Pennine Care
NHS Foundation Trust

DOCUMENT CONTROL	
Title:	**Research and Development Policy**
Version:	**4**
Reference Number:	**CL083**
Scope:	
This policy applies to all members of the Trust; Researchers both internal and external	
Purpose:	
The purpose of this policy is to inform investigators and staff about the processes, procedures, and arrangements the Trust has in place to ensure that our service users are able to participate in high quality research conducted in line with relevant guidance and legislation.	
Requirement for Policy	
Best Practice	
Keywords:	
Research, HRA, R&I, Grant Applications	
Supersedes:	
Version 3	
Description of Amendment(s):	
This was a full review of the Policy	
Owner:	
Research & Development Manager – Simon Kaye	
Accountability:	
Director of Service Modelling, Research and Innovation Executive Director of Nursing, Healthcare Professionals & Quality Governance	
Individual(s) & group(s) involved in the Development:	
This document has been developed in collaboration with the following interested parties: • Linda Booth – Clinical Research Officer	

Individual(s) & group(s) involved in the Consultation:	
The document has been circulated for consultation and comments have been taken into consideration and the document amended accordingly: • Associate Director Of Quality, Assurance & Research – Reagan Blyth • Research & Innovation Manager – Simon Kaye	
Equality Impact Analysis:	
Date approved:	01 July 2018
Reference:	CL083-EIA083
Freedom of Information Exemption Assessment:	
Date approved:	15th February 2019
Reference:	POL2018-20
Information Governance Assessment:	
Date approved:	28th February 2019
Reference:	POL2018-20
Policy Panel:	
Date Presented to Panel:	11th February 2019
Presented by:	Linda Booth
Date Approved by Panel:	11th February 2019
Policy Management Team tasks:	
Date uploaded to Trust's intranet:	15th February 2019
Date uploaded to Trust's internet site:	15th February 2019
Review:	
Next review date:	February 2022
Responsibility of:	Research & Development Manager
Other Trust documentation to which this policy relates (and when appropriate should be read in conjunction with):	
CL122	Safeguarding Families Policy
Policy Associated Documents:	
Other external documentation/resources to which this policy relates:	
	Freedom of Information Act (2000)
	Equality Act 2010
NIHR CRN Portfolio	https://www.ukctg.nihr.ac.uk/

NHS Standing Financial Instructions	(https://www.england.nhs.uk/wp-content/uploads/2018/04/nhs-england-standing-financial-instructions-v9.pdf)
NIHR Research Support Services (RSS) framework	https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/framework-for-research-support-services.htm
NIHR Industry Costing Templates	Association of British Pharmaceutical Industry (ABPI) model Clinical Trial/Investigation Agreements
	https://www.health-ni.gov.uk/articles/common-law-duty-confidentiality
Clinical Trials Toolkit website	http://www.ct-toolkit.ac.uk/
Governance Arrangements for RECs (GAfREC, September 2018) guidelines	https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures/
Integrated Research Application System (IRAS)	www.myresearchproject.org.uk
Development of research proposals	researchdevelopment.penninecare@nhs.net
GDPR Guidance	https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/
Excess Treatment Costs (ETC)	https://www.nihr.ac.uk/funding-and-support/documents/study-support-service/Researcher%20Routemap%20-%20How%20Excess%20Treatment%20Costs%20are%20managed%20in%20England%20-%20Version%207%20Sept%2018.pdf
Decision Tool	http://www.hra-decisiontools.org.uk/research/
HRA website	https://www.hra.nhs.uk/
Research & Innovation Office generic mail	researchdevelopment.penninecare@nhs.net
DH Guidance	Attributing the costs of health and social care Research & Development (AcoRD)
Research & Innovation Office generic email	researchdevelopment.penninecare@nhs.net.
Substantial and non-Substantial Amendments	https://www.hra.nhs.uk/approvals-amendments/

CQC Regulations **This guideline supports the following CQC regulations:**	
Regulation 17	Good Governance

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1. INTRODUCTION

All research carried out at the Trust, must follow standard procedures in order to obtain Trust authorisation and be conducted in line with the conditions of this authorisation. This ensures that each study complies with current legislation and guidance and that the Trust has the capacity and capability to support the study.

The purpose of this policy is to outline: the submission process for research involving Pennine Care NHS Foundation Trust (PCFT) staff, facilities, patients and/or patients' data; the grant funding application procedures, the regulatory review process, and the application procedure for confirmation of Trust capacity and capability.

2. PURPOSE

The purpose of this policy is to inform investigators and staff about the processes, procedures, and arrangements the Trust has in place to ensure that our service users are able to participate in high quality research conducted in line with relevant guidance and legislation

3. RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES

Chief Executive & Medical Director

The Chief Executive is accountable for ensuring adequate arrangements are in place and resources are available at the Trust to undertake research which meets the standards in the UK Policy Framework for Health and Social Care Research. The responsibility for this has been delegated to the Research and Development Lead (Medical Director).

