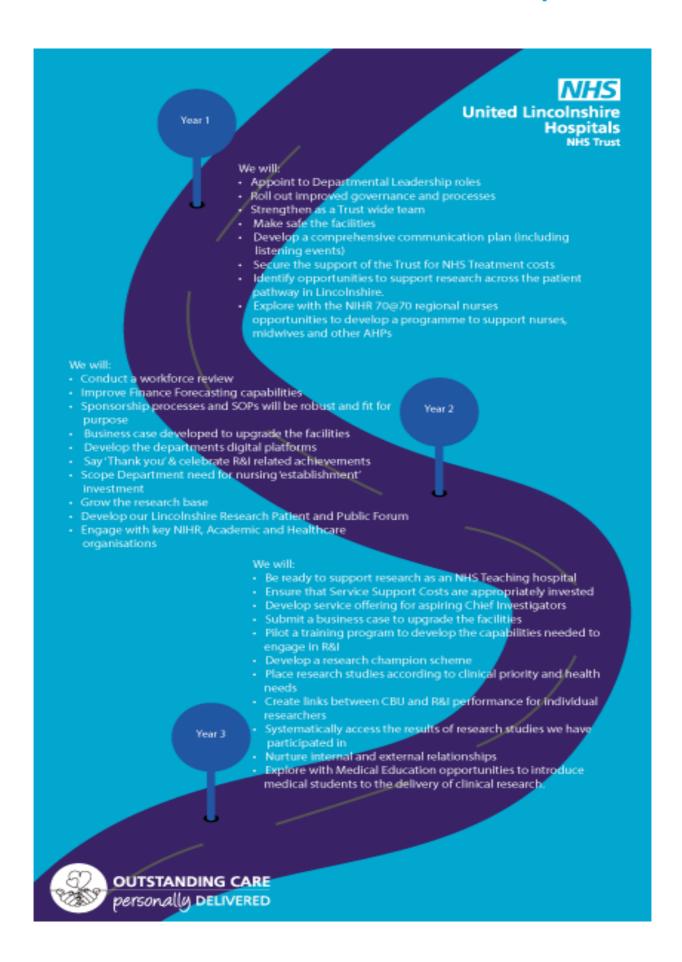


# Our Research & Innovation Strategy 2021- 2024





# **Research & Innovation Actions Roadmap**



**Executive Summary: Initiatives by year** 

Priority	Year 1	Year 2	Year 3
Strategic Objective	1: Strengthen the R&I Department		
	a valued and recognised part of the	standards, development and working e he ULHT, which can in turn improve pat	
	Appoint to Departmental Leadership roles	Conduct a consultation around the scope and roles within the Department and make changes if necessary	Plan to appoint to any gaps identified in Year 2
Support Our Team	Working with the Organisational Development we will form as a team, getting to know each other and exploring ways of working together	Ensure individuals within the department receive training to give them the tools to drive forward the transformational change that the department needs	
Improve Our Facilities	Take immediate action and investment to make safe the facilities at Lincoln County	Develop a business case to upgrade the facilities at Lincoln County and Grantham and District Hospital sites	Submit a business case to upgrade accommodation
	Establish the Departmental Governance flows by engaging fully in Trust governance	The processes and SOPs associated with sponsored research studies will be refreshed to ensure they are robust and fit for purpose	A training programme for perspective Chief Investigators will be developed and piloted
Danastmant	The processes and SOPs associated with hosted research studies will be refreshed to ensure they are robust and fit for purpose		
Department Governance (including Financial Integrity)	Roll out new financial processes across the department providing training and mentoring	Develop forecasting capabilities	Invest NHS Service Support Costs appropriately
Raising Awareness	Develop a comprehensive communication plan to maximise reach of communications (including newsletters, Trust induction, NIHR produced materials, posters, videos and events)	Develop our digital platforms, to ensure information is easy to find and up-to-date	Develop a research champion scheme to be piloted
Demonstrating Clinical Relevance		Explore how to effectively access the findings of research studies and agree a process of informing others in ULHT	Develop a system to place research studies according to clinical priority and health needs
Strategic Objective 2	2: Build our capacity & capability	· ·	
We will build the cap		t and future workforce to embrace and a offessional groups.	actively engage with research
Valuing Contributions	Roll out the 'R&I Certificate Scheme' across the portfolio of research studies	Develop, pilot and roll out plans to say 'Thank you' to the ULHT staff who support research studies & to celebrate R&I related achievements	Explore opportunities to create links between CBU and R&I performance for individual researchers.
	Secure the support of the Trust for NHS Treatment Costs and Excess Treatment Costs	Scope department need for a nursing 'establishment' investment, to allow increased research delivery activity	
Increasing Capacity	Hold a series of stakeholder listening events	Develop outputs from the stakeholder events into actions to support the growth of the research base	
Developing Capability			Develop and pilot a local training program to ensure that various staffing groups can develop research capabilities.

Strategic Objective 3: Engage with our patients, service users and the public

We will plan and nurture interactions with our patients and service users to develop awareness of and engagement in clinical trials.

Understand opportunities to take part in research	Access the national NHS patient survey results around opportunity to take part in research	Plan & hold a "Research Conversation" with the patients of ULHT and the public of Lincolnshire	Analyse the outputs of the Research Conversation, and plan further actions
Participants valued and informed		Develop and pilot plans to say 'Thank you' to the participants of research held at ULHT	Develop and test a process to send participants the findings of the research they have participated in
Integrate our Patient and Public Forum	Work with our Lincolnshire Research Patient and Public Forum to provide direction , structure and clarity for the group	Understand how best to engage LRPPF in the development of ULHT sponsored research	Agree a process for Chief Investigators to best access the input of our LRPPF

Strategic Objective 4: Develop a strong Network

We will explore and strengthen relationships with local and regional partners, allowing synergies to develop and to collaborate with a system-wide focus to the benefit of the patients of the healthcare system in Lincolnshire.

conaborate with a 3	ystern-wide rocus to the benefit of	ure patients of the fleathicare system in	Lincomanii c.
	Continue to be an active partner		
	in the regular meeting with the		
	NHS organisations in		
	Lincolnshire. Identify	Together with LCHS, LPFT and EMAS	
	opportunities to support research	agree a programme of work to improve	
Land Hadthana			Deliver the prejects identified in
Local Healthcare	across the patient pathway in	research opportunity across	Deliver the projects identified in
Providers	Lincolnshire	Lincolnshire	Year two
	Working with the University of	Working with key departments at the 2	
	Lincoln develop a Memorandum	local Universities we will re-engage	Work with the University to
	of Understanding on Joint	efforts to identify areas of interest	understand the requirements of
	Working for Effective Research	which could benefit from a	the Research Evaluation
	Governance	collaborative approach	Framework
	0010	oonacoranio approacii	Prepare conversations with the
			University of Lincoln to allow the
		Dovolon a plan to increase Decearch	,
A 1 1 -		Develop a plan to increase Research	development of a joint research
Academic		Capability Funding to levels required	strategy once the Medical
Partners		as a UHTT	School is transferred to them
	Proactively seek out and nurture		
	relationships with local NIHR		
	organisations (ARC, CRN and		
Other	RDS) and the Academic Health		
Stakeholders	Science Network		
512.15.15.4616			

Strategic Objective 5: Develop a Researcher Pathway

We will develop our offering to research interested staff members, forging a clear pathway from supporting delivery of clinical research, through becoming a Principal Investigator and on to aspiring Chief Investigators working to attract research grants. The Department will be aware of and support the research leaders of the future through their pathway.

Recognise	Conduct a survey of the ULHT workforce to identify areas of research interest and aspirations.	Hold a stakeholder event to further explore with research interested staff how ULHT can support them in their research pathways.	Work with Medical Education department to explore opportunities to introduce medical students to the delivery of clinical research.
Support	Explore with the NIHR 70@70 regional nurses the potential to develop a programme which will support nurses, midwives and other AHPs to lead research	Engage with the NIHR RDS and CRN East Midlands to ensure all opportunities for workforce development are being recognised and accessed	Launch the programme of support developed through the R&I Listening event and the work with the NIHR 70@70 Nurses

# Foreword:

The ULHT Research & Innovation Department is undertaking an ambitious and exciting 3-year improvement journey. This is vital for the Trust, its' staff, patients and service users as research and innovation is a thread through the core of Trust business as described through the Integrated Improvement Plan.



Our R&I Strategy is laying the foundations for the people of Lincolnshire to benefit from the real opportunities created by an embedded and progressive R&I Department.

The vision and objectives described in this Strategy will set the direction for research and innovation in ULHT. It outlines our strong commitment to improvement and working with external partners, such as local universities, NHS organisations and the NIHR, to achieve our Trust vision of "Outstanding Care Personally Delivered".

**Dr Neill Hepburn, Medical Director** 

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# The Purpose of the R&I Strategy

Welcome to our three-year Research & Innovation (R&I) Strategy. This Initiative, and the operational plans which will underpin it, mark an important step forward for our Trust.

Research within ULHT has delivered growth over 10 years, with active pockets across three of our sites (Lincoln County Hospital, Pilgrim Hospital, Boston and Grantham and District Hospital). However, a change of leadership within the department and the subsequent unprecedented changes as a result of the Covid-19 pandemic have provided a unique opportunity to review the department, consider our ambitions for R&I and plan how we are going to get there. A plan that will help to make a real difference for our research active staff members, our departmental workforce, our patients and our partners.

