care NHS Foundation Trust. This policy must be adhered to with regard to the receipt, management and use of funds over and above those used to cover the Trusts overheads and expenses incurred in hosting any commercially funded research.

### 4. DEFINITIONS

4.1	Any reference to “the Trust”	refers to Mersey Care NHS Foundation Trust
	Any reference to “Trust staff”	refers to staff from Mersey Care NHS Foundation Trust

### 5. DUTIES

#### **Research and Development Manager**

- 5.1 The R&D Manager, on a day to day basis, is directly responsible to the Medical Director for ensuring that accurate costs are calculated for involvement in commercially funded research projects including Trust overheads.
- 5.2 The R&D Manager is responsible for liaison with relevant Clinical Division named individuals, Line Managers or R&D Leads to ensure capacity and capability and financial agreement prior to any involvement by the Trust.
- 5.3 The R&D Manager will ensure that access to any payments received are managed in line with Trust standing financial orders and Department of Health criteria with regard to use of such payments.

#### **Medical Director**

- 5.4 The Medical Director is responsible for ensuring that all commercially funded research projects have been fully approved by Health Research Authority (HRA), including ethical approval and that capacity and capability has been, or will be issued by the R&D Manager.

#### **Finance**

- 5.5 The Management Accountant for the R&D budget will be responsible for ensuring that any monies received are held in a Trust managed account in collaboration with the R&D Manager and relevant Clinical Division named individuals.

### Staff

- 5.6 Staff who are approached to become involved in any commercially funded research project are responsible for informing and liaising with the R&D Manager and their Clinical Division from the earliest practicable time.

### Research Facilitation Forum (RFF)

- 5.7 The RFF are responsible for ensuring that involvement in any commercially funded research project is appropriate for participation by their Clinical Division and their service users and/or carers.

## **6. PROCESS**

- 6.1 It is the responsibility of all staff contacted about being involved in any research project to ensure that the project is being supported by the Trust, that a Capacity and Capability review has been completed, it has all regulatory approvals, the service is supportive and have adequate resources to deliver the study.
- 6.2 All payments received by Trust staff through their involvement in a research project must be made payable to Mersey Care NHS Foundation Trust and not to the individual involved. For commercial companies who have adopted the Model Clinical Trials Agreement, it is expected that one payment is agreed for each Trust involved to cover all expenses incurred as a result of being a local investigator site.
- 6.3 Mersey Care NHS Trust has first claim to any payments made by a Commercial Company for participation in a trial to cover any overheads incurred in hosting the Trial (these costs are usually covered by the commercial organisation in addition to the fees covering the expenses incurred by the recruitment of a local investigator – member of Trust staff).
- 6.4 Overheads incurred include:-
- R&D and other corporate management of the project;
  - any staffing costs incurred through hosting the project (due to staff performing functions above and beyond routine practice);
  - non staff costs such as postage, photocopying and storage of data or samples.
- 6.5 When payment for the participation in a project is provided according to the number of service users recruited by Trust staff, the agreed per participant fee should include the overhead charges as calculated by the R&D Department. If this is not the case the Trust will have the right to use a proportion of the payment to cover any overheads incurred – previously agreed with the local investigator.
- 6.6 All monies received must be held in a Trust managed account, which will be set up and managed by the R&D department in collaboration with the relevant Clinical Division named individual(s) e.g. Medical Director involved in the project, member(s) of staff involved in the project and the Finance

