NHS
North Lincolnshire
Clinical Commissioning Group

Research and Development Strategy

2016 - 2018

Version 5.2 Revised September 2016. M.Girdham

Index **Page No**

1.0 INTRODUCTION

The purpose of the strategy is to set out how the NHS North Lincolnshire Clinical Commissioning Group (NLCCG), noted hereafter as the 'CCG' will promote research activity and the utilisation of research methodologies to contribute to the achievement of achieving its duty to improve health care for the patients in the North Lincolnshire based on sound clinical evidence and in line with NHS England duty to promote research.

The strategy sets out an action plan for Research and Development (R&D) within the CCG, reflecting the changes and opportunities for R&D in Commissioning. The strategy sets out how these targets will be achieved and affirms the CCG's commitment to the promotion of research, service evaluation and innovation.

2.0 BACKGROUND

The UK Government has stated its firm commitment to promote research throughout the NHS which it sees as essential to continually improve effectiveness of health services and patient outcomes. Indeed, there is an expectation that the UK will be the first research-led health service in the world. To oversee delivery on an NHS wide footprint NHS England has a statutory duty to promote health and social care research funded by commercial and non- commercial organisations (NHS constitution 2015, Health and Social Care Act 2012).

A number of policy documents have placed a strong emphasis on research activity in the NHS:

- The NHS Constitution. One of these principles includes a commitment to:

"The promotion and conduct of research to improve the current and future health and care of the population"

- The NHS White Paper, Equity and excellence: Liberating the NHS.

"The Government is committed to the promotion and conduct of research as a core NHS role. Research is vital in providing the new knowledge needed to improve health outcomes and reduce inequalities."

- The Government Response to the NHS Future Forum Report made the following commitments with respect to CCGs and research:

"CCG's legal duties should reflect their key role in making sure that, at a local level, the need for good research, innovation and a strong evidence basis for clinical decisions is paramount."

Currently awaited is the finally released NHS England R&D vision to emphasise how research and research evidence is part of the day to day functionality of the NHS and is fundamental to creating an evidence based decision making culture within the wider commissioning community.

A resource guide for commissioners has been published in 2016 through the collaboration from the Association of Medical Research Charities (AMRC), Department of Health, National Institute of Health Research (NIHR), NHS England and the NHS R and D Forum. This offers a practical guide to support boards and governing bodies of NHS commissioning organisations and commissioners in:

- Delivering their statutory responsibilities in relation to research

- Developing evidence based commissioning
- Increasing participation in research
- Increasing their research capacity
- Identifying good practice examples and translating these into practice locally.

2.1 RESEARCH GOVERNANCE – HRA PROCESS SINCE MARCH 2016

The current Research Governance Framework (2005) outlines principles of good governance that apply to all research within the remit of the Secretary of State for Health. It sets out principles, requirements and standards, defines mechanisms to deliver them and describes monitoring and assessment arrangements.

Other relevant legal acts regulating research are the Medicines for Human Use (Clinical Trials) Regulations 2004, the Human Tissue Act 2004 and the Mental Capacity Act (2005). Some of the provisions within these acts create offences triable in a court with penalties ranging from a fine, to imprisonment for up to 3 years, or both.

Since the end of March 2016 the Health Research Authority (HRA) have introduced a new system of managing governance arrangements for research studies undertaken in England that will replace local 'approval' systems.

HRA approval provides a single authoritative assurance that the study complies with required legislation and guidance and, where applicable for the study type, that a favourable opinion from an independent ethical review is in place.

Sponsors are no longer required to obtain NHS assurance or Research & development (R&D) approval from NHS Organisations for studies which have HRA approval. Instead the Sponsor must agree and confirm with host organisations in which they undertake their research, that the host site has the capacity and capability to deliver the study and that the arrangements are in place to do so.

The HRA has defined the different stages that sponsors and NHS organisations go through to mutually agreeing that the study can open at that site. These stages are:

- **Assess:** Assessing whether or not the NHS organisation has the capacity and capability to participate in the study
- **Arrange:** Putting any practical arrangements in place to provide the capacity and capability to deliver the study.
- **Confirm:** Confirming that the NHS organisation has the capacity and capability in place to deliver the study and will deliver the study. This confirmation is given through a formal agreement or via a new statement of activities which will be introduced for non-commercial studies.

NHS organisations hosting research can accept assurance of legal compliance from the HRA

Thus, rather than issuing NHS permission for a study to start NHS organisations will confirm to the sponsor that they are ready to start delivering a study either by signing an agreement with

the sponsor or working with the sponsor to mutually agree the new 'Statement of Activities' by email.
Site-specific information (SSI) forms are not required for studies with HRA Approval. Sponsors are expected to share the study documents with sites and the new Statement of Activities will provide explicit confirmation of the activities expected to be undertaken at site accessed via http://www.hra.nhs.uk/?s=statement+of+activities)

Studies supported by the NIHR Clinical Research Network (CRN) with HRA approval will not use NIHR Central System for Permission CSP as NHS Permission is no longer required.