The purpose of this Strategy is to set out the vision and objectives of the Trust in relation to R&I from 2021-2024, demonstrating how we will meaningfully embed R&I plans into the core business of the Trust.

It identifies the key priorities for the R&I Department over the next three years, ensuring that we focus on the right things - the things that will allow our staff, patients and service users access to high quality research and innovation opportunities.

The first year of this work will see us stabilise the foundations of the department and then grow to take advantage of the many opportunities and partnerships surrounding the Trust. This is important as effective partnerships across the Lincolnshire health community are vital for achieving our overall goals and we are committed to working as one health and care system. Likewise, we recognise we are an important partner to the University of Lincoln, Bishop Grosseteste University and the East Midlands Clinical Research Network and are dedicated to playing an active role in these networks.

This Strategy aims to provide a clear statement of our intent, a strong commitment to Research & Innovation and a plan for the next stages of our journey.

# Why does R&I matter?

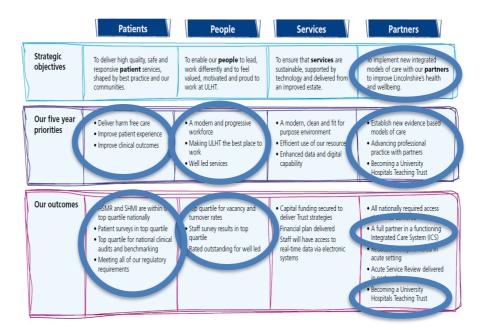
ULHT is undertaking a five-year Integrated Improvement Plan (IIP), ensuring we focus on the right things for both our patients and our staff. Through its IIP, we have made a clear statement that quality must be the organising principle of our health and care service. Quality matters to people who use our services and motivates and unites everyone working in health and care. In line with ULHTs IIP, we are committed to a value of Excellence, supporting innovation, improvement and learning throughout the Trust, and health Research is central to this.

ULHT recognises that there is a need for significant quality improvement, which can deliver better patient outcomes and improved operational, organisational and financial performance. Our improvement will be led effectively, embedded through the organisation and supported by systems and training. It will involve a process of continuously evaluating and improving what we do to make things better.

Research & Innovation is a central mechanism that is used to instigate improvements in many aspects of health and care. Research is conducted in all NHS settings, and without it clinicians would carry out their work in the same way without knowing if a new treatment or approach would be more effective. ULHT must harness and support its research activities in an improved way to allow the Trust to benefit from being a research active organisation.

We believe that a meaningful commitment to R&I is essential to achieving clinical excellence and will lead to better outcomes and experience for our patients and service users. Equally, we recognise that organisations with the R&I agenda at the core of their business attract and retain excellent staff and perform strongly. Our ambition to achieve University Hospital Teaching Trust status is an indication of the Trusts intentions. We cannot achieve this status without strengthening our research outputs considerably.

We are embarking upon a three-year plan that will bring R&I activities to the centre of the values which underpin the strategic direction of the organisation.



High profile external stakeholders also drive the need for quality research and innovation practice within the NHS:

#### **UK Government**

The Department of Health & Social Care established the National Institute for Health Research (NIHR) to improve the health and wealth of the nation through research. It is a framework through which to position, maintain and manage research, research staff and research infrastructure of the NHS in England.

The NHS Constitution describes how the NHS aspires to the highest standards of excellence and professionalism in the provision of care, and through its commitment to innovation and the promotion, conduct and use of research to improve the health and care of the population.

#### Patients & Service Users

Patients & the public expect research to be conducted within the NHS. A survey conducted in 2014 by the NIHR¹ found that 89% of people responding indicated they would be willing to take part in clinical research if they were diagnosed with a medical condition or disease. 95% said it was important to them that the NHS carries out clinical research.

#### Regulators

The Care Quality Commission recently included research in the 'well-led' domain of its inspection framework.

#### Research Evidence

Research into the benefits that are brought to research active Trusts was published in 2015<sup>2</sup> indicating that research active Trusts:

- Have lower mortality rates
- Increased patient benefits
- Are able to retain and attract talented clinical staff
- Are able to promote innovation, quality improvement and innovative clinical services development
- Are successful in the implementation of evidence based practices

We recognise that maintaining the present state is not always the best option for us as an NHS provider, nor the best option for our clinicians and patients. This Strategy sets out our intention to work in an innovative way, embracing research as part of the progress of the organisation. There has never been a more important time to invest in the research and innovation endeavours of ULHT. The clinical research landscape is complex, with many factors to navigate and the development of innovation has inherent risks - but with clear direction, planning and accountability, we will achieve the growth described within this Strategy.

<sup>&</sup>lt;sup>1</sup> NIHR Survey, 2014 https://www.nihr.ac.uk/news/nine-out-of-ten-people-would-take-part-inclinical-research/2377

<sup>&</sup>lt;sup>2</sup> Ozdemir et al (2015) Research Activity & the association with Mortality

# **Research Context**

### R&I within the healthcare setting

The 'UK Policy Framework for Health and Social Care Research' define research as:

"the attempt to derive generalizable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods"<sup>3</sup>

Health research aims to find knowledge that could lead to changes to treatments, policies or care. It assesses new treatments, technologies or methods, or can help better understand health and specific conditions. As new treatments develop, or as new applications of existing treatments are identified, the potential benefits and risks of the treatment are tested through clinical trials. "Research" can encompass a huge range of activities from laboratory based tasks through to treatment within a care setting.

ULHT could be a 'host' delivering another organisations research, with a Principal Investigator locally responsible. Alternatively, we could be the lead organisation, with the Chief Investigator being one of our staff members. Activities associated with the study will be carried out by the PI or CI, supported by a combination of R&I department workforce and other Trust staff, depending on the needs of the study. These requirements are communicated through key official documentation which include a Research Protocol and a contract or agreement.

There are 2 broad categories of research, distinguished by who is responsible for the piece of research (the Sponsor):

#### Commercial led research

Commercial led research studies tend to be randomised controlled trials involving a medicinal product or device. The full cost of research sponsored by a commercial organisation will be funded by that organisation. They can be single site, or multi-site studies, with our investigators either the Chief Investigator of the research, or fulfilling the role of Principal Investigator.

Commercial companies also work collaboratively with NHS bodies or non-NHS research funders to support non-commercial research, which is primarily for the public benefit (rather than direct commercial benefit).

#### Academic or NHS led research (non-commercial)

There are many types of academic or NHS led research, for example, these could be research completed by a student as part of an undergraduate or postgraduate degree, research focussing on staff members experience using questionnaires and interviews, or a multi-site, randomised controlled trial researching a medicinal product or medical device.

Research costs associated with these studies are funded through a number of routes,

<sup>&</sup>lt;sup>3</sup> https://www.hra.nhs.uk/media/documents/Final\_Accessibility\_uk-policy-framework-health-social-care-research .pdf

including self-funded (typical for student research), NIHR grants, Research Councils and Charity grants, awarded through open and transparent competition. The Treatment costs associated with these studies should be supported by the Trust or the Commissioning bodies (if a nationally recognised 'excess' cost). If the study is adopted on to the NIHR Portfolio, the Service Support Costs are funded through the Clinical Research Network East Midlands.

#### Phases of health Research

Research pathways take new treatments through four phases to become a new licenced medicine if it proves to be more effective than an existing treatment. Currently ULHT takes part in later phase trials (Phase 3 onwards).

**Phase 1:** Small numbers of people, often healthy volunteers, the medicine is being trialled in human volunteers for the first time. Researchers test for side effects and calculate what the right dose might be to use in treatment. Starting with small doses and only increase if the volunteers do not experience any (or minor) side effects.

**Phase 2:** The new medicine is tested on a larger group of people who are ill, to get an idea of its short term effects.

**Phase 3:** The medicine is tested in larger groups of people who are ill, and compared against an existing treatment or a placebo to see if it's better in practice and if it has important side effects. Trials often last a year or more and involve several thousand patients.

**Phase 4:** The safety, side effects and effectiveness of the medicine continue to be studied while it's being used in practice. This is not required for every medicine, and is only carried out on medicines that have passed all the previous stages and have been given a marketing licence (is available on prescription).

#### **Innovation**

Innovations, often the product of research, are new products, processes or services that offer a 'step-change' improvement. Innovation is central to the next 5 years at ULHT, and the R&I Department will be working closely with other internal partners in innovation (Improvement & Integration and Knowledge & Library Services), through the work stream 'To become a University Hospitals Teaching Trust'.

#### The NIHR

The National Institute for Health Research (NIHR) are an important organisation facilitating health research. They are the nation's largest funder and provide people, facilities, and technology that enable research to thrive.

Established in 2006 the NIHR mission is to improve the health and wealth of the nation through research. It delivers against this mission through five key work streams:



The NIHR Clinical Research Network (CRN) is part of the work stream which provides world-class infrastructure and a skilled delivery workforce. ULHT is a partner of the CRN East Midlands. This network includes the CRN team and 16 NHS Trusts and the CCGs across the geographic region of the East Midlands.

ULHT contributes to the delivery of the NIHR portfolio of studies and we benefit from receiving funding which is invested to enable the delivery of high-quality health and care research.