Chief investigator

The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site. In respect to student projects below Doctoral level (MPhil, MSc, and BSc); the academic supervisor will normally act as the Chief Investigator.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R&I policies and procedures are available to research staff.

It is the responsibility of the study CI or PI to distribute study-specific Procedures/ Standard Operating Procedures to appropriate members of the research team, and to ensure that up-to-date copies are filed in the Investigator Site file.

Principal Investigator
The Principal Investigator is the person responsible as an individual, or as the leader of researchers at a particular site, for the conduct of a study at a site. S/he will liaise with the necessary departments/Clinical Director/local Managers/Associate Director Research and other clinical colleagues as required, in order to discuss and make proper preparations for the study.

All Trust Staff
It is the personal responsibility of all staff to follow the Trust procedure relating to approval of research.

Definitions
CI – Chief Investigator
CRN – Clinical Research Network
CPMS – Central Portfolio Management System
CTA – Clinical Trial Authorisation
CTIMP – Clinical Trial of Investigational Medicinal Products ETC –
Excess Treatment Costs
GAfREC – Governance Arrangements for Research Ethics Committees
GCP – Good Clinical Practice
HRC – Honorary Research Contract
IRAS – Integrated Research Applications System
LOA – Letter of Access
MHRA - Medicines and Healthcare products Regulatory Agency
NIHR – National Institute for Health Research
NRES – National Research Ethics Service
PI – Principal Investigator
PIC – Participant Identification Centre
R&I – Research & Innovation
RDOCS – R&D Operational Capability Statement
REC – NHS Research Ethics Committee RGF –
UK Policy Framework for Health and Social Care
Research R&IC – Research & Innovation
Committee RSS – Research Support Service
SoE – Schedule of Events
SoA - Statement of Activities
NIHR CRN Portfolio – Database of high quality studies funded by a recognised funder

4. RESEARCH & INNOVATION OFFICE – RESPONSIBILITIES OF STAFF

The R&I Office consists of the following staff:

Director of service Modelling, Research & Innovation

Research & Development Manager

Research Governance Officer – Study Approvals

Clinical Research Officer – Performance & Delivery

Research Nurses (Project Managers) Research Study Delivery

Senior Research Coordinator (Contracts, Costings & grants)

The Trust actively collaborates in research alliances and clinical research networks and is committed to supporting the streamlining of research approval, governance, risk assessment and monitoring of research in compliance with the provisions of the and the proposed UK Policy Framework for Health & Social Care Research. The Trust has established research governance arrangements to meet required standards.

On behalf of the Chief Executive the Research and Innovation Office staff will:

- Advise on putting together grant funding applications and the appropriate costing of research proposals.
- Ensure that the implications for the Trust of hosting research are identified including excess treatment costs, service support costs, and service capacity.
- Maintain records of all Trust approved research projects.
- Host grants, monitor budgets and ensure that sub contracts are set up with any external organisations involved in Trust hosted grants.
- Advise researchers, receive, validate and manage submissions for R&I confirmation of capacity and capability.
- Approve requests for Trust sponsorship of research and establish arrangements in line with Research Governance Framework (RGF) specification of sponsor responsibilities.
- Ensure all applicable research has a favorable ethical opinion from an NHS Research Ethics Committee.
- Ensure all research has been assessed by the Health Research Authority (HRA) and they have given HRA approval.
- Confirm all research has an appropriate level of independent peer review.
- Ensure all amendments to projects are processed and approved.
- Ensure that researchers have appropriate contractual and indemnity arrangements in line with current national guidance.
- Ensure that Trust research budgets are established in line with NHS Standing Financial Instructions.
- Authorise the finances of each submission.
- Monitor and audit research.
- Record dissemination of completed research.
- Ensure appropriate arrangements are in place with other Trust departments for hosting research including support departments such as Pharmacy and Laboratories.
- Ensure all appropriate Trust Departments have been consulted (where necessary) such as Health Informatics and IG
- Provide information relating to performance management of the R&I function in line with the requirements of the Clinical Research Network, etc.

- Work towards streamlining research governance processes and removing unnecessary bureaucracy.
- Review preparations for clinical trials, including processing of contracts, clinical trial agreements and liaise with and advise study teams as required for clinical trial set-up.
- Ensure appropriate monitoring of Clinical Trials of Investigational Medicinal Products (CTIMPs) and ensure researchers are trained in Good Clinical Practice.
- Work towards meeting nationally agreed targets for confirming capacity and capability for research and recruitment to research studies.
- Promote/develop schemes to give Service Users the right to hear about research.
- Ensure researchers cite the Trust in publications.

In conjunction with the CI/PI, it is the responsibility of the R&I Office to make Trust Research and Innovation Procedures available to all research active staff where relevant.

Trust Management Accountant Research

To assist with costing grant applications, liaising with Senior Research Coordinator (Contracts, Costings & grants) as required.

To monitor research project budgets of Trust hosted grants and liaise with project teams about financial matters.

To monitor research income and expenditure and advise R&I Office on financial matters.

To ensure all research financial budgets are in line with Trust Standing Financial Instructions.

