Pennine Care NHS
NHS Foundation Trust

Policy Document Control Page

Title: Research & Development Policy

Version: 3

Reference Number: CL83

Keywords:

Research, Development, Governance, Framework, GCP

Supersedes

Supersedes: 2

Description of Amendment(s):

- **Change of title for Reagan Blyth**
- **Addition of Health Research Authority (HRA)**
- **Updated R&D Checklist (Appendix 1)**

Originator

Originated By: Reagan Blyth

Designation: Director of Service Modelling, Research and Innovation

Equality Impact Assessment (EIA) Process

Equality Relevance Assessment Undertaken by: Tanya Turgoose

ERA undertaken on: 10/02/2016

ERA approved by: Stephen Stewardson

EIA approved by Policy Manager on: 18/02/2016

Approval and Ratification

Referred for approval by: Stephen Stewardson

Date of Referral: 01/02/2016

Approved by: Quality Group

Approval Date: 02/02/2016

Date Ratified by Executive Directors: 14th March 2016

Executive Director Lead: Medical Director

Circulation

Issue Date: 15th March 2016

Circulated by: Performance and Information

Issued to: An e-copy of this policy is sent to all wards and departments

Policy to be uploaded to the Trust's External Website? YES

Review

Review Date: January 2018

Responsibility of: Reagan Blyth

Designation: Director of Service Modelling, Research and Innovation

This policy is to be disseminated to all relevant staff.

This policy must be posted on the Intranet.

Date Posted: 15th March 2016

TABLE OF CONTENTS

1. INTRODUCTION

This policy covers the appropriate conduct of research across Pennine Care NHS Foundation Trust, which is committed to supporting the conduct of quality research. Advice on the appropriate conduct of research and associated legislative requirements should be sought from the Trust's Innovation & Research (I&R) Department prior to research initiation or involvement.

2. AIM OF THE POLICY

This policy briefly outlines the position of Pennine Care NHS Foundation Trust in relation to research conducted across the Trust. Currently, limited research is conducted across the Trust and the policy will be expanded and revised as research activity increases, or when changes in national legislation or guidance occur in terms of research governance requirements.

3. SCOPE OF THE POLICY

The policy applies to:

i. All staff undertaking or supporting research

4. DUTIES AND RESPONSIBILITIES

The Chief Executive has overall responsibility for the quality of care, and for the appropriate conduct of research but the responsibility for has been delegated to the R&D Lead (Medical Director).

5. DEFINITIONS

GCP = Good Clinical Practice
DH RGF = Department of Health's Research Governance Framework
HRA = Health Research Authority

6. RESEARCH CONDUCT

The Trust has a dedicated Innovation & Research (I&R) Department, who review all research applications to ensure adherence the Department of Health's Research Governance Framework, Health Research Authority requirements and other legislation as appropriate, such as the Data Protection Act 1998, The Mental Capacity Act 2007,

and the Medicines for Human Use (Clinical Trials) Regulations 2004. Following successful outcome of review by the Innovation and Research Department, written permission for the study to start is issued by the Director of Service Modelling, Research and Innovation.

Research activities must not be undertaken within the Trust without written approval by the Director of Service Modelling, Research and Innovation.

A checklist is provided below detailing the documentation required prior to R&D approval (Appendix One).

7. INTELLECTUAL PROPERTY RIGHTS

The Trust has an Intellectual Property (IP) Policy in place. In accordance with relevant guidance, the Trust has appointed TrusTECH®, the NHS Innovation Hub for the North West, as its advisor organisation to give advice and assistance in the protection, management and commercialisation of its IP. TrusTECH® will keep all information confidential unless it is given consent to the contrary. The I&R Office will refer members of staff to TrusTECH® as appropriate.

Further information on TrusTECH® can be found by visiting the website: http://www.trustech.org.uk/

Audits of IP may periodically be arranged by the I&R Office via TrusTECH® to identify potential IP arising from R&D and other activities and ensure action is taken to protect any IP that may later be exploited.

8. COMPLAINTS

All complaints received relating to research will be dealt with according to the Trust's complaints Policy.

9. EQUALITY AND DIVERSITY

Pennine Care NHS Foundation Trust is committed to promoting equality and diversity in all areas of research activities, which are conducted. The Trust wants to ensure that

everyone has equal access to its services which the Trust provide irrespective of their race, age, gender, disability and sexual orientation.

10. APPENDIX ONE: R&D CHECKLIST

Research Project Submission Checklist for Researchers

Please refer to the guidance on page 2 before completing this form or submitting a project for consideration.