Through this partnership ULHT also accesses national and local resources and activities that support our organisation, staff, patients and service users to be research active. For example:

- Specialist training and workforce development
- Information systems to manage and report research
- Patient and public involvement and engagement initiatives
- Communications materials and expertise

#### **Academic Research**

Universities are a natural partner for the NHS in the pursuit of new knowledge through research. The relationships between academic institutions and NHS provider are key to realising research opportunities, through research programmes and clinical academic roles.

Within Lincolnshire we are lucky to have 2 academic institutions, both with relevant research interests and a desire to work more closely with ULHT.

The University of Lincoln research themes include 'Health and Wellbeing', and has experts leading multi-disciplinary studies. Potential areas of opportunity may lie with the Lincoln International Institute for Rural Health, the Community and Health Research Unit, the Diabetes Research Group at Lincoln, Image Engineering, Lincoln Medical School, the Lincoln nursing programmes and the Lincoln School of Pharmacy.

The Bishop Grosseteste University also has a suite of compatible interest areas, including Counselling, Children & Young people, Wellbeing & Resilience and Health & Social Care.

We can support academic research by facilitating students to develop their research skills as they conduct research as part of their qualification, or a more formal relationship can be demonstrated through the appointment of Clinical Academic posts. These are qualified doctors who combine working as a specialist doctor with research and teaching responsibilities with University partners.

Individuals aspiring to follow this path will be academic high achievers, with passion and drive to make new discoveries. They will need a higher degree, often achieving a PhD before consultant level.

These are exciting roles, but it is a very competitive field. Currently ULHT have few clinical academics with a research or teaching focus. This development pathway is not fully understood, or supported by the R&I Department. With plans to become a University Hospitals Teaching Trust, this is an area that the Trust is committed to addressing.

#### Workforce

A skilled clinical research delivery workforce is crucial to making research happen in the NHS. The delivery of high quality clinical research care requires clinical research nurses and midwives, allied health professionals, social care professionals, doctors, dentists and clinical research practitioners.

Alongside the development of a skilled academic research workforce, the NIHR provides a steer to invest in developing those with an interest in delivering research, but not necessarily wanting to become a clinical academic. This could include opportunities for those who may or may not have NIHR clinical research experience already, and should include the whole cross section of clinical staffing roles including pharmacists, radiographers, occupational therapists, nurses, midwives, doctors, physiologists, physiotherapists, radiotherapists, biomedical scientists and healthcare managers.

# Regulation

Research in the NHS is well regulated by a number of bodies associated with the Department of Health & Social Care, these include the:

- Health Research Authority protects the interests of patients and the public by ensuring studies comply with relevant legislation and guidelines, and obtain approval and input from Ethics Committees and appropriate Advisory Groups.
- Medicines and Healthcare products Regulatory Agency protects and improves public health with responsibility for ensuring that medicines and medical devices meet applicable standards.
- **Human Tissue Authority** regulates organisations that remove, store and use human tissue for research.

#### **Commercial Research**

Commercial contract research undertaken in the NHS could be pharmaceutical clinical trials, biotechnology agents or medical devices. There are two main routes for commercially sponsored research to be placed at ULHT.

- Commercial sponsors are interested in sites that deliver what they say they will (usually complete data sets), within the timeframe that they say they will. They will develop a relationship with an NHS Trust, and will place future business with those that have performed well.
- The NIHR CRN work closely with industry partners to showcase the UK as the
  place to deliver research. Part of the service offering is to place studies with sites
  who will set up quickly and efficiently, in line with a nationally agreed costing
  template and utilising model contracts. Also delivering the number of participants
  as agreed and ensuring a high standard of data returns.

There has been growth in the number of commercial contract research conducted in the NHS over the last 10 years and work continues to reduce set up times to ensure increased pace of healthcare innovation.

NHS Providers are obliged to recover the full costs of any commercial contract research they undertake to avoid subsidising this with tax payer funds. This is achieved through use of the NIHR Industry Costing template, which agrees a study specific price.

#### **Research Cost Attribution**

As a core activity the NHS is committed to supporting a portfolio of commercially and non-commercially funded research. It is important that the cost of a research study is identified and properly funded.

The Department of Health & Social Care guidance "Attributing the cost of health and social care Research & Development (AcoRD) provides a framework to identify, attribute and recover the various costs associated with research in the NHS. Research studies go through a process of identifying component activities and attributing them to a 'type' of activity:

- Research Costs the costs of the research itself that end when the research ends.
   They relate to activities that are being undertaken primarily to answer the research questions.
- NHS Treatment Costs the patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the research study had stopped.
- NHS Support Costs the additional patient care costs associated with the research, which would end once the research study had stopped, even if the patient care involved continued to be provided.

The application of these principles can be challenging, and the R&I community utilise 'AcoRD Experts' to assist with the attribution process. The attribution decision for a specific research-related activity is driven by the primary purpose of the activity, and works on the premise that the NHS bears the cost of caring for its patients even when they are involved in a research study.

#### **Funding Streams**

The funding of non-commercial research frequently involves a number of partner organisations which can introduce a degree of complexity. For non-commercial studies the normal funding streams for research are (broadly):

- Research costs are met by grant funders through the award of a research grant (for example through the NIHR, an NHS body, a Charity, a large Research Institute, a University or UK Research and Innovation).
- NHS Support costs are met by the Department of Health & Social Care budget, via the NIHR Clinical Research Network.
- NHS Treatment costs are met through normal commissioning process. In practice this means that the Commissioners support treatment activities through the NHS Tariff.

In addition, we might be asked to deliver research studies which are only part-funded or are un-funded, for example student research where no funds are transferred.

#### **Excess Treatment Costs (ETCs)**

A research study may deliver a patient care service that differs from standard treatment, and the associated NHS Treatment Costs may be less or may be greater. If greater, the difference is referred to as an Excess Treatment Costs, and these are attributed as Treatment Cost.

These are identified as part of a research funding application. The Chief Investigator is required to complete a Schedule of Events Cost Attribution Template (SoECAT) form. This form captures the different costs associated with the research and then calculates an average per patient ETC value for the study.

Studies identified as linked to specialised or NHS England's other direct commissioning functions may be asked to complete another template to finalise payable ETCs.

ETCs are paid to the recruiting research site and the payment due is calculated by multiplying the ETC per patient value by the number of study participants recruited there.

Each provider has an annual ETC threshold (ULHTs is circa £45,000) that must be reached before additional payments are made. When a provider has reached this threshold, ETC payments will then be made on a quarterly basis in arrears through the NIHR Local Clinical Research Networks.

The threshold does not apply to studies where NHS England is the responsible commissioner. Payments for these studies are made to the recruiting site directly by NHS England via the normal contractual route.

With regard to treatment costs after a study has ended, ethical approval requirements of the Health Research Authority mean that any post-trial funding arrangements will be determined before the trial begins.

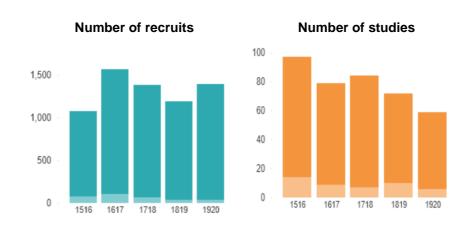
For non-commercial research NHS England may provide continued funding for an on-going intervention after a trial. For commercially funded trials these arrangements are the responsibility of those commercial parties.

# Where are we now?

### **Activity**

Research activity in the NHS can be difficult to measure consistently across organisations. Activities could include time to develop a grant application, time taken to share local information as part of site selection, setting up a study, screening and identifying potential participants, obtaining informed consent, treatment related activities, solving data queries, conducting follow up activities.

Most organisations use a proxy measurement for research activity, based on the NIHR Clinical Research Network High Level Objectives. In line with this approach, we will illustrate ULHTs performance over the last five years in terms of the number of Recruits (consent) into NIHR Portfolio studies and the number of active (recruiting) NIHR Portfolio studies.

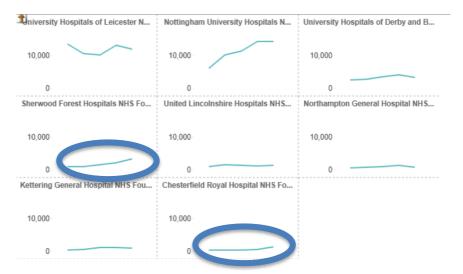


FY	Commercial recruits	Non- Commercial recruits	Total	Commercial studies	Non- Commercial studies	Total
1516	78	995	1073	14	83	97
1617	109	1454	1563	9	70	79
1718	69	1313	1382	7	77	84
1819	42	1152	1194	10	62	72
1920	37	1356	1393	6	53	59
Total	335	6270	6605	31	169	200

These recruitment figures present a broadly static picture, perhaps a dip in the number of studies recruiting in 2019-20 – but with some significant changes in staffing within the R&I department this impact is to be expected.

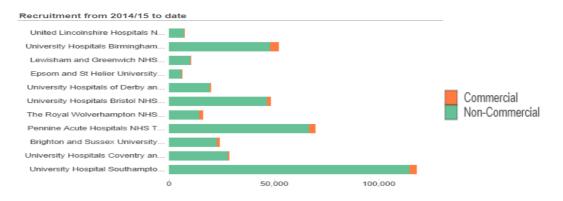
When considering the recruitment performance in the other acute settings within the East Midlands, it can be seen that some have been increasing the proportion of their recruitment contribution.