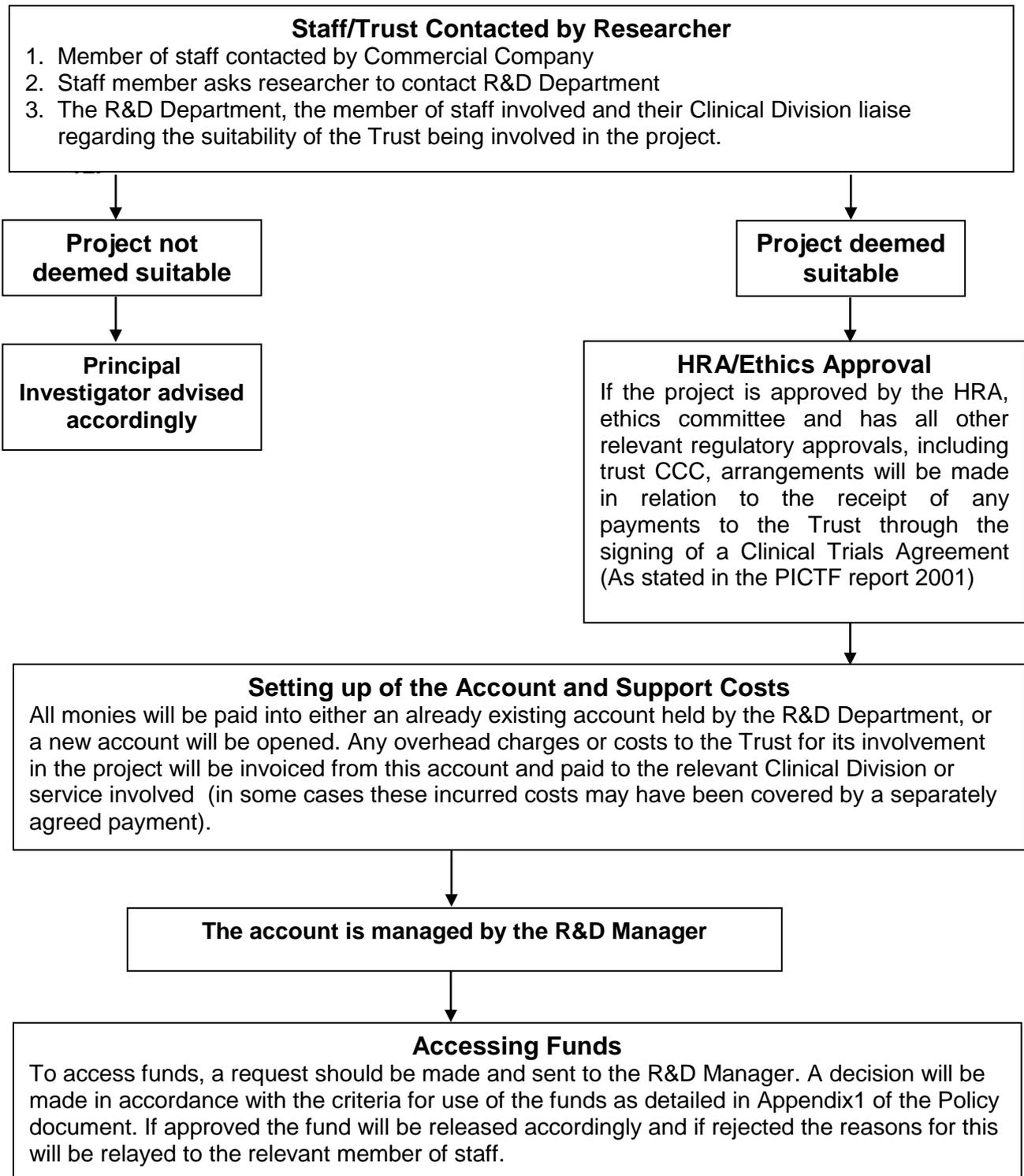
Department. Under no circumstances are employees to receive such payments in the form of personal payment to themselves or hold these payments in a personal account or in a research fund separate from the Trust. If the Trust is made aware, or it is believed that staff have received personal payments in respect of their involvement in a research project which could result in a financial detriment to the Trust the matter will be referred to the Trust's Anti-Fraud Specialist for investigation.

- 6.7 Access to the account will be through the R&D Department in collaboration with the Finance Department, who will ensure that the money is used in accordance with Mersey Care NHS Foundation Trust and Department of Health criteria with regard to the use of such payments. (See Appendix 1 for these criteria)

**Corporate/Local Procedure**

6.8 This is a corporate procedure for Mersey Care NHS Foundation Trust. Local procedures are not appropriate in this instance.

