York Hospitals NHS
NHS Foundation Trust

Research Policy

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1 Introduction & Scope

This Policy sets out the arrangements under which research will be conducted within the Trust, under headings as on the Contents page.

2 Definitions and Glossary of Acronyms

Alliance	As the context permits: (1) The North and East Yorkshire R&D Alliance, as established under the Alliance Agreement (2) One or more of the NHS organisations party to the Alliance Agreement
Alliance Agreement	The Agreement between the Trust and other NHS organisations for establishing and maintaining the Alliance as currently in force
Alliance Guidance	Guidance on research topics managed by the R&D Unit for use within the Alliance and published on its website www.northyorksresearch.nhs.uk
Alliance Standard Operating Procedures (SOPs)	Standard Operating Procedures for conduct of research managed by the R&D Unit for use within the Alliance and published on its website www.northyorksresearch.nhs.uk
Alliance Steering Group	The Steering Group comprising a representative of each of the Alliance organisations, as described in the Alliance Agreement
Chief Investigator (CI)	The person who takes overall responsibility for the conduct of a research study (over all sites, if a multi-site study)
Clinical Lead for Research	Senior member of Trust's clinical staff appointed to this position
CLRN	The North and East Yorkshire and Northern Lincolnshire Comprehensive Local Research Network

CLRN Board	The Board established by NIHR as part of the governance structure of the CLRN
CLRN Executive	The Executive Group established by NIHR as part of the governance structure of the CLRN
Commercial Research Income	Monies received by the Trust under the terms of research contracts with commercial undertakings including pharmaceutical and medical devices companies
Director of Applied Learning and Research	Senior member of Trust's staff with responsibility for managing Directorate of Applied Learning and Research
Directorate of Applied Learning and Research	The Trust Directorate with this name
Education Review Board	Trust body with responsibility for oversight of Applied Learning and Research Directorate activities and for reporting on them to the Trust's Board of Directors
Finance Manager	A member of the Finance and Performance Management Team
Head of R&D	Senior member of staff with management responsibility within the Alliance R&D Unit
HYMS-EMU	The HYMS Experimental Medicine Unit, a NIHR Clinical Research Facility operated by the Trust as a Hull York Medical School NHS partner organisation, under contract from the Department of Health

Intellectual Property Rights	Rights in any patent, registered or unregistered trademark, trade and business name, domain name, know-how, together with any registered or unregistered design right, copyright, database rights and any other industrial or commercial monopoly rights which now subsist or may in the future subsist in any part of the world together with rights to apply for the registration of such rights
Lead Research Nurse Co-ordinator(s)	Senior member(s) of nursing staff with responsibility for management and supervision of research nurses and the administrative staff who support them
MedIPex Ltd.	A company limited by guarantee which is the Yorkshire and Humber Intellectual Property Hub and provides intellectual property and related services to NHS Trusts in the Yorkshire and Humber region
MHRA	The Medicines and Healthcare Products Regulatory Agency
NHS Permission	Formal permission of an NHS organisation to conduct of a research study within the organisation, as required by the Research Governance Framework to be given before any research begins
NIHR	National Institute for Health Research
NIHR-RSS	National Institute for Health Research – Research Support Services Framework
Non-Commercial Research Funding	Grant funding received by the Trust under the terms of research contracts with non-commercial bodies
Principal Investigator (PI)	The person who, in a multi-site research study, takes overall responsibility for conduct of the research at that particular site
R&D	Research and Development

R&D Committee	The North and East Yorkshire Research and Development Committee as described in the Alliance Agreement
R&D Lead	The person appointed under the terms of the Alliance Agreement to represent the Trust on the R&D Committee. Duties of this post include providing clinical leadership for R&D within the Trust and reporting on R&D matters at Board level. This will usually be the Clinical Lead for Research
R&D Manager	Member of staff within R&D Unit with contract, finance and governance responsibilities
R&D Unit	The North and East Yorkshire Alliance R&D Unit as described in the Alliance Agreement
Research	Research as defined in the Research Governance Framework: "…the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods[1]." *[1] This definition includes studies that aim to generate hypotheses as well as studies that aim to test them.*
Research Governance Framework (RGF)	The Research Governance Framework for Health and Social Care (Department of Health, 2005) and any subsequent amendments thereto