#### Recruitment by year 2015-16 to 2019-20



Tracking data back to the year 2014-15, we can see that from April 2014 to March 2019 ULHT has contributed 4.16% of the acute setting recruitment in the East Midlands (8388 recruits out of a total of 201,442 recruits from 8 acute settings).

When benchmarking ULHT research activity to 10 acute organisations similar in terms of hospital attendance, we can see that ULHT are not recruiting to the same levels:



The charts show the most similar organisations at the top, with similarity decreasing down the chart.

# **Department Governance**

During 2019 Grant Thornton conducted an audit of the Research & Innovation Department, focussing on the potential risks:

- Research and development governance arrangements are not robust. Roles and responsibilities, management oversight, monitoring and reporting arrangements are not in place.
- Inadequate or non-compliance with the Trust's research and development policies and procedures which may lead to inefficient / ineffective processes, including:

- inadequate budget setting, oversight and monitoring
- under achievement of income targets
- inappropriate expenditure
- non-utilisation of grant funding, inappropriate grant expenditure and/or inaccurate grant submissions

The audit concluded a partial assurance with improvement required, recognising some moderate weaknesses in the existing controls. The recommendations are being addressed, with immediate action and further work built into the R&I Strategy.

### **Funding**

Funding for the department comes from three funding streams:

- ULHT Trust investment The direct Trust investment is restricted to posts within the Management and Leadership of the department.
- NIHR The majority of the R&I Department staff funding comes from the CRN East Midlands. This funding is provided to support the delivery of non-commercial portfolio research, through a dedicated workforce and associated supporting services (in essence the provision of NHS Service Support as described in the AcoRD framework). The amount of funding allocated is driven by 'activity' in previous years. For year 2020-21 the amount of funding awarded by the CRN East Midlands has been £975,332.22.

The NIHR also make a payment of "NIHR Research Capability Funding" (RCF), which aims to help research-active NHS organisations to act flexibly and strategically to maintain research capacity and capability.

As ULHT successfully recruited "at least 500 individuals" to non-commercial studies, conducted through the NIHR-Clinical Research Network (CRN), during the previous NIHR CRN reporting period, we therefore received £20,000 RCF in 2020-21.

• Income generated by research activity - Following the recommendations of the recent department audit, work is underway with a Trust Management Accountant to understand the financial situation of the department, including its earned income.

# **Department Staffing**

The R&I Department staff are enthusiastic and committed individuals. They are a hardworking team, passionate about what they do. Their positivity for their role is not currently reflected throughout the Trust, with research being seen as a 'nice to have', an 'add on' or even a 'burden' or 'cost pressure'.

The transformations happening within the Trust over the next five years are exactly the opportunity that the R&I Department needs to become visible and valued by staff and

patients.

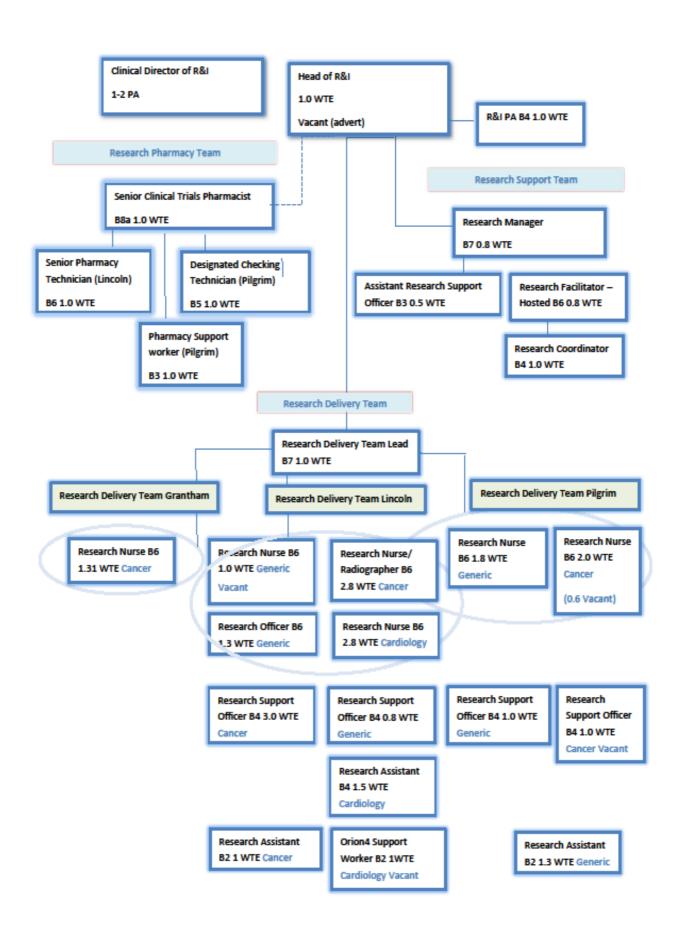
The department has undergone a period of instability, with a loss of leadership and management roles across the senior team of the department along with a reduction in other posts, team spirit has been eroded with individuals feeling undervalued.

The R&I Department currently consists of:

- a Support team (facilitating the set-up of research, sponsorship activities, data & reporting and department administration)
- a Research Delivery team (nurses, AHPs, Clinical Research Practitioners and administrators who support the delivery of research protocols within the Trust)
- a Research Pharmacy team (a pharmacist, technicians and a support worker who ensure that the pharmaceutical aspects of a clinical trial are managed properly, including dispensing, specialist handling and preparation)

The current structure of the department needs to be strengthened to achieve our vision. Currently the Support team lacks resource specifically around portfolio management, supporting professional development, relationships within the organisation, grant development and sponsorship (including specialist services like statistical support). Research Delivery will require growth to allow research to become part of the expected activities across the Trust. The current staffing levels (including vacancies) are:

Team	AFC Band	Number of individuals	WTE
Head	8c	1	1
Support	7	1	0.6
Support	6	1	0.8
Support	4	2	2
Support	3	1	0.5
Pharmacy	8a	1	1
Pharmacy	6	1	1
Pharmacy	5	1	1
Pharmacy	3	1	1
Delivery	7	1	1
Delivery	6	16	13.01
Delivery	4	8	7.3
Delivery	2	4	3.3
TOTAL		39	33.51



The model of the Trust-wide Research Pharmacy has recently begun to transform from a very isolated team, to one more integrated with the Trust Pharmacy service. This allows the research pharmacy team to keep up their competencies in pharmacy whilst members of the pharmacy team are being trained in research activities.

The Support team are based at Lincoln County Hospital with the Delivery and Research Pharmacy teams working at three sites (Lincoln County Hospital, Pilgrim Hospital, and Grantham and District Hospital). Some members of the department will travel to any site to work, others remain at their base site. We have recently instigated monthly team meetings for all of the R&I Department to attend. Individual teams based at our sites also hold regular 'huddle' meetings.

#### Trust workforce involvement

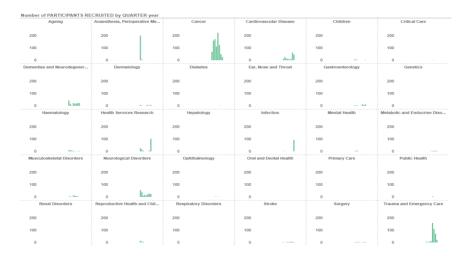
We currently hold Service Level Agreements with a number of supporting departments to secure their services to enable the delivery of research studies (for example Radiology, Pathology, Radiotherapy). The activities carried out tend to be NHS Treatment activities.

The Trust employs a handful of individuals who are active in seeking to obtain research grants and assume the role of Chief Investigator, in addition to their clinical role. The capacity to carry out these activities is met in an inconsistent way, with most fitting in these activities in their own time, some having time allocated in job planning.

We do not currently have any Chief Investigators actively delivering a study sponsored by ULHT with externally secured funding.

The Trust relies on a pool of around 50 Principal Investigators (PI) to deliver hosted research studies. The PI cover at each site varies and is impacted by the clinical service and personal interest. The funding structure to support PI time is inconsistent, with some receiving PA time for research, or research and audit, and others not. There is currently a lack of clarity around this within the R&I Department and the Trust. Most of our Principal Investigators are medics or surgeons.

Data split by the NIHR 30 clinical specialties for the years 2018-19 and 2019-20 shows significant activity levels in Cancer (including oncology and malignant haematology), Cardiovascular Disease and Trauma & Emergency.



There are opportunities for more NIHR Portfolio studies to be placed here at ULHT. The Portfolio is vibrant and active in all 30 of their speciality categories. The limiting factors for ULHT are:

- the availability of willing, interested and supported potential Principal Investigators
- the capacity of the R&I Delivery workforce to take on additional studies whilst balancing the current active work plus the follow up visits, data collection and queries
- the capacity of supporting services needed to deliver the protocol requirements
- the buy in from the Clinical Business Units to welcome the research and support it to deliver its outcomes

#### **Facilities**

The R&I facilities at the Lincoln County Hospital and Grantham & District Hospital sites are in a poor state of repair, with estate issues impacting upon the working environment. Recent Health & Safety audit findings noted leaking ceilings, cracked masonry, ruined carpets and impractical steps. The Pharmacy team have small areas of space allocated within Pharmacy, which pose a challenge ergonomically and in terms of storing vital research study files close to hand. While R&I provision at Pilgrim is very impressive - it is modern and well laid out. There is space for the whole team based in that location to work together in a department, with a small laboratory to process and store samples and clinic room in which to see patients.