6.9 **Flow chart illustrating the corporate procedure for receiving, managing and using payments received by members of staff as a result of their involvement in a commercially funded research project.**



## **7. CONSULTATION**

- 7.1 The potential need for this policy to be further developed or reviewed may be identified by any member of Trust staff. The need for this policy to be reviewed must be brought to the attention of the RFF via the R&D Manager for Mersey Care NHS Foundation Trust. This policy is directly influenced by the national and regional agenda and will need to be reviewed as and when there are changes in recommendations or procedures with regard to commercially funded research projects.
- 7.2 This revised version of the Policy has been reviewed by Research Facilitation Forum (RFF) representing the Clinical Divisions.

## **8. MONITORING**

- 8.1 The Trust will monitor compliance with this policy through auditing, by the R&D Manager and the relevant Management Accountant, of any budget created and utilised in relation to payment for commercially funded projects.

9. EQUALITY AND HUMAN RIGHTS ANALYSIS

Equality and Diversity - Policy Screening Checklist

<b>Policy Title: POLICY AND PROCEDURE FOR THE RECEIPT, MANAGEMENT &amp; USE OF PAYMENTS RECEIVED BY TRUST STAFF FOR THEIR INVOLVEMENT IN COMMERCIALY FUNDED RESEARCH PROJECTS</b>	CBU: All
Name of person/s auditing / authoring policy: R&D Manager	

**Policy Content:**

- For each of the following checks is this policy sensitive to people of different age, ethnicity, gender, disability, religion or belief, and sexual orientation?
- The checklists below will help you to see any strengths and / or highlight improvements required to ensure that the policy / procedure is compliant with equality legislation.

1. Check for DIRECT discrimination against any minority group of SERVICE USERS:							
Question: Does your policy contain any statements which may exclude people from using the services who otherwise meet the criteria under the grounds of:		Response		Action required		Resource implication	
		Yes	No	Yes	No	Yes	No
1.0	Age?		X				
1.1	Gender (Male, Female and Transsexual)?		X				
1.2	Learning Difficulties / Disability or Cognitive Impairment?		X				
1.3	Mental Health Need?		X				
1.4	Sensory Impairment?		X				
1.5	Physical Disability?		X				
1.6	Race or Ethnicity?		X				
1.7	Religious, Spiritual belief (including other belief)?		X				
1.8	Sexual Orientation?		X				
If yes is answered to any of the above items the policy may be considered discriminatory and requires review and further work to ensure compliance with legislation.							
2. Check for DIRECT discrimination against any minority group relating to EMPLOYEES:							
Question: Does your policy contain any statements which may exclude employees from operating the under the grounds of:		Response		Action required		Resource implication	
		Yes	No	Yes	No	Yes	No
2.0	Age?		X				
2.1	Gender (Male, Female and Transsexual)?		X				
2.2	Learning Difficulties / Disability or Cognitive Impairment?		X				
2.3	Mental Health Need?		X				
2.4	Sensory Impairment?		X				
2.5	Physical Disability?		X				
2.6	Race or Ethnicity?		X				

2.7	Religious, Spiritual belief (including other belief)?		X				
2.8	Sexual Orientation?		X				
If yes is answered to any of the above items the policy may be considered discriminatory and requires review and further work to ensure compliance with legislation.							
<b>PAGE 1: TOTAL NUMBER OF ITEMS ANSWERED 'YES' INDICATING DIRECT DISCRIMINATION = 0</b>							
<b>3. Check for INDIRECT discrimination against any minority group of SERVICE USERS:</b>							
<b>Question:</b> Does your policy contain any conditions or requirements which are applied equally to everyone, but disadvantage particular persons' because they cannot comply due to:		<b>Response</b>		<b>Action required</b>		<b>Resource implication</b>	
		Yes	No	Yes	No	Yes	No
3.0	Age?		X				
3.1	Gender (Male, Female and Transsexual)?		X				
3.2	Learning Difficulties / Disability or Cognitive Impairment?		X				
3.3	Mental Health Need?		X				
3.4	Sensory Impairment?		X				
3.5	Physical Disability?		X				
3.6	Race or Ethnicity?		X				
3.7	Religious, Spiritual belief (including other belief)?		X				
3.8	Sexual Orientation?		X				
If yes is answered to any of the above items the policy may be considered discriminatory and requires review and further work to ensure compliance with legislation.							
<b>4. Check for INDIRECT discrimination against any minority group relating to EMPLOYEES:</b>							
<b>Question:</b> Does your policy contain any statements which may exclude employees from operating the under the grounds of:		<b>Response</b>		<b>Action required</b>		<b>Resource implication</b>	
		Yes	No	Yes	No	Yes	No
4.0	Age?		X				
4.1	Gender (Male, Female and Transsexual)?		X				
4.2	Learning Difficulties / Disability or Cognitive Impairment?		X				
4.3	Mental Health Need?		X				
4.4	Sensory Impairment?		X				
4.5	Physical Disability?		X				
4.6	Race or Ethnicity?		X				
4.7	Religious, Spiritual belief (including other belief)?		X				
4.8	Sexual Orientation?		X				
If yes is answered to any of the above items the policy may be considered discriminatory and requires review and further work to ensure compliance with legislation.							
<b>PAGE 2: TOTAL NUMBER OF ITEMS ANSWERED 'YES' INDICATING INDIRECT DISCRIMINATION = 0</b>							