Research Support Staff	Research Nurses, Junior Doctors, Research Assistants, Pharmacy, Laboratory, Radiology and other Support Department Staff and Administrative Staff who are: • employed by the Trust (with funding from any source); • have job descriptions requiring them to work at least 0.2 wte on the conduct of a research project or projects; • are not Chief or Principal Investigators; • are not conducting research as part of a registered postgraduate degree course.
Researchers	Staff who are: • Employed by the Trust or • Employed by a university or other external organisation and undertake research in the Trust under honorary contract; And undertake their research as Chief or Principal Investigators or as part of a registered postgraduate degree course.
Regulations	The Medicines for Human Use (Clinical Trials) Regulations 2004, the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, The Medicines for Human Use (Clinical Trials) Amendment (No. 2) Regulations 2006, The Medicines for Human Use (Clinical Trials), The Blood Safety and Quality (Amendment) Regulations 2008, The Miscellaneous Amendments Regulations 2009 and any subsequent amendments thereto – collectively known as the UK Clinical Trial Regulations
Sponsor	The organisation with overall responsibility for a research study as defined in the Research Governance Framework and (for clinical trials of investigational medicinal products) the Regulations
Trust Research Award Fund	Monies held by the Trust in a fund to be used by the R&D Committee to make research awards

3 Policy Statement

3.1 Content of the Trust's Research Portfolio

The Trust will determine the desired content of its research portfolio by identifying specialties in which support will be invested for:

- NIHR portfolio clinical trials;
- NIHR portfolio research other than clinical trials;
- Other externally-initiated (commercially or non-commercially funded) research;
- Internally-initiated research.

This determination will be made by a biennial review and consultation led by the Clinical Lead for Research and presented to the Trust's Executive Board for approval.

The CLRN, the R&D Committee and the R&D Unit will be informed of the outcome of this process and will take it into account in introducing studies to the Trust or processing applications for Trust sponsorship or NHS Permission.

3.2 Research initiated by members of the Trust's staff

Except where research is being undertaken for a work-related qualification supported by the Trust under its Learning Leave Policy or Consultant Study Leave Policy, staff who initiate research within the Trust are expected to obtain or identify funding to cover its costs, including their own time. The normal expectation is that external funding will be sought, from appropriate commercial or non-commercial sources.

Staff initiating research should discuss their plans at the earliest stage with their Directorate Manager or Service Head, the R&D Unit, and any other departments in the Trust that would be involved in the proposed project. They should also refer to Alliance SOPs, particularly those concerning research sponsorship.

The Trust will identify individuals to receive dedicated support to develop research collaborations and submit grant applications, particularly for NIHR portfolio-eligible funding. This will be done annually, in a process led by the Clinical Lead for Research.

3.3 The North and East Yorkshire R&D Alliance

The Trust works in formal collaboration with NHS partners to ensure provision of effective research management, governance and support within the organisation. Under the Alliance Agreement it hosts the R&D Unit and employs its staff, led by the Head of R&D. It also administers the R&D Committee which is the shared decision-making body on research governance for the Alliance partners.

In accordance with the Alliance Agreement the Trust has the following arrangements in place:

Management of the Head of R&D and membership of the Alliance Steering Group on behalf of the Trust – Director of Applied Learning and Research.

Trust R&D Lead and member of the R&D Committee – Clinical Lead for Research.

3.4 Research Management and Governance

All research that takes place within the Trust must be clearly identified as research and managed in accordance with the Research Governance Framework.

To ensure that all research projects are identified as such, any investigative project – including clinical audit, service evaluation and patient surveys – must be classified before work begins, in accordance with the Alliance Guidance "Classifying Investigative Projects."

In addition to the Trust's organisational responsibility, all staff who are involved in research in any way have individual responsibility to comply with the RGF which is mandatory Department of Health Guidance. This includes individual and organisational responsibility for compliance with the law relevant to research in the NHS.