#### **Department SWOT**

The key current Department SWOT is captured in this analysis:

Strengths	Weaknesses	
Engaged, enthusiastic and skilled Principal Investigators	General low levels of awareness of and support for research	
Good skill mix across the R&I Department  Pockets of significant research activity - Commercial Haematology and Cardiology portfolios are very strong	Lack of knowledge of research interests within the Trust  Geographical spread of the Trust - cost of replicating staffing across sites	
Highly motivated R&I workforce	Out dated and inadequate departmental governance (including poor financial management processes)	
	A lack of research inclusion in Doctors job planning and no robust link between research performance and appraisal process	
	Heavy reliance on medical workforce to lead research	

Opportunities	Threats
Chance to galvanise the department and Trust – including department restructure, review / develop key job descriptions	Low confidence that activities completed are being are being invoiced for CRN activity driven funding model
Covid-19 has increased the profile of clinical research both nationally and locally	NHS England Excess Treatment Cost system approach means ULHT is unlikely
Relationships growing with healthcare partners in the county of Lincolnshire	to bring income in to support Excess Treatment Costs incurred as part of research (unless activity increases).
Common interests with academics from both the University of Lincoln and the Bishops Grossette University	A lack of formal succession planning for Principal Investigators of the future
Trust Executive team supportive of clinical research – in line with an aspiration to become a Teaching Hospital	No clear feedback of research findings  Low numbers of Chief Investigators and successful grants where ULHT is the lead

# **Development of the Strategy**

The R&I Strategy and Vision have been developed through targeted, informal consultation with internal and external stakeholders (as listed in Appendix 1) including:

- Patients & service users through the Lincolnshire Research Patient & Public Forum
- Research management leaders from Lincolnshire (EMAS, LCHS and LPFT)
- Local Authority / Local Universities
- R&I Department staff / ULHT staff
- R&I Managers from other similar Trusts
- NIHR Clinical Research Network East Midlands

We have taken this document to the ULHT People & OD Committee. They have provided constructive feedback particularly around the need for measureable outputs and a cost impact.

We recognise that to consult with our stakeholders fully will take more time and have therefore separated the Strategy into two phases:

- Year one which will focus on putting the foundations in place internally and engaging in wider consultation with ULHT staff, patients and service users, academic institutions, other healthcare providers and the NIHR.
- Years two and three which will implement actions based on the objectives already developed, but with scope to build on the consultations conducted in Year one.

The initiatives and actions proposed for Year one mostly involve an investment of staff time, mainly within the R&I Department, however the actions will allow the Trust to have a better understanding of the current financial situation of the Department and a transparency around where the responsibility for defined costs actually sit.

During Years two and three there is likely to be a need for financial investment in the R&I initiatives proposed. These investments will be fully costed and approved, and will have measurable outputs described as part of the scoping work of each initiative prior to each kick off process.

# Where do we want to be?

By 2024 supporting the delivery of research and innovation will be an expected part of working at ULHT. With patients across our healthcare system being given the opportunity to take part in high quality, relevant research.

Our Board, our leaders, our clinicians and supporting staff will be aware of research and innovation, and the findings of research and new innovations will be made available to the Trust in a timely fashion.

Our vision, strategically aligned to the ULHT Vision of "Outstanding Care, Personally Delivered" is:

# Research and Innovation are embedded as part of our high quality, patient-centred care

# What success looks like

In 2024 departmental leadership will be in place, with clear role and remit. The Leadership of our Department will be engaged with the Trust IIP and will network across the organisation and beyond, to ensure that we are leading and supporting the ULHT Excellence value with everything we do. The leadership will be accountable to the Executive Leadership Team via the Medical Director of ULHT, and will ensure that the Department continues to evolve to meet the Trust aspiration to become a University Hospitals Teaching Trust.

The R&I department will work together as a 'team' with a culture of 'one'. Displaying behaviours that reflect trust, respect and cooperation. We will understand the purpose of our roles, and our contribution to the R&I Strategy and the vision of the Trust. We will feel valued and supported, with opportunities to develop and contribute to "Outstanding Care, Personally Delivered". The R&I team will have adequate facilities to carry out its work in safety and comfort. With clear plans in place to develop a professional and modern space. Trust staff (including the R&I Department) will have access to appropriate research related learning and training opportunities. The Department will offer a range of services to support the development and delivery of research.

The R&I Department Governance will be robust, reporting into the Trust governance structure. Departmental Standard Operating Procedures and processes will be, up-to-date and fit for purpose, with all relevant staff aware of these.

The Department will have good visibility of its current financial position, and its forecast income and expenditure. There will be clarity around the split of earned income between the Principal Investigator and the R&I Department – with PIs having visibility of, and appropriate access to these funds. Those conducting 'Service Support Cost' activities will receive funding back to their Department.

The contribution of the Lincolnshire Research Patient & Public Forum is valued throughout the R&I Department. The Forum itself will be well supported, and linked to the Trust Patient Experience team, and similar Forums within the Lincolnshire region. The group has clear purpose, direction and outputs. The Chief Investigators of the Trust and Lincolnshire-wide stakeholders will value the contributions of the Forum to their design and delivery of research.

Staff, patients and service users of ULHT and the public of Lincolnshire will know that we are a research active organisation. There will be visual evidence of our commitment to research and innovation throughout the organisation. Staff members will hear about research during their induction period and regularly thereafter, during their early years of their careers and onwards.

The R&I Department and Clinical Business Units will support our researchers. Departments will work with students to support the delivery of research as part of an academic qualification; we will nurture those interested in research fellowships. Time spent supporting the delivery of research will be seen as part of a clinician's role, a valuable contribution and appropriately accounted for in workload planning.

Becoming a Principal Investigator will be celebrated as an example of excellence in contributing to innovation. Our research active clinicians will have time to perform their research activities.

Research will be valued by our clinical areas, with studies placed according to clinical need, and research findings available in a timely way.

The R&I department will have a knowledge of the research interests and aspirations of its staff members (including nurses, midwives, AHPs, Clinical Scientists, medics and surgeons). A strong link developed with departments such as the Improvement Academy and the Audit and Service Evaluation team, allowing intelligence to develop around where people are seeking to understand and improve.

We will define a 'researcher pathway' which clearly indicates levels of involvement in clinical research from student research, to supporting the delivery of a hosted piece of research, to taking a lead on this, to fellowship pathways and developing unique research questions and securing funding to deliver this research. We will recognise where individuals are in terms of their research experience, and provide appropriate support.

For our researchers who aspire to secure grants and deliver their own research studies, the R&I Department and Clinical Business Units will ensure that time is given for this activity and that agreed outputs are seen through. It is recognised that securing research funding is highly competitive and we will ensure we are working to give our researchers the best possible chance at success.

The R&I department will offer a range of services to support our researchers tailored to where they are on the pathway and their professional group, with a goal of increasing chances of success.

In line with the national AcoRD guidance, the Trust will pay for the NHS Treatment costs incurred during a research study. This high-level agreement will increase the effectiveness of the study set up process, and will release CRN Infrastructure funding to increase the capacity of the R&I Delivery Team. Additional potential growth will be explored in recognition of the R&I Delivery & Pharmacy teams conducting NHS Treatment activities. We will understand if it is appropriate for the Trust to contribute a 'nursing establishment' to the Department.

The R&I department will be engaged in dialogue with the patients and service users of ULHT. We can be confident that we understand the level of opportunity to take part in research. With growth in our department and the research active specialties of the Trust, the patients of Lincolnshire will have an increased opportunity to take part in high quality clinical research.

Participants in research will feel valued and learn how their input has contributed to new knowledge, by receiving both a "thank you" and the results of the research.

We will network beyond our organisation borders to deliver research as a healthcare system. We will work closely with EMAS, LCHS and LPFT, seeking out common purpose and opportunity to improve what we do together. Our county-wide healthcare partners will be able to develop research with our full participation and support; and will know that areas of common purpose are being actively sought out, to ensure a joined up Lincolnshire response. We will also see past the traditional boundaries to ensure that patients or service users within our neighbouring healthcare providers can take part in studies that require input from the ULHT, in a streamlined and seamless fashion.

Our relationships with our academic partners are an indicator of our success in creating a research culture. Our research managers will be well linked and working towards common goals and to achieve clinical research strategic aspirations. Partnerships will develop between academics and clinicians across a broad range of subject areas, including clinical, social sciences and management studies. We will set up and deliver academic driven research in a timely fashion (both student and faculty staff). For our academic partners in Lincolnshire, they will feel confident that they can work with us to deliver their research endeavours in a streamline way.

Initiatives with the University of Lincoln will be critical to achieving our Trust ambition of becoming a University Hospital Teaching Trust. We will have preparations in place to satisfy the research criteria of becoming a University Hospital Teaching Trust.