R&I Pharmacist

To review any studies that involves the use of medicinal products, to advise Study Teams, to liaise with the relevant Pharmacy departments elsewhere, to liaise with the Medicines Management Committee. The Health Research Authority have plans to undertake pharmacy reviews of studies as part of the HRA Approval process. When these plans are implemented, the Trust R&I Pharmacist will then focus on capacity and capability to ensure the study is deliverable locally.

Trust authorized signatory – Medical Director and R&I Lead

To sign contracts or other required documentation on confirmation of a satisfactory review by the Director of Research & Innovation/Research and Development Manager.

Services hosting Research

The R&I Office will inform the services about approved research projects. The service leads will support the service staff in ensuring that researchers obtain access to patients, clinical meetings, and patient identifiable information strictly in line with the approved Positional Statement and ensure adherence to all relevant Trust policies. The

service manager will nominate a person who will liaise with the researcher on behalf of the service.

All Researchers

The Trust requires all Trust employees, full-time, part-time, salaried or honorary, students, and those who are not employees who plan or who are authorised to conduct research in the Trust or to use Trust facilities or resources in the conduct of research, to observe the highest standards in the conduct of their research. In pursuing such high standards, they shall:

- Work with the R&I office in costing proposals that involve the Trust and ensure appropriate agreement is in place before submitting funding applications.
- Notify the Trust R&I Office at the earliest stage in the development of research proposals which involve the Trust.
- Provide the Trust R&I Office with a copy of any research proposals submitted which involve Trust patients, staff, data or facilities.
- Not start any research project prior to receiving written Trust management agreement, HRA approval and a favourable ethical opinion if required.
- Ensure that they only undertake research activities for which they have relevant training, qualifications and experience.
- Ensure that they have appropriate contractual status and indemnity arrangements to undertake research at the Trust.
- Follow relevant legislation and guidance on the appropriate conduct of research including the UK Policy Framework for Health and Social Care Research, the EU Directive for Clinical Trials, Mental Capacity Act, Human Tissue Act, Clinical Trial Regulations and other relevant legislation and guidance.
- Only conduct research that is in line with the approved protocol including the arrangements for obtaining the consent of participants for all aspects of the research.
- Ensure that research participants have information about whom to ask questions about the research and to how to raise any complaints.
- Adhere to all relevant Trust policies and procedures.
- Comply with relevant legislation and guidance on confidentiality including the Data Protection Legislation, NHS Code of Confidentiality and Caldicott Principles.
- Regularly submit recruitment data to the R&I Office.
- Provide audit information as requested by the R&I Office.
- Take steps to secure the safety of those associated with research.

Research Support Services Framework

The NIHR Research Support Services (RSS) framework is a set of tools and guidelines to support a consistent and streamlined approach to managing health research studies in the NHS. The RSS framework was developed in collaboration with a wide range of stakeholders, including senior R&I managers and investigators, who identified research processes that could be speeded up or simplified and steered working solutions to help overcome problems.

5. GDPR

As part of the GDPR implementation from 25th May 2018, the use of consent as the legal basis for research became more challengeable. The GDPR introduced the new 'public task' condition (in article 6) which gave the Trust the lawful basis to process health data for research purposes when supported with appropriate 'fair processing'.

Other guidance such as the common law duty of confidentiality must also be adhered to.

The information Governance team should be consulted on any queries in relation to the appropriate use of consent, prior to action being taken.

6. TRUST POSITION

In consultation with the Trust Research Team, Information Governance Team, Health Informatics Team, and the Data Protection Officer, it has been agreed that until further notice (clear steer to the contrary from the regulatory body/HRA/NHSE) that the Trust's position regarding research is as follows:

The Trust will screen records for suitability to participate in research using the 'Public Task' Article 6(1)(e) and the Article 9(2)(j) condition for special from the GDPR.

The Trust will only allow the Pennine Care Research Department to perform this screening, acting in the capacity as extended members of the clinical team.

The Trust has prepared a R&D Positional Statement which is on PCFT Research intranet site.

7. PROCESSES AND PROCEDURES

When research involving PCFT is at protocol development stage the Chief Investigator and/or Research Team should contact the Research & Development Manager of R&I Office for guidance/assistance with the preparations/study set- up and liaise with any potential internal/external stakeholders. They may also liaise with the Greater Manchester Clinical Research Network.

The proposal as appropriate should be reviewed by the following and comments incorporated:

- Health Economist
- Statistician (all clinical trials)
- User Groups. Grant awarding bodies such as NIHR ask about the level of active service user involvement in development design, research, analysis and dissemination. The Trust supports meaningful service user involvement in research.

8. GRANT APPLICATIONS

Grant applications requiring Trust resources (including excess treatment costs) are not to be submitted to funders without Trust authorisation.
All grant applications in progress that involve Trust patients, staff or facilities must be provided to the R&I Office in good time with sufficient information for the costs of Trust involvement to be identified by the Senior Research Coordinator (Contracts, Costings & grants) and provided by the Trust Management Accountant for Research.