In particular, clinical trials of investigational medicinal products are subject to detailed legislation and there is organisational and individual responsibility to conduct them in accordance with the Regulations.

The R&D Unit is responsible for providing research management and governance services within the Trust, including (but not limited to):

- co-ordination of the process for giving NHS Permission before any study begins;

- putting in place appropriate contracts for research and managing contractual arrangements;
- publishing and managing detailed Guidance and Standard Operating Procedures relating to research;
- representing the Trust in its capacity as Sponsor of a clinical trial or other research project;
- research quality assurance including arranging or providing monitoring on behalf of the Trust when it sponsors research, and providing care organisation auditing to assure RGF compliance.

All letters giving NHS Permission on behalf of the Trust will be issued by the Head of R&D in accordance with the relevant Alliance SOP.

All research contracts will be signed on behalf of the Trust by the Chief Executive, in accordance with the relevant Alliance SOP and the Trust's Scheme of Delegation.

In all matters of research management and governance the R&D Unit reports to the R&D Committee which:

- Works in accordance with the Committee Constitution appended to the Alliance Agreement;
- Under that Constitution has responsibilities including all decisions on Trust sponsorship of research projects; management of identified research risks; acting as a grant awarding body in relation to any funding available for this purpose;
- Reports to the Education Review Board and similarly as required by the other Alliance member organisations.

All Trust staff involved in research are responsible for:

- familiarising themselves with, and working to Alliance Guidance and Alliance SOPs;
- ensuring that they are appropriately qualified and trained for their research activities, keeping personal research training records and attending any training the R&D Unit informs them they should undertake;

- liaising with the R&D Unit to ensure that no research takes place without the necessary approvals in place and that the Trust's management of research is at all times based on correct and up to date information.

3.5 Trust compliance with NIHR-RSS Standards

The Trust has committed to compliance with NIHR-RSS Standards for management of research in the organisation. It publishes a Research Operational Capability Statement on the Alliance website and this will be regularly reviewed by the Executive Board. In all cases where this is appropriate (as indicated on the Alliance website) the NIHR-RSS Study Planning Tool will be used to assess each potential study being introduced to the Trust and plan for mitigation of any identified operational risks. This process is co-ordinated by the R&D Unit and requires consultation with researchers and support departments. All staff are responsible for assisting the R&D Unit to make this assessment so that the organisation's response to sponsors and other external organisations can be as timely and complete as possible.

3.6 Relationship with the CLRN

3.6.1 As CLRN host organisation

Under contract with NIHR the Trust is the CLRN host organisation. In that capacity it hosts the Core Management Team of the CLRN and employs its staff.

The CLRN Core Management Team Senior Manager will be line managed by the Director of Applied Learning and Research.

The CLRN Clinical Director and any Co-Clinical Directors, if not employees of the Trust, will be granted honorary contracts of employment with the Trust in order to ensure appropriate accountability to the Trust in its capacity as CLRN host organisation.

As host organisation the Trust may provide the services of a member of the Finance Department to attend meetings of the CLRN Executive.

The Trust will retain the element of funding provided for the host function in order to provide finance, human resources and other host services for the CLRN.

3.6.2 As a CLRN member organisation

The Trust is also a member of the CLRN and, with the other member organisations, is entitled to membership of the CLRN Board. The Trust's representative on the CLRN Board will be the Director of Applied Learning and Research.

The CLRN Board oversees membership of the CLRN Executive to ensure that it represents different elements of health care in the CLRN area (for example primary care, secondary care, mental health). If a Trust representative is chosen by the CLRN Board to be the secondary care representative on the CLRN Executive, that representative will be the Clinical Lead for Research.

CLRN allocations of Service Support Costs relating to specific projects will be communicated to the R&D Unit and managed in accordance with Section 3.13.4.