In primary care the participating site is predominantly the GP practice (unless it is a CCG hosted study). As independent contractors the GP site confirms capacity and capability to initiate the study (as per HRA document dated 21/03/16, *HRA Approval in Primary Care settings: Principles of Study Set –up).*
The NY and Humber R and D office currently supports the processes for study set –up by addressing any outstanding local assurance issues. For example, to initiate a study that involves testing on a medicinal product (CTIMP) a local pharmacy technical review is required which takes place with the local R and D office liaison with medicines optimisation.
NOTE: In the case where a study is hosted by the CCG, for example, interviewing CCG staff the local R and D office facilitates the coordination of the assessment for capacity and capability.

3.0 THE RESEARCH INFRASTRUCTURE- PROMOTING & SUPPORTING RESEARCH

The Health and Social Care Act (HSCA) places a clear duty on the Secretary of State, NHS England and Clinical Commissioning Groups (CCG) to promote research.

Currently, a national infrastructure of research networks provides support to researchers, NHS organisations, academic institutions and commercial companies to facilitate research and to encourage participation in research. Research promotion is a statutory requirement for CCGs who have been granted powers to fund research activities (HSCA 2012, section 17, para.13).

In Appendix 1 the principal bodies are identified that working with NHS England will promote and support research.

North Lincolnshire is linked to the research infrastructure via the Yorkshire and Humber Local Clinical Research Network (LCRN).

4.0 EVIDENCE BASED COMMISSIONING

The CCG wishes to utilise and promote the principle that commissioning health services, delivering services and individual patient care are based on best evidence, underpinned by high quality evidence based research

Professionals within the CCG are expected to hold differing levels of evidence, knowledge and information (dependable on role) to translate and disseminate research and innovation in to practice. Accessing and facilitating appraisal of evidence to support and inform commissioning decisions will be a crucial element.

A systematic method of promoting a culture where commissioning decisions are based on evidence will involve the engagement with NICE, PHO, Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) and use of approved research databases.

Links with local Higher Educational Institutions (HEIs), Royal Colleges and other relevant bodies, for example the Academic Health Science Network (ASHN) will be strengthened to support knowledge transfer, the translation of research into practice and rapid implementation of evidence based improvement which translates in to practice.

Local clinical networks will also be utilised to provide local insights and nurture a culture of being more research aware to support the use of evidence for clinical improvement and to inform commissioning plans.

5.0 NHS NORTH LINCOLNSHIRE CCG STRATEGIC AIMS & OBJECTIVES FOR R&D

The CCG is committed to promoting research, service evaluation and innovation when addressing the healthcare priorities of the population in North Lincolnshire to ensure commissioning decisions are based on best available evidence. The CCG recognises that maximising the quality and effectiveness of patient care is best realised through a strategic approach in taking part, attracting and funding research studies that best match the population characteristics in North Lincolnshire as well as working towards attracting more high quality commercial studies into this area. Maximising the benefits of research through innovation, income, knowledge improvement are key to improving patient/public outcomes.

5.1 Aims

The CCG aims to positively engage with the research agenda and be evidence–driven organisation utilising research methodologies to:

1. Improve the health of patients/public by commissioning research that supports the development of best evidence, innovation and commissioning priorities.
2. Develop a research culture characterised by increased patient and public involvement and engagement in research studies both as participants and researchers.
3. Increase knowledge and understanding of specific treatments and care delivery to determine if service provision is effective in terms of improved outcomes and value for money.
4. Inform commissioning, service provision and identify gaps in the evidence base.

5.2 Objectives

- Identify CCG Research Champions to assist in identifying research topics in line with commissioning priorities.
- Strengthen and support a culture of evidence based commissioning underpinned by research, innovation and clinical effectiveness.
- Ensure the inclusion and opportunities for patients to be involved in research through our main providers' contractual requirements.
- Develop proactive engagement with partners for knowledge transfer, the translation of research and innovation into practice and rapid implementation. For example NICE, PHO, CLARHC's, AHSN's, The Cochrane Library, local Higher Education Institutions**.**

- Meet the responsibilities to promote and support research including excess treatment costs associated with non– commercial research.
- Support the engagement of patients and public in research both as participants and researchers.

The CCG will develop an action plan to deliver against these objectives.

5.3 Implementation of the objectives

To address the actions the CCG recognises it will be necessary to have appropriate resources and support, which the CCG will look to ensure principally through engagement with the Yorkshire and Humber LCRN and emerging AHSN's. Support will be provided via the North Yorkshire and Humber R&D team.