All grant applications must be submitted to the Senior Research Coordinator (Contracts, Costings & grants) in the Trust R&I Office. The Sponsor must be identified at this stage and the application submitted with the signatures of the Chief/Principal Investigators.

9. TRUST APPROVAL OF COSTS FOR RESEARCH PROPOSALS

Researchers should involve the R&I Office and Finance Department at an early stage in the development of research proposals involving the Trust to ensure they are properly costed in line with relevant guidance including the arrangements for treatment costs.

Identification of costs
In line with the DH guidance, "Attributing the costs of health and social care Research & Development (AcoRD)", researchers should ensure that in the proposal they have clearly identified:

- **Research costs** – the costs of the R&D itself. They include the costs of data collection and analysis and other activities needed to answer the questions that a piece of R&D is addressing. Research costs are usually met by research funders.
- **NHS Service Support Costs** include the additional patient-related costs associated with the research, which would end once the R&D activity in question had stopped, even if the patient care service involved continued to be provided. Service Support Costs are met from the CRN budget.
- **Excess Treatment Costs** (ETCs) – patient care costs which would continue to be incurred if the patient care service in question continued to be provided after the R&D activity had stopped. The Director of Research should be informed when a grant application involves ETCs.

ETC - What happens for studies that are ongoing after October 2018?

- ETCs related to patients recruited after 1 October 2018 will be managed via the new system. Any ETCs related to patients recruited before 1 October 2018 will not be included and should be funded through existing mechanisms.
- Studies with ETCs that relate to CCG commissioned services will be transitioned into the new model. CCGs have been asked to submit data on their commitments for studies recruiting after 1 October and sponsors have been asked to support this data collection

- Existing Studies that will continue to recruit after 1 October with ETCs relating to specialised commissioned services should continue with existing arrangements.

The NHS based costs (which include research, service support and ETCs) included in grant applications must be approved by the Trust prior to submission of the application to the funding body, and, in the case of University staff, prior to the application being signed off by the University. Applications to NIHR/DH funding schemes should be agreed with Senior Management in the R&I Office, who will advise, following liaison with the Finance Department, on costings to be included for NHS salaries, resources and Trust overheads (where applicable).

Researchers must provide sufficient timely information to the Trust to enable the progression of funding service support and treatment costs. Trust support for projects is dependent upon funding being available. Applications requiring liaison with University R&I Offices and requiring approval of ETCs should be submitted at least two months prior to the deadline.
If a grant application requires disclosure of a researcher's unprotected Intellectual Property, the researcher can obtain a standard confidentiality statement from the R&I Office to accompany the grant submission. Where government or charity organisations retain ownership of the Intellectual Property arising from their funded research, the research contract will include terms relating to ownership and disclosure of Intellectual Property, which should be checked by the R&D Manager/Director of Research.

Trust Approval of Costs of "Own Account" Research

Any own account research costs must be agreed with the relevant Service, which should specify the level of support in writing prior to commencement of the research.

Trust Approval of Costs of Commercial Research

The Trust will participate in commercial research projects costed in line with the NIHR Industry Costing Templates.

- All clinical trials involving Trust patients should be governed by a contract between the Sponsor and the Trust as the corporate body responsible for the care of the clinical trial subjects.
- In no case should an individual employee of the Trust or University enter into a contract in a personal capacity with a clinical trial sponsor to undertake a clinical trial involving Trust patients.
- A financial schedule will be negotiated for each clinical trial. This will be prepared in line with NHS costing standards and the NIHR Industry Costing Template. This will cover all financial issues associated with medical, scientific and nursing staff, and the costs of all services including clinics, clinical investigations, hotel charges (e.g. bed days), laboratories, imaging, medical records, patient expenses, set up costs, administrative charges and pharmacy services. Identification

and calculation of the relevant costs and overheads incurred to the Trust and service hosting the research will be undertaken by the Clinical Research Network in conjunction with the Grants Co-ordinator in the R&I Office.

- There should not be separate Agreements or financial arrangements with any NHS Trust departments such as pharmacy. (However, if the Trust are the hosting organisation and the CTA is issued to the Trust, commercial studies can involve the CRF and PCFT pharmacy and sub-contracts will need to be set up for these services by the Senior Research Coordinator (Contracts, Costings & grants)

The financial schedule will include:

- Central set up costs (R&I Office and Pharmacy)
- Costs for each patient contact (costed by grade of staff, time and unit costs, and costs of services and facilities, each item will include an appropriate overhead rate)
- Transfer costs (expenses incurred by and reimbursed to third parties)

Work is not automatically considered "commercial" simply because there is industrial funding. Commercial companies also support non-commercial research jointly with the NHS bodies or non-NHS research funders.

- An agreement about dispersal of the funding (Central costs, Pharmacy costs, Directorate costs and amount available to the investigator to support future research) will be made for each study.
- No agreement about involvement in commercial studies can be entered into prior to submission to the R&I Office to obtain the written approval of the Director of Research/Medical Director.