CLRN proposals to allocate funding for salary, 'on-costs' or associated costs of employing Research Support Staff; or sessional payments or 'backfill' for Researchers, will be made by the CLRN Senior Manager following consultation with members of Trust staff as the Director of Applied Learning and Research shall determine. Depending on the nature of the proposed investment this is likely to include some or all of the following: the Clinical Lead for Research, the Head of R&D, the Finance Manager with responsibility for R&D, the Lead Research Nurse Co-ordinator and any Directorate Managers and Clinical Directors whose departments are affected by the proposal. All agreements made on such arrangements will be evidenced by written agreements or exchanged letters signed (on behalf of the CLRN) by the Clinical Director and (on behalf of the Trust) by the Director of Applied Learning and Research.

If the CLRN proposes to fund newly created posts or services the Trust's normal Business Case process will be used, including consideration of available accommodation and facilities.

3.7 Relationship with other NIHR networks

The Trust is part of the Yorkshire Cancer Research Network and the Yorkshire Stroke Research Network; it may become a member of other NIHR networks as they develop their activities in the area.

Trust representation on management or similar groups for these networks will be provided by the Head of R&D or another suitable member of R&D Unit staff.

Proposals to fund salary, 'on-costs' or associated costs of employing Research Support Staff to work in 'topic-specific' NIHR networks may be made by the network co-ordinating centre, with or without financial support from the CLRN. Consultation on such proposals within the Trust will be co-ordinated by the Head of R&D and may include some or all of the following: the Clinical Lead for Research, the Director of Applied Learning and Research, the Finance Manager with responsibility for R&D, the Lead Research Nurse Co-ordinator and any Directorate Managers and Clinical Directors whose departments are affected by the proposal. All agreements made on such arrangements will be evidenced by written agreements or exchanged letters signed (on behalf of the 'topic-specific' network) by the relevant Network Clinical Director and (on behalf of the Trust) by the Director of Applied Learning and Research.

If there is a proposal to fund newly created posts or to provide accommodation and host services for NIHR Network staff employed by other organisations the Trust's normal Business Case process will be used.

3.8 Relationship with other external research partners

The Trust seeks to work collaboratively with academic institutions, other NHS Trusts or other research organisations wherever this is desirable to further its strategic research objectives. The Trust welcomes opportunities for members of its staff to contribute to relevant committees of partner organisations.

Appropriate contracts will be negotiated and put in place by the R&D Unit whenever the Trust collaborates with external partners in relation to sponsoring, funding, hosting or providing services for research.

3.9 The HYMS Experimental Medicine Unit

HYMS-EMU is operated by the Trust as a HYMS NHS partner, with core funding from NIHR. Its purpose is to provide facilities and safe systems of working for Phase 1 clinical trials and other forms of early-stage translational research. The following arrangements apply:

EMU operates within the governance structure of the Trust. Its team of research nurses and administrative staff is led by the Unit Co-ordinator, who is managed by the Head of R&D. The Unit is run to Alliance SOPs.

A Steering Group including representatives of the Trust and HYMS, is responsible for guiding development of EMU and considers the suitability of all potential EMU projects at an early stage.

All projects run within EMU are subject to Trust research management and governance arrangements in the usual way.

3.10 Employment and management of Researchers

The Trust has specific responsibilities under the RGF in relation to its role as an employer of Researchers.

The R&D Unit is responsible for:

- providing SOPs and information on training requirements for Researchers;
- in collaboration with the CLRN and other elements of NIHR, providing in-house courses or information on accessing courses offered by external providers;
- ensuring that externally-employed Researchers have honorary contracts of employment or formal letters of access when required:
- issuing honorary contracts of employment for research except where clinical honorary contracts have already been issued that cover research activity;
- issuing Research Passports in accordance with NIHR guidance;
- annually, or on request, providing Directorate Managers with details of current research projects in their directorate or conducted by their staff;
- obtaining full information about the proposed resource implications and financial arrangements for all projects;
- consulting Directorate Managers and Finance Managers prior to grant of NHS Permission for any project.