6.0 EQUALITY & DIVERSITY STATEMENT

The CCG is committed to embedding a culture of inclusiveness and continues to strive to meet the needs and aspirations of our patients, service users, carers and staff in commissioning services which respond to individual needs. We recognise and value people as individuals and accommodate differences wherever possible by making adjustments to working arrangements or practices.

As a commissioner of health services, we work with other health care providers and contractors to ensure that valuing diversity and promoting fair access to services are core elements of care and that full consideration is given to all equalities issues when planning or redesigning services and when assessing the health needs of the local population. In partnership with local communities and other local organisations in the health and social care sector, we aim to reduce inequalities in health.

All research activities carried out in the North Lincolnshire CCG will be formally assessed to ensure compliance with the equality and diversity policies. The research involves patients from all backgrounds and gives them equal opportunity to be involved in research activities. In case there are special needs, the research protocols make provision to address this. All research activity has been assessed for ethical issues and obtained formal ethical approval when required.

As part of performing an equality impact analysis, this strategy is not expected to have an adverse effect on people who share protected characteristics.

7.0 SUSTAINABILITY

7.1 The policy has been assessed against the CCG's Sustainability themes. Please see Appendix 2.

8.0 BRIBERY

8.1 The CCG follows good NHS business practice as outlined in the Business Conduct Policy and has robust controls in place to prevent bribery. Due consideration has been given to the Bribery Act 2010 in the development of this policy document and no specific risks were identified.

9.0 ROLES & RESPONSIBILITIES

Within the reporting structure of the CCG the lines of responsibility are as follows:

The Chief Officer is ultimately accountable for ensuring a clear duty to demonstrate a commitment to promote research. This duty is delegated to the Director of Quality and Governance/Executive Nurse who is responsible for ensuring that research and evidence based practice takes place locally in line with national policy.

All CCG officers are responsible for ensuring research activity is undertaken in line with national Research Governance requirements and are required to seek advice from the Director of Quality & Governance / Executive Nurse in relation to any proposed research activity and/or clinical audit activity.

Support for implementing the CCG R&D Strategy will be provided by the North Yorkshire and Humber R&D team hosted from the 1st December 2015 by East Riding of Yorkshire Clinical Commissioning Group (ERY CCG) through an agreed Memorandum of Understanding (MoU).

All research activity is reported to and overseen by The Director of Quality & Governance/ Executive nurse. Assurance reports identifying research governance compliance and implementation of the Strategy will be given to the Quality group with periodic updates to the governing body via the Quality group.

10.0 PERFORMANCE MONITORING AND REPORTING

NHS England has published an Improvement and Assessment framework 2016/17 to ensure compliance and monitoring of performance which will build in to the CCG commissioning cycle. Publically available research activity reports will be produced on a 6 monthly basis by the R&D team.

11.0 SUMMARY

This document sets out a 2 year strategy for promoting high quality research within the CCG which will be of benefit to the population of the North Lincolnshire CCG. The strategy places a strong emphasis on how the CCG will deliver on the promotion of research and how the CCG in doing this will work with a number of stakeholders across the research community. The action plan sets out the key milestones and will be performance managed against the identified objectives.

12.0 REFERENCES

Determining Arrangements for Supporting Research in Primary and Community Care: A Discussion paper (2012) DOH

Equity and Excellence: Liberating the NHS (2010) DOH

Health and Social Care Act (2012) DOH

Human Tissue Act (2004) legislation.gov.uk

HRA web link: www.hra.nhs.uk

Innovation, Health and Wealth (2011) DOH

Mental Capacity Act (2005) legislation.gov.uk

NHS Constitution (2015), 'The NHS Constitution, The NHS belongs to us all', [Online], Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/480482/NHS_Constitution_WEB.pdf

NHS England (2013) Research and Development Strategy 2013 – 2018. *(Await final release of document)*

NHS England (2016) CCG improvement and assessment framework 2016/17

Research, Evaluation and Evidence: a guide for commissioners. (2016) Designed by Bath Research and Development.

The Medicines for Human Use (Clinical Trials) Regulations (2004) legislation.gov.uk

The Academy of Medical Sciences (2011) A New Pathway for the Regulation and Governance of Health Research, London.

Our Strategic Intent (2013) NHS Improving Quality

Our Vision for Research in the NHS (2013) Association of Medical Research Charities

13.0 GLOSSARY

R&D – Research and Development

CCG's – Clinical Commissioning Groups

CTIMP- Clinical trial of an Investigational Medicinal Product

HSCA – Health and Social Care Act

HRA – Health Research Authority

LCRN –Local Clinical Research Network

NICE – National Institute for Health and Care Excellence

PHO – Public Health Observatory

CLAHRC's – Collaborations for leadership in applied health research and care

HEI's – Higher Educational Institutions

AHSN – Academic Health Science Network

NIHR - National Institute for Health Research

CRN – Clinical Research Network

NIHR CRN – National Institute for Health Research Clinical Research Network

DOH – Department of Health

RCGP – Royal College of General Practitioners

Appendix 1

Research Infrastructure linked to North Lincolnshire CCG

NHS England.