10. TRUST SIGNATURE FOR RESEARCH CONTRACTS

Research funded by either non-commercial or commercial organisations may be subject to a written contract/agreement between the researcher(s), the Trust and the funding organisation. To obtain a Trust signature on contracts, a copy of the contract, signed by the funding organisation and the chief/principal investigator, must be sent to the R&I Office.

The R&I Office will then obtain authorisation from the Director of Research/Medical Director.

Finance and Director sign off is done at application submission stage for non-commercial grants.

This is not approval to proceed with the research and Trust R&I agreement must still be sought before the study can commence

11. PEER REVIEW

If a study has undergone a competitive funding application process, and has been successful, the study has already received an appropriate level of peer review.

If a study has not yet received an appropriate level of peer review, the CI must initiate a request for an independent peer review. This can be requested by the CI directly to the peer reviewer or administered by the R&I Office.

Minimum appropriate levels of peer review agreed within the Trust are as follows:

Study Type	**Appropriate Peer Review**
Clinical Trials sponsored by the Trust	Two independent peer reviews
Clinical Trials sponsored by another organisation	Sponsor's responsibility, this must be confirmed by the Sponsor
Other Studies	One independent peer review
Student Studies	Academic Supervisor*

*All Academic Supervisors are tasked to perform this function for Undergraduate and Master's level Postgraduate student researchers. PhD student projects however will need evidence of Academic or independent peer review.

Peer Review can also be sought prior to a grant application in order to enhance the chance of success.

Evidence of Peer Review must be returned to the R&I Office and to the PI in order that the PI can incorporate any agreed/proposed changes.
The PI, Director of Research and/or R&I Office must review the Peer Review(s) to see if the Protocol is of sufficient quality to progress through the R&I Office approval process, and, if appropriate, confirm changes have been made to the Protocol and re-submitted to the same or another Peer Reviewer.

12. SUCCESSFUL FUNDING AWARD

If the grant is hosted by the Trust a grant budget will be set up by the Management Accountants and sub contracts will be arranged by the Senior Research Coordinator (Contracts, Costings & grants) with any external organisations involved on the project.

If the grant involves the Trust but is hosted elsewhere the research admin office of the hosting organisation should contact the Senior Research Coordinator (Contracts, Costings & grants) in respect to setting up a sub contract.

When/if funding has been secured (if required), a Study or Site File must be established. The Ethics Submission and R&D Approval process must then be initiated by the PI, if this has not already begun.

13. ADVICE ON THE DIFFERENCES BETWEEN RESEARCH, CLINICAL AUDIT AND SERVICE EVALUATION

Advice is available on the HRA website on how to differentiate between research, clinical audit and service evaluation.

The decision tool can be used to decide if a project requires NHS REC approval:

If researchers are still unsure as to whether or not their study needs ethical approval, please contact the R&D Manager for advice.

RESEARCH	**CLINICAL AUDIT**	**SERVICE EVALUATION**
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/ explores themes following established methodology.	Designed to answer the question: "Does this service reach a predetermined standard?"	Designed to answer the question: "What standard does this service achieve?"
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of a simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of a simple interview or questionnaire.
Quantitative research - study design may involve allocating patients to intervention groups.	No allocation to intervention groups: the health care professional and patient have chosen the intervention.	No allocation to intervention groups: the health care professional and patient have chosen the intervention

14. ETHICAL REVIEW

When a study protocol has been favourably peer reviewed and funding has been awarded and/or where appropriate costs have been agreed by PCFT and/or an academic institution, a favourable ethical opinion must be sought.

Research requiring NHS Research Ethics Committee (REC) review is outlined within the Governance Arrangements for RECs (GAfREC, September 2018) guidelines.

15. HRA APPROVAL

HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Research Ethics Service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study. Projects are submitted for HRA approval via the Integrated Research Application System (IRAS).

Before applying for HRA Approval the sponsor is expected to have identified potential participating sites and, in most cases, have discussed the project with local researchers, Trust services and the research management staff supporting them.

Where applicable, for non-commercial studies, the application to the HRA should include the **Statement(s) of Activities and Schedule(s) of Events** documents for each type of research site in your study. Please ensure that you refer to the guidance provided when completing these documents.

For commercial studies, you should include in your application the draft template agreement you propose to use with sites, a costing template (for studies which are part of the NIHR CRN Portfolio the costing template should be validated before application for HRA Approval) and a template delegation log.

16. STATEMENT OF ACTIVITIES/SCHEDULE OF EVENTS

For non-commercially sponsored studies the HRA use the Schedule of Events and Statement of Activities templates (see below) to capture all information around study activities being undertaken at a local level.

Following application for HRA Approval and receipt of the HRA Initial Assessment letter (or HRA Approval Letter where no Initial Assessment letter needs to be issued), the sponsor can supply the local document package to sites, including the local research office and the Local Clinical Research Network (LCRN).

The HRA approval letter will provide details on whether participating sites need to individually confirm their capability and capacity to deliver the study.

If an individual participating site agreement is required, each site must confirm capability and capacity to deliver the study before research can take place on their site.