Directorate Managers are responsible for:

- Keeping a list of all research projects undertaken by staff in their directorate;
- In collaboration with Clinical Directors or managers of non-medical Researchers, participating in:
    - the biennial Trust portfolio review described in 3.1 above;
    - the annual identification of individuals to receive particular support described in 3.2 above;
- Making ‘backfill’ arrangements and modifying job plans / descriptions as required to give effect to agreements made under these elements of this Policy;

- Facilitating attendance by their staff at training they are required to undertake in connection with their research activity.

Clinical Directors and managers of non-medical Researchers are responsible for:

- Ensuring their own knowledge and understanding of the requirements for research by undertaking training in Good Clinical Practice, as required for staff who work on clinical trials of investigational medicinal products, in accordance with the Alliance SOP on training requirements for researchers.
- (in consultation with the Clinical Lead for Research and the R&D Unit) ensuring that staff will have research supervision appropriate for their level of research knowledge and experience. This is distinct from clinical supervision and may be provided separately; arrangements with HYMS and other academic staff may be appropriate. Clinical Directors and Managers should consider that research supervision may be required at any level of clinical seniority.
- including the research activity in the staff member's appraisals, with inclusion in the process of any research supervisors involved.

The Medical Staffing Department (Human Resources Directorate) is responsible for:

- Ensuring that all substantive and honorary contracts of employment issued to medical staff take into account the research activity in which they may be engaged and provide inclusion in the Trust's arrangements for clinical negligence cover. In particular, honorary contracts issued to medical staff or job plans incorporated in such contracts by reference will expressly include any involvement in authorised research within the Trust and not restrict research only to specific days or times.

3.11 Employment and management of Research Support Staff

As for Researchers (see Section 3.10) the R&D Unit is responsible for:

- providing SOPs and information on training requirements for Research Support Staff;

- in collaboration with the CLRN and other elements of NIHR, providing in-house courses or information on accessing courses offered by external providers.

All Research Support Staff will be employed within structures that provide for:

- Effective management and supervision of the research element of their work;
- Supervision appropriate for maintaining standards within any professional group to which they belong;
- Appropriate accommodation and facilities, including provision of secure storage of research materials and data.
- Appraisal of their research activity by a person with appropriate knowledge of research processes.

Recognising that this will not always be possible, the Trust's preferred model for employment and management of Research Support staff is within Research Support teams, providing services to Investigators as a group, rather than working as individual Research Support staff within a clinical team.

All Nurses who work in the Trust as Research Support Staff, and the administrative staff who support them, will be line managed by, or receive professional supervision from, the Lead Research Nurse Co-ordinator. Those who are employed with funding from one of the NIHR networks will have additional liaison relationships with network co-ordination staff.

3.12 Management of intellectual property

Intellectual Property Rights that arise from the involvement of the Trust and its staff in research should be managed in accordance with the Trust's Intellectual Property Policy. Any enquiries should be directed to the R&D Unit who may refer the matter to MedIPex Limited, the Yorkshire and Humber NHS Innovation Hub.

3.13 Financial arrangements

The Trust receives research related income from a number of sources including commercial organisations – usually pharmaceutical or medical devices companies – research councils, government departments, elements of the NIHR and charities.

Some of this income will relate exclusively to individual research studies (study specific income), some will relate to a programme of

research and some will be to provide overarching support to Trust departments who support research.

3.13.1 Responsibilities

The Trust's Finance Managers are responsible for managing all research related income and expenditure. The R&D Manager, within the R&D Unit, has primary responsibility for costing research within the Trust and will provide assistance to the Finance Managers where appropriate.

The CLRN is responsible for ensuring that Service Support Funding and other agreed funding elements are paid to the Trust.

The designated Finance Manager with responsibility for R&D is responsible for providing finance services to the CLRN (host services), the Trust as CLRN member organisation and the Alliance.

3.13.2 Study specific costs, income and expenditure

All costs and income relating to a study are identified during the checks carried out for the Trust Sponsorship or NHS Permission application. Except where there are no significant cost issues involved (for example simple questionnaire studies) the R&D Unit will ask the Finance Manager for the relevant directorate(s) to review and approve the financial arrangements. For studies where the NIHR-RSS Study Planning Tool is used (see 3.5) this will help to identify issues pertinent to cost assessment at the earliest stage.