NHS England holds the statutory duties to promote the use of research and the use of evidence obtained from high quality research. This supports the NHS outcomes Framework objectives by building the evidence base and identifying best practice. By commissioning research that delivers benefits for patients and families and increasing patient and public engagement in research this will support the further development of evidence base and innovative practice.

The National Institute for Health Research (NIHR)

The NIHR is the research arm of the NHS with an annual budget of almost £1 billion. During 2011/2012 the budget included £202.2 million for research across a broad range of programmes and initiatives. The NIHR is part of the Department of Health and is the first main route for Health Research providing transparent, competitive funding to support clinical and applied health research, the training and development of health researchers, systems to support research and the NHS infrastructure for research.

The NIHR Local Clinical Research Network – Yorkshire and Humber

The NIHR Clinical Research Network (NIHR CRN) is a subsidiary of the NIHR and is the clinical research delivery arm of the NHS. It operates nationally across England through a national coordinating centre and has since April 2014 been re configured in to 15 Local Branches of which Yorkshire and Humber forms one of the NIHR Local Clinical Research Networks.

The Yorkshire and Humber Local Clinical Research Network is hosted by Sheffield Teaching Hospitals NHS Foundation Trust. Our Local network helps to increase the opportunities for patients to take part in clinical research, ensures that studies are carried out efficiently, and supports the Government's Strategy for UK Life Sciences by improving the environment for commercial contract studies in the NHS in Yorkshire and Humber.

The Local Clinical research Network delivers research across 30 Clinical specialities of which primary care is one of these specialities supporting a wide range of research which look at, for example; promoting a healthier lifestyle, disease diagnosis and prevention, management of long term illnesses such as diabetes, prevention of future ill –health and treating common conditions such as tonsillitis or influenza.

Academic Health Science Networks (AHSNs)

The AHSN are partnerships between one or more universities and health care providers focusing on research, clinical services, education and training. They are intended to ensure that medical research breakthroughs lead to direct clinical benefit to patients. Together they will cover the whole of England with the same boundaries as the emerging NIHR CRN.

CLAHRC Yorkshire and Humber – Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber. CLAHRC ‘s help to ensure research evidence is used to improve health services, this has been achieved by conducting applied research, translating research into healthcare practice, and increasing capacity of health services to undertake more applied research and translate it into practice.

Faculty of Health and Social Care – University of Hull

The Faculty of Health and Social Care is a well - established centre for education and research in the field of Health care. The Faculty is committed to high academic standards and involves the collaboration with our NHS partners to support research partners.

Health Research Authority (HRA)

The Health Research Authority (HRA) was established in 2011 to protect and promote the interests of patients and the public in health research and to steam line the regulation of research. The HRA are responsible for Research Ethics Committee(s), the National Social Care Research Ethics Committee, Gene Therapy Advisory Committee and the Confidentiality Advisory Group.

Hull, York Medical school (HYMS)

Hull, York Medical School is a partnership between the universities of Hull and York and the NHS. Medicine is the focus of the undergraduate programme but post graduate courses are also available.

APPENDIX 2

SUSTAINABILITY IMPACT ASSESSMENT

Staff preparing a Policy/Board Report/Committee Report/Service Plan/Project is required to complete a Sustainability Impact Assessment. Sustainability is one of the Trust's key Stratergoies and the Trust has made a corporate commitment to address the environmental effects of activities across Trust services. The purpose of this Sustainability Impact Assessment is to record any positive or negative impacts that this activity is likely to have on each of the Trust's Sustainability Themes. For assistance with completing the Sustainability Impact Assessment, please refer to the instructions below.

Policy/ report/Service Plan/ Project Title:				
Theme(Potential impacts of the activity)	Positive Impact	Negative Impact	No Specific impact	What will the impact be, how can it be mitigated? (action)
Reduce Carbon Emission from buildings by12.5% by 2010-11 then 30% by 2020		✓		
New builds and refurbishments over £2million (capital costs) comply with BREEAM Healthcare requirements.		✓		
Reduce the risk of pollution and avoid any breaches in legislation		✓		
Goods and services are procured more sustainability.		✓		
Reduce carbon emissions from road vehicles		✓		
Reduce water consumption by 25% by 2020		✓		
Ensure legal compliance with waste legislation.		✓		
Reduce the amount of waste produced by 5% by 2010 and by 25% by 2020		✓		
Increase the amount of waste being recycled to 40%		✓		
Sustainability training and communications for employees		✓		
Partnership working with local groups and organisations to support sustainable development		✓		
Financial aspects of sustainable development are considered in line with policy requirements and commitments.		✓		