17. IRAS SUBMISSION

The Chief Investigator (CI) or their delegated representative must complete the Integrated Research Applications System (IRAS) form to apply for a favourable ethical opinion and HRA assessment, obtaining any advice as required via the Research Office (PCFT or Universities as appropriate).

The IRAS submission process:

- Complete the IRAS integrated dataset for the study and follow the IRAS instructions shown on the various tabs. The IRAS website contains a freely available online training module to support anyone new to using IRAS.
- Sponsorship must be defined on the application form in IRAS and details added for the respective Sponsor signatory.
- Forward the application form for review by the Research & Innovation Office or University Research Office if they are the Sponsor.
- Forward electronic copies of all documents to be submitted to the Ethics Committee, to the Research & Innovation Office generic email.
- The CI must obtain the appropriate authorisations for the IRAS form, including the Sponsor authorisation. Authorisations can be requested electronically by following the step-by-step instructions provided in IRAS. Following electronic authorisation, changes cannot be made to the IRAS form as this will invalidate any signatures that have been obtained.
- The Sponsor, on receipt of the request for electronic authorisation, will sign off the submission electronically
- The CI will check the submission for completeness and will then contact the appropriate Research Ethics Committee to book in at a meeting. The CI will then submit the IRAS application electronically. A unique code is automatically applied to the footer of the form when electronic 'submission' has been completed.
- The CI will communicate directly with the REC to secure a favourable opinion, and must copy all communications to/from the REC to the Research & Innovation Office
- Following validation by the REC Administrator, the CI must communicate with the Local PIs and HRA assessment team to initiate global compliance and governance checks.

18. HEALTH RESEARCH AUTHORITY ASSESSMENT

At the same time as the project is being considered for Ethics Review Health Research Authority (HRA) will undertake an initial assessment of the study to ensure that there is sufficient information to undertake a full assessment and identify what further information will be required during full assessment.

A HRA initial assessment letter will be sent to the applicant which confirms the application, together with the template agreements, statements of activity, costing templates, schedule of events to be used in the study and set up information, has been received. This is when the researcher can formally send the local information package to sites. For some studies this step will not be required and a HRA Approval letter will be issued.

The HRA Assessment provides confirmation of compliance with legislation and that an adequate level of insurance is in place.

Once both HRA assessment and REC review (where required) are complete the CI will receive notification of the outcome ("HRA Approval" or "not approved") in the form of a letter/email and guidance on what should be done next.

Researchers cannot commence a study in the NHS in England until HRA Approval has been issued.

19. AUTHORISATION FROM REGULATORY AND OTHER BODIES

CIs must also submit to the appropriate bodies incorporated within IRAS. See further information below for MHRA. To understand if any of these bodies are applicable to the study and therefore required, use the information tags on the filter questions for further advice:

- ARSAC - Administration of Radioactive Substances Advisory Committee
- GTAC - Gene Therapy Advisory Committee
- MHRA - Medicines and Healthcare products Regulatory Agency
- NOMS - National Offender Management Service - Ministry of Justice
- CAG – Confidentiality Advisory Group (appointed by HRA)

Portfolio Adoption

All studies which meet the National Institute for Health Research Clinical Research Network (NIHR CRN) eligibility criteria are eligible for inclusion on the portfolio and subsequent network support, subject to local agreement.

The IRAS submission form will include questions about submission for NIHR portfolio support. Select the relevant options and answer the questions accordingly if you wish to apply for network support. A Portfolio Adoption Form will then partially populate with data derived from the integrated dataset and the additional form will appear on the left of the

screen. The CI must complete and submit this form to the NIHR CRN online. Instructions are provided on the 'Submission' tab on IRAS.

The CI will be contacted directly by the NIHR Clinical Research Network (NIHR CRN) to confirm eligibility and next steps.

MHRA – Medicines & Healthcare products Regulatory Authority
The application or administration of any product or device in a non-approved, non-standard, or novel fashion may be classified as a Clinical Trial of Investigational Medicinal Products (CTIMP). Where there is any doubt, advice must be sought from the R&I Office. All CTIMPs and Clinical Trials of Medical Devices must be submitted to the MHRA for authorisation. If, following consideration by the R&I Department, there is any doubt as to the classification of the study, documentary proof must be obtained from the MHRA of the status of the study (CTIMP/non-CTIMP).

IRAS Submission – studies led by another Centre
The local PI is not the CI and therefore must await instructions from the CI regarding the status of the IRAS submission before proceeding with local site set-up, which involves assessment of local capacity and capability.

20. CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPS)

As well as the tasks already defined above:

For CTIMPs (and multi-centre studies) the CI must also ensure Agreements and Responsibilities are secured/outlined with all Sites and all Research Personnel. Referring to:

RDSOP03 Definition & Delegation of Investigator Responsibilities for CTIMPs

RDSOP10B IMP Management and Accountability

RDSOP20 End of Study Notification

RDSOP21 Retention of Data, Off-site Archiving & Destruction of Documents

RDSOP32 Gaining MHRA Approval

RDSOP14 Trust Sponsorship of Research

RDSOP13 Contract Management

For Trust sponsored CTIMPs - The CI must liaise with the Head of R&I Office and the R&I Pharmacist for advice/ assistance whilst the protocol and the Clinical Trial Authorisation (CTA) to the MHRA are being completed. The CI must obtain a letter from the Sponsor delegating the CTA task to the CI following review by the above, and the final submission (CTA) provided to the Research & Innovation Office (in electronic format).