For all studies with expected income over £20K the R&D Manager will ask the Trust's Costing Accountant to create a new study specific cost centre.

Study specific invoicing arrangements along with copies of any relevant contracts and cost centre details will be provided to the relevant Finance Manager, who will be responsible for raising all invoices and ensuring income is coded to the correct cost centres.

The R&D Manager will assist where required with managing study specific invoicing, including identifying the amount to be invoiced based on study recruitment.

The Finance Manager will also be responsible for internal journaling of study specific income to Trust departments and processing any payments to third parties from study specific income.

3.13.3 Study specific costing

Studies for which an application is being made for Trust sponsorship will be costed by the R&D Manager with assistance from the relevant Finance Manager if required as part of the sponsorship application process. This will be taken into account by the R&D Committee in the sponsorship decision. In case of project changes during the regulatory applications, the relevant Finance Manager will be asked to review costing and income plans prior to grant of NHS Permission.

Externally sponsored (hosted) studies will be costed by either the CLRN (NIHR portfolio studies) or the R&D Manager (non-portfolio studies) as part of the NHS Permission process.

For commercially sponsored studies the NIHR costing template will be used, whether or not the study is an NIHR portfolio study. The template provides a standardised approach to overheads, capacity building factors and a market forces payment by results factor. The Trust will look to receive income for the research from commercial sponsors in accordance with national guidance.

For non-commercially sponsored research the Trust will aim to recover costs in accordance with current Department of Health guidance. Research costs should be covered by the funder and treatment costs (including excess treatment costs) will be met through normal commissioning arrangements. Service support costs for NIHR portfolio studies will be met by the CLRN.

3.13.4 CLRN service support funding

The CLRN Senior Manager will agree block funding to Trust departments with the Trust's designated Finance Manager for R&D. As individual NIHR portfolio studies are reviewed the CLRN will be responsible for identifying study specific service support costs. The designated Finance Manager will be responsible for ensuring that the cumulative total of service support costs identified for each department do not exceed the block funding allocated. As the total approaches the block allocation the designated Finance Manager and the CLRN Senior Manager will review and reallocate further service support block funding to ensure that no Trust department is subsidising NIHR portfolio research.

3.13.5 Disposition of research funds within the Trust

For research funded by non-commercial organisations the Trust's expectation is that its costs will be covered.

Research funded by commercial organisations is income-generating activity on the part of the Trust and the Trust recovers overheads at the rate of 20% of the direct study costs. Commercial study receipts will be utilised as follows:

80% - transfers to cost centres to cover study costs (e.g. budgets for Research Support Staff services, Laboratory budget for study tests); with remainder to Principal Investigator's Directorate Research Fund.

10% - retained centrally for general Trust use.

10% - allocated to a ring-fenced Trust Research Award Fund

The funds in the Trust Research Award Fund cost centre will be made available to the R&D Committee to award as grant funding to Trust researchers. The R&D Committee will issue calls for proposals as it considers appropriate given the amount of money available, for research that may include pilot studies designed to support subsequent external grant applications. Collaboration with clinical or academic colleagues will be encouraged in order to promote quality proposals. The R&D Committee will act as the grant awarding body in accordance with the Committee Constitution; the process will be competitive and involve independent peer review.

The aim of the Trust Research Award Fund is to provide 'pump-priming' support for research initiated within the Trust, and to make this available across specialty areas, including those in which there are limited opportunities to generate income from commercial drug development.

In exceptional cases it may be possible to retain within the directorate where the income has been generated some of the 10% that would otherwise be transferred to the Trust Research Award Fund. Applications to do this, with full explanation of the circumstances, should be made to the R&D Committee, with the support of the relevant Clinical Director. The decision of the R&D Committee will be final.

3.14 External inspection

All research-active staff will ensure that their research is fully and accurately documented in accordance with Alliance SOPs and will facilitate monitoring or auditing of the project as may be required by the protocol, the study contract or Alliance SOPs.