5. Check for ACCESS discrimination							
Question: Are policies / procedures available in the following mediums:		Response		Action required		Resource implication	
		Yes	No	Yes	No	Yes	No
5.0	English	x					
5.1	Somali		x		x		
5.2	Chinese (Simplified & Traditional)		x		x		
5.3	Kurdish (Sorani)		x		x		
5.4	Arabic		x		x		
5.5	Russian		x		x		
5.6	French		x		x		
5.7	Turkish		x		x		

5. Check for ACCESS discrimination (Continued)							
Question: Are policies / procedures available in the following mediums:		Response		Action required		Resource implication	
		Yes	No	Yes	No	Yes	No
5.8	Farsi		x		x		
5.9	Portuguese		x		x		
5.10	Romanian		x		x		
5.11	Braille		x		x		
5.12	British Sign Language		x		x		
5.13	Audio Tape / Video Tape		x		x		
5.14	Statement included acknowledging interpretation services and availability of other mediums as requested.		x		x		

If No is answered to any of the above items the policy may be considered discriminatory and requires review and further work to ensure compliance with legislation.

**PAGES 2 & 3: TOTAL NUMBER OF ITEMS ANSWERED 'YES' in section 3 & 4 and 'No' in section 5 INDICATING ACCESS DISCRIMINATION = 14**

**Equality and Diversity Compliance / Percentage Calculation**

Number of 'Yes' answers for DIRECT discrimination.	(A) 0
Number of 'Yes' for INDIRECT discrimination.	(B) 0
Total Yes for answers for POLICY CONTENTS discrimination.	(A+B) 0
Percentage content negative compliance.	Divide 36 x 100 = 0
Total 'Yes' for access compliance.	
Percentage access negative compliance.	Divide 15 x 100 = 93%

Signatures of authors / auditors:

Date of signing

## 10. APPENDIX 1

- 10.1 Any money received by the Trust or by Trust staff as a result of taking part in or recruiting service users, carers or staff into a commercially funded research project, must be used in accordance with the criteria as set out below. These criteria are in place to ensure that Mersey Care NHS Foundation Trust and the staff it employs adhere to Department of Health requirements with regard to the use and management of monies received from Commercial Companies funding research.
- 10.2 **Criteria for the use of Funding accrued through payments for involvement in commercially funded projects.**
- 10.3 The individual requesting to access funds must be the individual who has accrued the funds through their involvement in externally funded research projects or has been given written permission by the relevant member of staff who has accrued the funds to access the money.
- 10.4 Funds must be used for the purposes of activity relating to research, including attending conferences, funding further research, funding training courses for the purpose of building the capability and capacity of staff, services users and/or carers in research skills and other related activities.
- 10.5 NB There may be cases where staff may wish to donate money they have received from commercial companies through their involvement in a commercially funded project to charity. This will need to be agreed with the relevant parties within the Trust including the Clinical Division involved in the Research, the R&D Manager and the Finance Department. As stated in this policy, the Trust will have first call on any payments to cover any overheads or support costs incurred as a result of hosting any research.