A copy of the protocol will be reviewed by the R&I Pharmacist. Following assessment the R&I Pharmacist will provide agreement to undertake the CTIMP by e-mail directly to the Research Office.

CTIMPs must be reviewed and approved before R&I confirmation of capacity and capability will be granted

21. COMMERCIALLY SPONSORED STUDIES

The PI must ensure he/ she has full knowledge of and meets his/ her obligations and responsibilities in accordance with the Clinical Trial Agreement with the company. In particular:

- Management of the study and the patients in accordance with the protocol
- Management of the study in accordance with study specific SOPs.

Where there is no relevant SOP provided by the Sponsor, the relevant

Trust SOP will apply.

- Management of the research team members
- Training and adherence to Good Clinical Practice (GCP) and Clinical Trials Regulations for all team members
- Procuring Confidentiality to the Commercial Company (from all team members)
- Publication rights
- Intellectual Property arrangements

The PI must liaise with the Senior Research Coordinator (Contracts, Costings & grants) and R&I Accountant to organise payment and management of study funds following contract signature. During the notification process, the R&I Office will request a research budget for the grant be set up to receive study funds and it is the responsibility of the PI to manage these funds in liaison with the R&I Accountant.

22. TRUST CONFIRMATION OF CAPACITY AND CAPABILITY

Overview

Pennine Care NHS Foundation Trust's Research & Innovation Office is responsible for ensuring all research taking place at the Trust is managed appropriately and approved.

A new national process for the approval of research projects was fully rolled out on 1st April 2016, meaning that all research taking place in the NHS in England is now approved outside of Trusts by the Health Research Authority.

The HRA Approval Process involves the HRA being responsible for reviewing and approving research studies, and the Trust then confirming they have the capability and capacity to undertake the research study at site.

Researchers must not commence any research project at the Trust until written confirmation of capacity and capability is received from the R&I Office. At this point all the relevant checks and agreements with relevant services will have taken place and the Trust will be ready to go ahead with the research.

Before HRA approval is received

The researcher should contact the R&I Office at an early stage of planning their study so their application can be completed in liaison with services, and realistic recruitment numbers agreed. An application form is then completed via IRAS and submitted simultaneously to the NHS Research Ethics Committee (REC) and the Health Research Authority (HRA) for approval. A meeting to discuss the ethics application should then be booked by the Central Booking Service (CBS). An Initial Assessment letter may also be issued by the HRA at this point.

An application to confirm Trust capacity and capability to support the study should be made to the Trust R&I Office, this may be at the same time as the IRAS form is completed or after receiving either REC favourable opinion or HRA approval.

A full set of documents is required by the R&I Office as follows:

- Copy of IRAS application form (combined REC and R&D form) as submitted for HRA Approval
- Protocol
- Any amendments
- Participant information and consent documents (without local logos/ headers)
- Relevant model agreement (where applicable)
- NIHR Costing template (validated) – commercial studies
- Schedule of Events (see HRA website) – non-commercial studies
- Delegation log including PI declaration (standard template available) – commercial studies
- Statement of Activities (see HRA website) – non-commercial studies
- Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
- Copy of HRA Initial Assessment letter
- CVs of researchers and if student research, CV of supervisor;
- Evidence of insurance/indemnity for non-NHS sponsored studies;
- HRA Initial Assessment letter;

- If Regulatory Approval letters have been received these should also be submitted with the application.

Once all the above documents have been received it will be deemed a valid application.

When the Statement of Activities and Schedule of Events is submitted the Trust is formally 'selected as a site'.

Once site selection has taken place, the R&I Office will send the study to the service that the researcher wishes to access so that they can confirm they have the capacity and capability to accommodate the study. The researcher should also have approached relevant services prior to submission to ascertain their interest in undertaking the study.

For studies that require drug storage/dispensing/transport, capacity and capability will also have to be agreed with the Pharmacy department. Similarly, if laboratory storage or blood tests will be required this will also need to be arranged before capacity and capability can be confirmed. For CTIMP set-up thorough checks will be required before any confirmation can be given.

After HRA approval is received

REC approval must be received before HRA Approval is granted. The HRA Approval letter will then be issued and should be forwarded to the R&I Office by the researcher. Assuming all internal Trust checks have been made with the relevant departments the R&I Office can confirm capacity and capability for the study on behalf of the Trust. This will be done by email to the Day to Day Contact/PI/CI with a copy of the Statement of Activities signed off by the R&I Office.

23. RESEARCH PASSPORT & HONORARY CONTRACTS

Research cannot commence until confirmation of capacity and capability has been received and active members of the research team have the appropriate contracts in place.