We will be recognised as an engaged partner of the NIHR (including the Clinical Research Network and Research Design Service). The Clinical Research Network East Midlands will know us as a fully engaged partner in our joint activities. They will know that they can count on our input in network business and ULHTs contribution in terms of delivering NIHR Portfolio research effectively. They will be able to use initiatives in ULHT as an example of excellent practice to share with others. We will ensure that we provide perspective as part of the on-going partnership working.

# How will we get there?

We are currently well underway with delivering some immediate improvements, tackling the most urgent departmental governance issues highlighted by the recent audit and changing the operations of the department in line with the pandemic situation.

We plan to transition from this short-term, reactive action to a more comprehensive and planned approach to growth and partnership. We will do this by planning to meet five Strategic Objectives. Our Year 1 measurable outcomes are detailed in Appendix 2.

#### Strategic Objective 1: Strengthen the R&I Department

The R&I Department will have the structure, direction, standards, development and working environment it deserves. Transforming it into a valued and recognised part of the ULHT, which can in turn improve patient care and develop the research workforce of the future.

#### Our 3-year priorities

- Support Our Team
- Improve Our Facilities
- Department Governance (including Financial Integrity)
- Raise Awareness
- Demonstrating Clinical Relevance

Year 1 2021 -2022

#### **Priority: Support Our Team**

#### **Action**

Appoint to Departmental Leadership roles.

#### **Expected Outcome**

The Departmental Leadership will drive forward the Strategic development of R&I within ULHT.

#### **Action**

Working with Organisational Development we will form as a team, getting to know each other and exploring ways of working together.

#### **Expected Outcome**

The R&I Department will develop relationships and understanding of each other's roles within the department and recognise opportunities for improvement.

#### **Priority: Improve Our Facilities**

#### Action

Take immediate action and investment to make safe the facilities at Lincoln County

Hospital site.

#### **Expected Outcome**

Minimising the risk of staff coming to harm during the course of their work at ULHT.

#### **Priority: Department Governance**

#### **Action**

Establish the Departmental Governance flows by engaging fully in Trust governance – reporting upwards to the Quality Governance Committee with a Departmental Governance meeting.

#### **Expected Outcome**

Established lines of accountability internally and within the ULHT structure.

#### **Action**

The processes and SOPs associated with hosted research studies will be revised, ensuring they are robust and fit for purpose.

#### **Expected Outcome**

The department will be working to up-to-date, efficient and effective processes.

#### **Action**

We will roll out new financial processes across the department providing training and mentoring.

#### **Expected Outcome**

Well understood and transparent processes ensuring we can understand the potential cost implications and income associated with each study, and be assured that income streams due are being received.

#### **Priority: Raising Awareness**

#### **Action**

Working with the Trust Communication department develop a comprehensive communication plan including newsletters, Trust Induction, NIHR produced materials, posters, videos etc.

#### **Expected Outcome**

The plan will maximise reach of R&I communications, raising the profile of research within ULHT with research becoming visible to staff and patients within the hospitals. Interested individuals will be able to find information easily.

#### Year 2 2022 -2023

#### **Priority: Support Our Team**

#### **Action**

Conduct a consultation around the scope and roles within the Department to ensure we have the right roles for a modern, forward looking R&I department and make changes if necessary.

#### **Expected Outcome**

Roles that are suitable for an effective R&I function, filled by well-trained and suitably skilled workforce.

#### **Action**

Ensure individuals within the department receive training to give them the tools to drive forward the transformational change that the department needs.

#### **Expected Outcome**

An empowered workforce with the skills to undertake improvement that will have a beneficial impact on their work.

#### **Priority: Improve Our Facilities**

#### Action

We will develop a business case (including an options appraisal and financial breakdown) to upgrade the accommodation at Lincoln County and Grantham and District Hospital sites.

#### **Expected Outcome**

Clarity around the potential options available and the cost implications.

#### **Priority: Department Governance**

#### **Action**

The processes and SOPs associated with sponsored research studies will be refreshed to ensure they are robust and fit for purpose.

#### **Expected Outcome**

We will have the necessary SOPs in place to allow us to recommence the sponsorship of research.

#### **Action**

Forecasting capabilities will be develop allowing a realistic picture of research income to be established.

#### **Expected Outcome**

An ability to make strategic investment into the R&I Department and the clinical specialties.

#### **Priority: Raising Awareness**

#### Action

Develop our digital platforms, to ensure information is easy to find and up-to-date.

#### **Expected Outcome**

ULHT staff can easily access up to date information about the R&I services.

#### **Priority: Demonstrate Clinical Relevance**

#### **Action**

Explore how to effectively access the findings of research studies and agree a process of informing others in ULHT.

#### **Expected Outcome**

Departments and stakeholders will be informed of the outcomes of the research they have supported.

#### Year 3 2023-2024

#### **Priority: Support Our Team**

#### **Action**

Appoint to any gaps remaining in the Department structure following the exercise conducted in year 2.

#### **Expected Outcome**

A Department with all appropriate staffing levels throughout the three teams.

#### **Priority: Improve Our Facilities**

#### Action

We will submit a business case to upgrade the accommodation at Lincoln County and Grantham and District Hospital sites.

#### **Expected Outcome**

The Department will hope to gain the support of the Trust Board to move to improved, adequate facilities.

#### **Priority: Department Governance**

#### Action

A training programme for prospective Chief Investigators will be developed and piloted.

#### **Expected Outcome**

Assurance that roles and responsibilities are clearly communicated and understood by potential Chief Investigators wishing ULHT to act as Sponsor for their research.

#### Action

Launch an initiative to invest NHS Service Support Costs back to the department that incurred the costs. Making a plan for the Departmental CRN budget to contain a line to support this scheme

#### **Expected Outcome**

Clinicians/departments who consent patients into research studies will receive the financial recognition due for this activity.

#### **Priority: Raising Awareness**

#### **Action**

Develop a research champion scheme to be piloted and rolled out through the ULHT

#### **Expected Outcome**

Within each CBU there will be Champions available to raise awareness of the research being conducted in that area, and provide a link to the R&I department.

#### **Priority: Demonstrate Clinical Relevance**

#### **Action**

Work with CBU leaders to develop a system to place research studies according to clinical priority and Lincolnshire health needs.

#### **Expected Outcome**

The Trust and our patients would receive true benefit from the research delivered at ULHT.

#### Strategic Objective 2: Build our capacity & capability

We will build the capacity and capability of our current and future workforce to embrace and actively engage with research and innovation. Encouraging participation from all professional groups.

#### Our 3-year priorities

- Valuing Contributions
- Increasing Capacity
- Developing Capability

Year 1 2021 - 2022

#### **Priority: Valuing Contributions**

Roll out the 'R&I Certificate Scheme' across the portfolio of research studies.

#### **Expected Outcome**

Staff will receive an award to celebrate their research delivery achievement, and show that we value their contribution.

#### **Priority: Increasing Capacity**

#### **Action**

Work to obtain agreement that Treatment Costs will be funded by the Trust / CBU (including investigational medicinal products). Ensuring awareness and understanding of the NHS England Excess Treatment Cost pilot with agreement to fund ETCs up to the point of the threshold (approx. £45,000 per annum).

#### **Expected Outcome**

Clarity around responsibilities for supporting activities associated with research in accordance with the costing framework for research studies (AcoRD). Effective set up of research studies and R&I Funding currently used to support Treatment Costs reinvested. Adherence to the NHS England pilot on improving research.

#### Action

We will hold a series of stakeholder listening events.

#### **Expected Outcome**

An opportunity for us to hear the barriers and enablers to getting involved in research. A set of ideas and issues can then be used to further develop plans for the development of R&I in ULHT.

#### Year 2 2022 - 2023

#### **Priority: Valuing Contribution**

#### **Action**

Develop, pilot and roll out plans to say 'Thank you' to the ULHT staff who support specific research studies. In addition develop a mechanism to learn about and celebrate R&I related achievements.

#### **Expected Outcome**

Those who have given their time and skills will know that their efforts are recognised, celebrated and appreciated. Others will learn of the progressive actions of their colleagues and may become inspired.

#### **Priority: Increasing Capacity**

#### **Action**

Work with the Director of Nursing to understand if R&I can make a case to the Trust for a nursing 'establishment' investment, to allow increased research delivery activity.

#### **Expected Outcome**

This commitment from the Trust would allow the Research delivery team to support more research studies.

#### **Action**

Develop outputs from the stakeholder events into actions to support the growth of the research base, to include growth through CBUs and staff group.

#### **Expected Outcome**

A set of plans to begin to grow the involvement of researchers in the ULHT.

#### Year 3 2023 - 2024

### **Priority: Valuing Contributions**

#### **Action**

Explore opportunities to create links between CBU and R&I performance for individual researchers.

#### **Expected Outcome**

Research valued as part of individual roles / job plan and appraisals.

#### **Priority: Developing Capability**

#### **Action**

Work with subject matter experts (for example the CRN East Midlands and the Association of Research Managers & Administrators) to develop and pilot a local training program to ensure that distinct groups of staff within the ULHT can develop the capabilities needed to perform their role in research and innovation.

#### **Expected Outcome**

A training offering for the research interested workforce.

Strategic Objective 3: Engage with the our patients, service users and the public We will plan and nurture interactions with our patients and service users and the public of Lincolnshire to develop awareness of and engagement in clinical trials.