Short Project Title	Principal Investigator / Local	Chief	Sponsor

CORE – These documents are required for all projects. Those marked * may not be applicable to all projects.			
Type	Document(s)	Comments	Provided
Docs	REC or HRA approval letter and a copy of all documents listed on the approval letter.		
	Localised versions of all information sheets and consent forms (on Pennine Care headed paper)		
Forms	* For those not subject to HRA review: • R&D Form (signed by sponsor and Chief Investigator) • SSI Form signed by Principal Investigator or local collaborator		
	* For those subject to HRA Review: • Localised Statement of Activities • Localised Schedule of Events		
Legal	* Evidence of insurance/indemnity cover *(For studies subject to HRA review. The HRA approval letter will act as assurance that this requirement is met)*		
	* Project Contract or Site Agreement		

Researchers			
Type	Document	Comments	Provided
All	Chief Investigator CV		
	Principal Investigator CV		
	GCP certificates **(for CTIMP projects only)**		
Those not employed by Pennine Care	**HEI Employed:** Research Passport and associated pre-engagement checks. **Note:**		
	NHS Employed: NHS to NHS confirmation of pre-engagement checks		
	HEI Student (non-healthcare placement): Research Passport and associated pre-engagement checks.		
	Students (healthcare placement e.g. nursing, physiotherapy, medicine, clinical psychology) No additional paperwork required.		

SPONSOR – These documents are required for any project sponsored by Pennine Care.			N/A
Type	Document	Comments	Provided
Docs	Sample Case Report Form (CRF)		
	Delegation log		
Legal	Confirmation of funding award		
	Evidence of independent peer review		

IMP – These documents are required for any project using an Investigational Medicinal Product.			N/A
Type	Document	Comments	Provided
Docs	Investigator Brochure or SmPC		
	Sample Serious Adverse Event (SAE) report form		
MHRA	CTA application to MHRA (signed and dated)		
	MHRA correspondence		
	MHRA approval letter		

EXTRA – These documents may be required depending on project specific needs.			N/A
Type	Document	Comments	Provided
Legal	ARSAC approval and certificate		
	IRMER approval		
	Service Level Agreement		

Research Project Submission Guidance for Researchers

The checklist details the core documentation required for all projects. In addition, researchers will be expected to provide any additional documentation dependent on the type of project and sponsorship arrangements.

All documents must be received before the project can undergo review by the Innovation and Research Department, and approval by the Director of Service Modelling, Research and Innovation. Documents must be sent electronically.

Please complete the checklist above and return this along with your submission. Please ensure you have completed the brief header details to identify your project, and the checklist itself, adding any comments or narrative where necessary.

Document specific guidance			
Set	Document		Guidance
CORE	Documents listed as approved by the REC or HRA		All of these documents should have a version number and date matching that referenced on the REC/HRA approval letter.
	Localised information sheets and consent forms e.g. PIS, ICF, GP/Carer information		The template for Pennine Care headed paper is available from the Innovation & Research Department.
	Guidance as to whether your research study will be subject to review by the Health research Authority can be found at: http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/	R&D Form **(required for studies not subject to HRA approval only)**	This form is part of the study-wide approval process. Pennine Care must be listed in Part C as a participating site or PIC (as appropriate) and the form must be signed by the Chief Investigator (CI) and study Sponsor.
		Site Specific Information (SSI) form **(required for studies not subject to HRA approval only)**	This form is part of the local approval process and must be compliant with Research and Development policy, including involvement of a Pennine Care local collaborator or principal investigator (q2) and appropriate R&D authorisation (q23). Please provide a draft copy to the Innovation & Research Department for review before it is locked and signed. This allows any changes to be made easily without the need to re-lock and sign the form.
		HRA Statement of Activities **(required for studies subject to HRA approval)**	This form is part of the local approval process and must be compliant with Research and Development policy, including involvement of a Pennine Care local collaborator. The form should be completed by the sponsor or delegate and then submitted to the Innovation & Research Department in order that a capability and capacity review can be undertaken and the relevant sections completed by the Innovation & Research Department. Please note that electronic signature of this form by the Trust will act as written approval by the Director of Service Modelling, Research and Innovation approval for the study to commence at Pennine Care.
		Localised Schedule of Events	This form is part of the local approval process must be completed in line with the form guidance. Note: For commercial studies, the Industry Costing

Document specific guidance			
Set	Document		Guidance
		(required for studies subject to HRA approval)	Template will be completed in place of this form.
	Project Contract or Site Agreement		A contract template is available from the Innovation & Research Department. For most studies this will be addressed by the R&D approval letter or HRA Statement of Activities document.
STAFF	PI & CI CV		This should be one to two pages maximum and should include key requirements such as qualifications, GMC number, current post, research experience and GCP training.
	GCP certificate		All personnel undertaking CTIMP research must have a GCP certificate or suitable evidence of research experience. All GCP certificates must be dated within the last two years.
	Those not employed by Pennine Care		Detailed guidance of HR requirements can be found at: http://www.nihr.ac.uk/policy-and-standards/research-passports.htm#HR%20Good%20Practice%20resource%20pack
IMP	MHRA correspondence		All correspondence between the Sponsor and the MHRA regarding this project will be required.
EXTRA	ARSAC approval and certificate		ARSAC certification is only required if the project includes exposure to radioactive material.
	IRMER review and approval		IRMER review and approval is required when the project includes exposure to ionising radiation.
	Service Level Agreement		Required for projects sponsored by Pennine Care which will involve sub-contracting aspects of the research to another institution.

Advice and guidance on all of the above can be provided on a case by case basis by the Innovation and Research Department.

Telephone: 0161 716 3184
Email: researchdevelopment.penninecare@nhs.net