Proposed members of the research team who are not employed by the Trust may require an honorary research contract or letter of access from the Trust. A Research Passport form has to be completed by this proposed member of research staff and the pre-employment assurances and checks performed by the principal employer. Further information about the application process is available from the R&I Office.

The PI has responsibility to ensure any members of his/her team have the appropriate contracts in place prior to commencing work on a research project.

24. AMENDMENTS

All changes relating to the study **must be notified** to the R&I Office. This may include changes in staff, changes to ethics approved study paperwork, changes to start and end dates, or if the study is on hold or abandoned.

Some amendments are considered Substantial Amendments by the Health Research Authority, and others are non-Substantial Amendments and the submission process to the REC differs.

All amendments, whether substantial or otherwise must be notified to the R&I Office in order for the R&I Office to review. The Research Office will liaise with appropriate departments if necessary to approve the amendment. If no response is received within 35 days, the amendment is automatically approved by the Trust

When submitting a notice of amendment to the R&I Office, always enclose the following:

- Notice of Substantial Amendment (or communication to the REC)
- All amended documents submitted to the REC (protocol, patient information leaflet etc.)
- HRA and/or REC approval of the amendment if required
- MHRA approval (if CTIMP)

Incomplete submissions will be deemed invalid.

Amendments should not be implemented without appropriate HRA/REC and MHRA (if CTIMP) approval.

25. INTELLECTUAL PROPERTY

Where there is potential for intellectual property arising from research, then the CI/PI should contact the R&I Office for further guidance. Refer also to the Trust IP policy on the intranet.

26. TRAINING REQUIREMENTS

All researchers should only conduct research for which they are adequately qualified and experienced and those involved in this procedure should also be adequately qualified and experienced.

27. EQUALITY IMPACT ANALYSIS

As part of its development, this document was analysed to consider / challenge and address any detrimental impact the policy may have on individuals and or groups protected by the Equality Act 2010. This analysis has been undertaken and recorded using the Trust's analysis tool, and appropriate measures will be taken to remove barriers and advance equality of opportunity in the delivery of this policy / procedure

28. FREEDOM OF INFORMATION EXEMPTION ASSESSMENT

Under the Freedom of Information Act (2000) we are obliged to publish our policies on the Trust's website, unless an exemption from disclosure applies. As part of its development, this policy was assessed to establish if it was suitable for publication under this legislation. The assessment aims to establish if disclosure of the policy could cause prejudice or harm to the Trust, or its staff, patients, or partners. This assessment has been undertaken using the Trust's Freedom of Information Exemption Guide, and will be reviewed upon each policy review.

29. INFORMATION GOVERNANCE ASSESSMENT

This Policy has been analysed to ensure it is compliant with relevant information law and standards as in place at the time of approval, and are consistent with the Trust's interpretation and implementation of information governance components such as data protection, confidentiality, consent, information risk, and records management.

Compliance will be reviewed against any changes to legislation / standards or at the next review of this document.

30. SAFEGUARDING

All staff have a responsibility to promote the welfare of any child, young person or vulnerable adult they come into contact with and in cases where there are safeguarding concerns, to act upon them and protect the individual from harm.

All staff should refer any safeguarding issues to their manager and escalate accordingly in line with the Trust Safeguarding Families Policy and Local Safeguarding Children/Adult Board processes.

31. MONITORING

The effective application of this policy / guideline, including adherence to any standards identified within will be subject to monitoring using an appropriate methodology and design, such as clinical audit.

Monitoring will take place on a biannual basis and will be reportable to the Quality Group via the Clinical Effectiveness and Quality Improvement Team.

32. REVIEW

This policy will be reviewed three-yearly unless there is a need to do so prior to this; e.g. change in national guidance.

33. REFERENCES

Equality Act 2010

Freedom of Information Act 2000

NIHR CRN Portfolio- https://www.ukctg.nihr.ac.uk/
NHS Standing Financial Instructions - https://www.england.nhs.uk/wp-content/uploads/2018/04/nhs-england-standing-financial-instructions-v9.pdf

Research Development - researchdevelopment.penninecare@nhs.net

NIHR Research Support Services - https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/framework-for-research-support-services.htm
Common law duty of confidentiality - https://www.health-ni.gov.uk/articles/common-law-duty-confidentiality

GDPR Guidance - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

Clinical Trials Toolkit website - http://www.ct-toolkit.ac.uk/

NIHR Industry Costing Templates - Association of British Pharmaceutical Industry (ABPI) model Clinical Trial/Investigation Agreements

HRA Website - https://www.hra.nhs.uk/

Governance Arrangements for RECs (GAfREC, September 2018) guidelines - https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures/

Integrated Research Application System (IRAS) -www.myresearchproject.org.uk

Research & Innovation Office generic mail - researchdevelopment.penninecare@nhs.net

DH Guidance - Attributing the costs of health and social care Research & Development (AcoRD)

Substantial Amendments and non-Substantial Amendments - https://www.hra.nhs.uk/approvals-amendments/