#### **Our 3-year priorities**

- Understand opportunities to take part in research
- Participants valued and informed
- Integrate our Patient and Public Forum

Year 1 2021 - 2022

#### **Priority: Understanding opportunities**

#### **Action**

Work with the Trusts Patient Experience team to access the results of the national patient surveys, specifically the data around opportunity to take part in research.

#### **Expected Outcome**

To understand how the Trust performs against the measure, and how other similar Trusts perform.

#### **Priority: Integrate our Patient and Public Forum**

#### **Action**

We will work with our Lincolnshire Research Patient and Public Forum to provide direction, structure and clarity for the group.

#### **Expected Outcome**

The Forum will feel well supported and recognise that their efforts are truly benefiting the research and innovation endeavours of ULHT. There will be a clear strong relationship between the Department and the Forum.

Year 2 2022 - 2023

#### **Priority: Understanding opportunities**

#### **Action**

Work with the Lincolnshire Patient and Public Forum and the Trust Patient & Public involvement group to plan a "Research Conversation" with the patients and service users of ULHT and develop a questionnaire to measure understanding of the value of being involved in clinical research.

#### **Expected Outcome**

The conversation will begin to give the R&I Department an insight into what our patients, service users and the public think of when it comes to 'research' and 'innovation'. It will also give us a baseline measurement of the understanding of the value of being involved in clinical research.

#### Priority: Participants valued and informed

#### Action

Develop and pilot plans to say 'Thank you' to the participants of research.

#### **Expected Outcome**

People who have given their time will know that their efforts are appreciated.

#### **Priority: Integrate our Patient and Public Forum**

#### Action

We will work with our Lincolnshire Research Patient and Public Forum to understand how we can best engage them in the development of ULHT Sponsored research.

#### **Expected Outcome**

An understanding of how logistically this would be most efficient from the Forums perspective.

#### Year 3 2023 - 2024

#### **Priority: Understanding opportunities**

#### **Action**

Work with the Lincolnshire Patient and Public Forum to analyse the topics/themes coming from our Research Conversation, and plan further actions to develop this work stream as necessary.

#### **Expected Outcome**

The outcome of this action will be a targeted plan to raise the profile and understanding of research and innovation with our patients, service users and public of Lincolnshire.

#### Priority: Participants valued and informed

#### **Action**

Investigate, develop and test a process of accessing the results of research studies we have participated in, and then share those with participants.

#### **Expected Outcome**

The Trust and our research participants will be aware of the findings of the studies we have been involved in, and will know that we place value on that contribution.

#### **Priority: Integrate our Patient and Public Forum**

#### Action

Agree a process for our Chief Investigators to best access the input of our Patient and Public Forum.

#### **Expected Outcome**

The Forum will be able to benefit the Chief Investigators of ULHT, by providing a lay

perspective to the design and development of research protocols.

#### Strategic Objective 4: Develop a strong Network

We will explore and strengthen relationships with local and regional partners, allowing synergies to develop and to collaborate with a system-wide focus to the benefit of the patients of the healthcare system in Lincolnshire.

#### **Our 3-year priorities**

- Local NHS Healthcare providers
- Academic partners
- Other stakeholders

Year 1 2021 - 2022

#### **Priority: Local NHS Healthcare providers**

#### **Action**

Continue to be an active partner in the regular meeting with the NHS organisations in Lincolnshire. Identify opportunities to support research across the patient pathway in Lincolnshire.

#### **Expected Outcome**

This forum is allowing the research office leaders from ULHT, LPFT, LCHS and EMAS to get to know and understand skills, strengths and their organisational drivers. Research studies will be delivered seamlessly across boundaries in true partnership. Giving patients and service users opportunities that would otherwise be unavailable to them.

#### **Priority: Academic Partners**

#### **Action**

Working with the University of Lincoln develop a Memorandum of Understanding on Joint Working for Effective Research Governance

#### **Expected Outcome**

This will allow academic research studies to move through set up in the most streamlined way possible.

#### **Priority: Other Stakeholders**

#### **Action**

We will proactively seek out and nurture relationships with local NIHR organisations (ARC, CRN and RDS) and the Academic Health Science Network.

#### **Expected Outcome**

Be well connected and able to identify any opportunities to benefit ULHT.

Year 2 2022 - 2023

#### **Priority: Local NHS Healthcare providers**

#### Action

Together with LCHS, LPFT and EMAS agree a programme of work to improve research opportunity across Lincolnshire.

#### **Expected Outcome**

A plan of joint improvement projects that will be scheduled for kick off during year 3.

#### **Priority: Academic Partners**

#### **Action**

Working with key departments at the 2 local Universities we will re-engage efforts to identify areas of interest which could benefit from a collaborative approach.

#### **Expected Outcome**

A plan of joint improvement projects that will be scheduled for kick off during year 3.

#### **Action**

Develop a plan to increase Research Capability Funding to levels required as a University Hospital Teaching Trust status.

#### **Expected Outcome**

A clear direction around increase in activity needed for this purpose.

#### Year 3 2023 - 2024

#### **Priority: Local NHS Healthcare Providers**

#### **Action**

Together with research leaders across Lincolnshire, deliver the projects identified in year 2.

#### **Expected Outcome**

Experience of working collaboratively on value adding projects.

#### **Priority: Academic Partners**

#### **Action**

Work with the University to understand the requirements of the Research Evaluation Framework.

#### **Expected Outcome**

A solid understanding of how ULHT could support this requirement as a University Hospital Teaching Trust.

#### Action

Prepare conversations with the University of Lincoln to allow the development of a joint research strategy once the Medical School is transferred to them

#### **Expected Outcome**

Foundation discussions in place to allow this collaboration when the time is appropriate

#### Strategic Objective 5: Develop a Researcher Pathway

We will develop our offering to research interested staff members, forging a clear pathway from supporting delivery of clinical research, through becoming a Principal Investigator and on to aspiring Chief Investigators working to attract research grants. The Department will be aware of and support the research leaders of the future through their pathway.

#### **Our 3-year priorities**

- Recognise
- Support

#### Year 1 2021 - 2022

#### **Priority: Recognise**

#### **Action**

Conduct a survey of the ULHT workforce to identify areas of research interest and aspirations.

#### **Expected Outcome**

The R&I Department will have an awareness of which staff members are interested in research, at what 'level' they are at, and what areas of research they are interested in.

#### **Priority: Support**

#### **Action**

Explore with the NIHR 70@70 regional nurses (in particular Nottingham University Hospitals Trust) the potential to develop a programme which will support nurses, midwives, and other AHPs to lead hosted and own research.

#### **Expected Outcome**

An opportunity to support our non-medical workforce to develop research aspirations, learning from those with robust experience in this area.

#### Year 2 2022 - 2023

#### **Priority: Recognise**

#### **Action**

Hold a stakeholder event to further explore with research interested staff how ULHT can support them in their research pathways.

#### **Expected Outcome**

This listening event will lead to the development of a plan to support the varied staff groups and experience levels to continue with their research journey.

#### **Priority: Support**

#### **Action**

Engage with the NIHR RDS and CRN East Midlands to ensure all opportunities for

workforce development are being recognised and accessed.

#### **Expected Outcome**

Our workforce will have the opportunity to access high quality workforce development specifically for researchers or research interested individuals.

Year 3 2023 - 2024

#### **Priority: Recognise**

#### Action

Work with the ULHT Medical Education department to explore opportunities to introduce medical students to the delivery of clinical research.

#### **Expected Outcome**

The identification of potential areas to develop to allow trainees to think about clinical research delivery as part of their role within the NHS.

#### **Priority: Support**

#### **Action**

Launch the programme of support developed through the R&I Listening event and the work with the NIHR 70@70 Nurses.

#### **Expected Outcome**

A number of initiatives to enable our staff members to become more research active.

# How will we be monitored?

The development of the R&I Strategy is an agreed Improvement Scheme within the Trust Integrated Improvement Plan. Monitoring has been through the IIP route.

We anticipate that the delivery of the R&I Operational Action Plan will also be monitored through the Integrated Improvement Plan, with monthly oversight by the Executive Team chaired by the CEO.

Each Operational Action will have an identified lead and a delivery lead for each project. These will report regularly to the senior responsible officer (the Head of R&I).

In line with the R&I Operational Action Plan the Head of R&I will produce regular Performance Highlight Reports. These reports will report by exception, focussing on progress, sharing success stories and escalating risks and issues for intervention.

It is hoped that the R&I Strategy will be incorporated into the Trust annual plan from 21/22 onwards, this is a fantastic step towards integrating R&I into the core business of ULHT.

# **Appendix 1**

## Informal consultation

During the development of this Strategy many of the stakeholders of Research & Innovation in ULHT have been consulted. This has mostly taken place through discussion and utilising some formal survey results. The parties consulted have included:

- Research participants through the NIHR Patient Research Experience Survey
- Patients & service users through the Lincolnshire Research Patient & Public Forum
- Research management leaders from Lincolnshire (EMAS, LCHS and LPFT)
- Local Authority
- University of Lincoln
- Bishop Grosseteste University
- R&I Department staff
- ULHT staff (including members of the Executive Leadership Team, members of the Divisional Leadership Team and some ULHT Principal Investigators / Chief Investigators)
- R&I Managers from other similar Trusts
- NIHR Clinical Research Network East Midlands
- NIHR Research Design Service

During the first year of the Strategy formal consultation will be conducted through initiatives within all 5 Strategic Objective areas. These consultations will feed into initiatives designed for years 2 and 3 of the Strategy.