## 11. BIBLIOGRAPHY

- 11.1. Department of Health (2001) '*Research Governance Framework for Health & Social Care*' and updated second edition April 2005

## 12. IMPLEMENTATION PLAN

	<b>Issues identified / Action to be taken</b>	<b>Time-Scale</b>
<p><b>Co-ordination of implementation</b></p> <ul style="list-style-type: none"> <li>How will the implementation plan be co-ordinated and by whom?</li> </ul> <p><i>Clear co-ordination is essential to monitor and sustain progress against the implementation plan and resolve any further issues that may arise.</i></p>	<p>This policy is a review of the original policy, formalises ongoing practice and is therefore already being adhered to in relation to the management of clinical trials. The policy will need to be highlighted to Clinicians so they are aware of this when making a decision whether to take part in a Commercial Trial. The Medical Director will highlight the existence of this policy to the relevant members of clinical staff. The Chief Pharmacist will also be made aware of the policy along with relevant staff in the Finance Dept.</p>	<p>Within 2 months of the ratification of the policy.</p>
<p><b>Engaging staff</b></p> <ul style="list-style-type: none"> <li>Who is affected directly or indirectly by the policy?</li> <li>Are the most influential staff involved in the implementation?</li> </ul> <p><i>Engaging staff and developing strong working relationships will provide a solid foundation for changes to be made.</i></p>	<p>The policy directly effects clinical staff involved in the conduct of commercially funded research. The Medical Director and the R&amp;D Manager will oversee and monitor adherence to the Policy.</p>	<p>Ongoing</p>
<p><b>Involving service users and carers</b></p> <ul style="list-style-type: none"> <li>Is there a need to provide information to service users and carers regarding this policy?</li> <li>Are there service users, carers, representatives or local organisations who could contribute to the implementation?</li> </ul> <p><i>Involving service users and carers will ensure that any actions taken are in the best interest of services users and carers and that they are better informed about their care.</i></p>	<p>Any decision concerning the conduct of a Clinical Trial in the Trust is made in the best interests of Service Users. The approval process will enable service users to have a say in relation to whether we wish to be involved in a project or not.</p>	

<p><b>Resources</b></p> <ul style="list-style-type: none"> <li>• Have the financial impacts of any changes been established?</li> <li>• Is it possible to set up processes to re-invest any savings?</li> <li>• Are other resources required to enable the implementation of the policy eg. increased staffing, new documentation?</li> </ul> <p><i>Identification of resource impacts is essential at the start of the process to ensure action can be taken to address issues which may arise at a later stage.</i></p>	<p>The intention of the policy is that any income received for recruiting participants into a trial will be utilised by the Trust to support service developments and education and training in the areas where the project is being hosted and supported. The process for the management of this system is detailed in the policy.</p> <p>Initially there may be some additional work for members of staff in the Finance Dept in setting up specific accounts to hold any income. However this is likely to be minimal and will be reviewed with the R&amp;D Manager.</p>	<p>Ongoing</p>
<p><b>Securing and sustaining change</b></p> <ul style="list-style-type: none"> <li>• Have the likely barriers to change and realistic ways to overcome them been identified?</li> <li>• Who needs to change and how do you plan to approach them?</li> <li>• Have arrangements been made with service managers to enable staff to attend briefing and training sessions?</li> <li>• Are arrangements in place to ensure the induction of new staff reflects the policy?</li> </ul> <p><i>Initial barriers to implementation need to be addressed as well as those that may affect the on-going success of the policy</i></p>	<p>There are currently very few commercially funded research projects in Mersey Care and this policy is adhered to. It will be in place when any future new projects are proposed.</p>	

<p><b>Evaluating</b></p> <ul style="list-style-type: none"> <li>• What are the main changes in practice that should be seen from the policy?</li> <li>• How might these changes be evaluated?</li> <li>• How will lessons learnt from the implementation of this policy be fed back into the organisation?</li> </ul> <p><i>Evaluating and demonstrating the benefits of new policy is essential to promote the achievements of those involved and justifying changes that have been made.</i></p>	<p>The evaluation of the effectiveness and impact of this policy will be conducted when the Trust increase it's involvement in commercially funded clinical trials. The impact of the policy on the decision making process of clinicians on whether to be involved or not, will be monitored on an ongoing basis by the R&amp;D Manager and the Research Governance Committee.</p>	
<p><b>Other considerations</b></p>	<p>NA</p>	