The Trust's response to external inspections of research, including MHRA clinical trial inspections will be co-ordinated by the R&D Unit in accordance with the Trust's External Inspections Policy and relevant Alliance SOPs. All staff in clinical or support departments included in the subject matter of the inspection will:

- provide the R&D Unit, on request, with any information required to compile the inspection dossier prior to the inspection;
- attend briefings arranged by the R&D Unit;
- attend inspection interviews as may be required by the inspectors;
- implement required actions or recommendations contained in the inspection report that are relevant to their research;
- assist the R&D Unit to make any general procedural revisions that may be necessary in response to inspection findings.

4 Equality Impact Assessment

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at an unreasonable or unfair disadvantage over others.

In the development of this policy, the Trust has considered its impact with regard to equalities legislation.

5 Accountability

- **Director of Applied Learning & Research**
    - Responsible for reporting in to the Trust Board and the Chief Executive for the review of the policy.
- **Head of R&D**
    - Responsible for co-ordinating review of the policy.
- **Directors/ Directorate Managers/Senior Managers**
    - Responsible for ensuring staff comply with the policy.

6 Consultation, Assurance and Approval Process

6.1 Consultation Process

Prior to presentation of this document to the Executive Board the following interested individuals and groups were asked to review and comment on the draft:

- The R&D Committee (which includes the R&D Leads for each of the Alliance organisations);
- The Education Review Board;
- The Clinical Director and Senior Manager of the CLRN;
- The Trust's:
    - Clinical Lead for Research;
    - Clinical Directors;
    - Directorate Managers;
    - Finance Manager responsible for R&D;
    - Lead Research Nurse Co-ordinators
    - Head of Corporate Finance;
    - HYMS Director of Clinical Studies.

6.2 Quality Assurance Process

Following consultation with stakeholders and relevant consultative committees, this policy has been reviewed by the Trust's Quality Assurance group to ensure it meets the NHSLA standards for the production of procedural documents.

6.3 Approval Process

Following completion of the Quality Assurance Process, this policy will be submitted to the Executive Board for approval.

7 Review and Revision Arrangements

7.1 Process for Reviewing a Procedural Document

This Policy will be reviewed every two years unless changes to relevant legislation or structural organisational changes require earlier review.

8 Dissemination and Implementation

8.1 Dissemination

This Policy will be published on the Trust's Intranet Site (Horizon). Its existence will be noted on the Alliance website www.northyorksresearch.nhs.uk where staff employed by the Trust will be referred to the Intranet. It will also be publicised in Team Brief and in the R&D Unit's regular email newsletter.

8.2 Implementation of Procedural Documents

This policy will be implemented one calendar month after the date on which it is publicised in Team Brief.

9 Document Control including Archiving Arrangements

9.1 Register/Library of Procedural Documents

This policy will be stored on the Trust's electronic portal, Horizon, on the policies and procedures site and will be stored both in an alphabetical list as well as being accessible through the portal's search facility.

9.2 Archiving Arrangements

On review of this policy, archived copies of previous versions will be automatically held on the version history section of each policy document on Horizon. It is the responsibility of the Publisher(s) to ensure that version history is maintained on Horizon.

9.3 Process for Retrieving Archived Documents

To retrieve a former version of this policy from Horizon, the publisher of this policy, identified on the front sheet, should be contacted.

10 Monitoring Compliance With and the Effectiveness of Procedural Documents

10.1 Process for Monitoring Compliance and Effectiveness

The R&D Unit has a Research Monitoring Officer, whose routine checking of research projects aims to identify a high proportion of instances of non-compliance.

10.2 Standards/Key Performance Indicators

The Outcome Indicators mandated by the NIHR-RSS Framework will be used.

11 Associated Documentation

Alliance SOPs and Alliance Guidance – published on www.northyorksresearch.nhs.uk

12 References

Department of Health (2005) Research Governance Framework for Health and Social Care, 2nd edition www.dh.gov.uk/en/Aboutus/Researchanddevelopment/Researchgovernance/index.htm

National Institute for Health Research website: www.nihr.ac.uk

Medicines and Healthcare Products Regulatory Agency website: www.mhra.gov.uk

13 Appendices

None