# **Appendix 2**

# **Year 1 – Measurable Outcomes**

# **Securing the Foundations for growth**

Priority	What does 2024 look like?	Year 1 Initiatives	Year 1 Measurable Outcome	Cost implication		
	ive 1: Strengthen the R&I Department					
The R&I Department will have the structure, direction, standards, development and working environment it deserves. Transforming it into a valued and recognised part of the ULHT, which can in turn improve patient care and develop the research workforce of the future.						
	Departmental leadership is in place with clear role and remit. R&I work together as a 'team' with a culture of 'one'. Behaviours that reflect trust, respect and cooperation.	Develop the role descriptions for Head of R&I and Clinical equivalent, advertise, appoint and induct into role.	Head of R&I and Clinical Director of R&I appointed.	No additional cost.		
Support Our Team		Working with the Organisational Development, we will undertake the "Building Respectful Teams" programme.	An improvement in the 'Pulse Check' staff survey (from survey taken at kick off of BRT project).	No additional cost.		
Improve Our Facilities	The R&I team has adequate facilities to carry out its work in safety and comfort.	Take immediate action and investment to make safe the facilities at Lincoln County	Trust Health & safety audit finds no shortcomings in the safety of the facilities.	Potential cost to make safe steps.		
	The R&I Department will conduct its local Governance meeting that will report into the Trust governance structure. Departmental Standard	Establish the Departmental Governance flows by engaging fully in Trust governance	R&I Report presented regularly at relevant Trust Committee meeting.	No additional cost.		
	Operating Procedures and processes will be robust, up-to-date and fit for purpose, with all relevant staff aware of these. The Department will have good visibility of its current financial position, and its forecast income and expenditure. There will be clarity around the split of earned income between the Principal Investigator	Refresh the processes and SOPs associated with hosted research.  SOPs approved through the Department Governance meeting and shared with appropriate staff.	100 % of R&I Department staff signed off against 100% of hosted SOPs.	No additional cost.		
Department Governance (including Financial Integrity)	and the R&I Department – with PIs having visibility of, and access to these funds. Those conducting 'Service Support Cost' activities will receive funding back to their Department.	Roll out new financial processes across the department providing training and mentoring	100 % of R&I Department staff signed off against 100% of R&I Finance SOPs.	No additional cost.		
	Staff, patient and service users of ULHT and the public of Lincolnshire will know that the ULHT is a research active organisation. There will be visual evidence of our commitment to research and innovation throughout the organisation. Staff members will	Develop a comprehensive communication plan to maximise reach of R&I communications (including newsletters, Trust induction, NIHR produced materials, posters, videos).	Plan in place and agreed through RIGG.	£1,000 materials budget.		
Raising Awareness	hear about research during their induction period and regularly thereafter.	Develop a measure against this Objective. For example, work with the Trust to include a question around research awareness in the Staff Survey / Visual stocktake around the Trust.	Agree measure with Communication Department.	No additional cost.		
Demonstrating Clinical Relevance	Research will be placed according to clinical need. Research findings will be made available to the clinical areas that took part in those studies in a timely way.	NA	NA	NA		

Strategic Objective 2: Build our capacity & capability

We will build the capacity and capability of our current and future workforce to embrace and actively engage with research and innovation. Encouraging participation from all professional groups.

Valuing Contributions	The R&I Department will acknowledged Staff supporting the delivery of research. They will know that R&I and their CBU value their contribution.	Roll out the 'R&I Certificate Scheme' across the portfolio of research studies.	Increase in the number of Research Certificates issues to the staff of ULHT during the year 2021-22 (baseline taken in March 2021).	No additional cost.
	Our research active clinicians will have time to perform their research activities. In line with the national AcoRD guidance, the Trust will pay for the NHS Treatment costs incurred during a research study. The R&I Department will give the CBU a potential cost / cost saving	Secure the agreement of the Trust to fund NHS Treatment Costs and Excess Treatment Costs (developing an indicative Cost Statement and process for confirming potential cost).	Agreement from the Executive Lead for Finance that the Trust will support the cost of the NHS Treatment costs incurred during research.	Potential cost of NHS Excess Treatment Costs up to £45,000.
	breakdown of each study taken forward. A high-level agreement to fund these costs will increase the effectiveness of the study set up process, and will release some CRN Infrastructure funding to increase the		One year data of the NHS Treatment Cost / Saving resulting from Research to be reported to the Executive Lead for Finance.	No additional cost.
Increasing Capacity	capacity of the R&I Delivery Team. In recognition that the R&I Delivery & Pharmacy teams conduct NHS Treatment activities, we will scope and understand if it is appropriate for the Trust to contribute a 'nursing establishment' to the Department.	Throughout the year, hold a series of stakeholder listening events to understand the barriers to taking on research responsibilities.	Events held across all 4 Divisions with attendance from managers, administrators, medics, surgeons, nurses, midwives, clinical scientists and other AHPs.	No additional cost – virtual platforms utilised. This is likely to lead to costs in years two and three.
Developing Capability	The Trust staff (including the R&I Department) will have access to appropriate learning and training opportunities. The R&I Department offer a range of services to support the development and delivery of research.	NA .	NA	NA

Strategic Objective 3: Engage with our patients and service users

We will understand our patients and service users opportunities to take part in research, we will plan and nurture interactions with our patients and service users, and take action to increase opportunity to become involved.

Understand opportunities to take part in	The R&I department is engaged in dialogue with the patients and service users of ULHT. We can be confident that we understand patients opportunities to take part in research	We will gain access to the national NHS survey's to understand the current position of our organisation in terms of % of patients offered an opportunity to	Report to the Trust the current position of patients offered a research opportunity.	No additional cost.
Participants valued and informed	Participants in research studies will know that their contribution is valued by the Trust, and they will be made aware of the findings of the research study they took part in.	take part in research.  NA	NA	NA
Integrate our Lincolnshire Research Patient & Public Forum	The contribution of the Lincolnshire Research Patient & Public Forum is valued throughout the R&I Department. The Forum itself is well supported, and linked to the Trust Patient Experience team, and similar Forums within the Lincolnshire region. The group has clear purpose, direction and outputs. The Chief Investigators of the Trust and Lincolnshire-wide stakeholders will value the contributions of the Forum to their design and delivery of research.	Provide direction, structure and clarity for the Lincolnshire Research Patient & Public Forum.	Forum Terms of Reference, Role Description and PPIE Strategy developed and agreed by the Research & Innovation Governance Group.	Additional time invested by R&I Department Staff.

Strategic Objective 4: Develop a strong Network

We will explore and strengthen relationships with local and regional partners, allowing synergies to develop, shared interests to be developed and to collaborate with a system-wide focus to the benefit of the patients of the healthcare system in Lincolnshire. We will also prepare the foundations for an application to become a University Hospital Teaching Trust.

Local NHS Healthcare Providers	We will network beyond our organisation borders to deliver research as a healthcare system. We will work closely with EMAS, LCHS and LPFT. We will seek out common purpose and opportunity to improve what we do together.	Drive regular meetings with the NHS organisations in Lincolnshire. Through these, identify opportunities to support research across the patient pathway in Lincolnshire.	Number of studies delivered with an involvement from one of our neighbouring NHS Trusts.	No additional cost.
	Our relationships with our academic partners are an indicator of our success in creating a research culture. We will work together to achieve each partners clinical research strategic aspirations, encourage partnerships between academics and clinicians, and setting up and delivering academic driven research in a timely fashion (both student and faculty staff research interests).	Develop a Memorandum of Understanding on Joint Working for Effective Research Governance with the University of Lincoln.	MoU approved by both the Trust and the University.	No additional cost.
Academic Partners	Our relationship with the University of Lincoln will be critical to achieving our Trust ambition of becoming a University Hospital Teaching Trust. We will have preparations in place to satisfy the research criteria of becoming a University Hospital Teaching Trust.			
	ULHT recognised as an engaged partner of the NIHR (including the Clinical Research Network and	Develop a plan with the RDS to support the Trust to make successful grant applications.	Plan approved by the RIGG.	No additional cost – but may lead to further costs in years two and three.
Other Stakeholders	Research Design Service).			i two and tillee.
Stakeholders  Strategic Object	ive 5: Develop a Researcher Pathway	Ensure regular communication with the CRN.	Evidence of regular meetings throughout the year.	No additional cost.
Stakeholders  Strategic Object  We will develop clinical research	ive 5: Develop a Researcher Pathway our offering to research interested sta n, through becoming a Principal Invest . The Department will be aware of and	Ensure regular communication with the CRN.  aff members, forging a clear tigator and on to aspiring Chad support the research leader	meetings throughout the year.  pathway from supporting of ief Investigators working to rs of the future through the	No additional cost.  delivery of o attract eir pathway.
Stakeholders  Strategic Object  We will develop clinical research	ive 5: Develop a Researcher Pathway our offering to research interested sta	Ensure regular communication with the CRN.  aff members, forging a clear tigator and on to aspiring Ch	meetings throughout the year.  pathway from supporting of the supporting of the supporting to the support to the supp	No additional cost.