

## Board of Directors – 30<sup>th</sup> July 2014

### Research and Development Strategy 2014 - 16

#### 1. Introduction and background

This document sets out the strategic direction for Research and Development for York Teaching Hospital NHS Foundation Trust for 2014 – 16. This strategy will be reviewed in 2016 in light of the impending changes to the national research infrastructure.

In 2011 Professor Dame Sally Davies (Chief Medical Officer for England) commented 'Health research matters to each and every one of us'.

Research plays a vital role in improving outcomes for patients by increasing our understanding of health and disease, by developing and refining interventions and by enhancing service delivery. Our vision is to i) strengthen the research culture within the Trust and imbed research as a core activity and ii) establish a national and international reputation for delivering excellent research whether that be generated by ourselves or others.

We will do this within the context of a sustainable infrastructure that manages this activity to the highest standards.

We intend to:

- increase the opportunities for patients to participate in, and benefit from, research
- attract, develop and retain staff who have the capability or potential to generate and / or conduct high quality research
- strengthen our research partnerships
- maximise our involvement in research in order to contribute to the economic stability of the Trust

#### 2. Strategic Aims for Research and Development

##### 2.1 Aims and Objectives 2010 – 2013

During the past three years the Trust's research portfolio (York Hospital site) has been harmonised around 12 clinical specialties where the majority of the clinical research has taken place. Funding for Consultant SPA research time and research nurse capacity has been aligned with those 12 specialties which are: Anaesthetics, Cardiology, Dermatology, Emergency medicine, Gastroenterology, Obstetrics and Gynaecology, Oncology, Ophthalmology, Renal medicine, Rheumatology, Sexual Health and Stroke.

We have seen a steady increase in the number of research projects taking place within York Teaching Hospital NHS Foundation Trust (YTHFT). At the beginning of the previous strategy (2009 /2010), 201 research projects were active in YTHFT and 2458 patients were recruited to these studies. At the end of the period covered by the strategy (2012/13), 346 research projects were active in YTHFT (253 in York and 93 in Scarborough) and 3772 patients\* were recruited to these studies (3503 in York and 269 in Scarborough). \*This recruitment figures only relates to studies on the National Institute for Health Research (NIHR) portfolio - about 70% of all the studies we do - so is an underestimate of the total figure.

It is becoming evident, however, that without further investment, YTHFT may reach a critical point in terms of the maximum number of studies it can host.

During the lifetime of the previous strategy we have seen the successful completion of a number of investigator led studies, including several clinical trials of investigational medicinal products. These latter studies were generated by staff working in Anaesthetics, Ophthalmology, Renal Medicine and Sexual Health; four of the departments previously highlighted as having staff with the experience and capability to generate their own research.

The number of projects initiated by Trust staff, particularly projects funded by external grant funding, has not increased. However in 2012 we made our first major national research funding application (to the Health Technology Assessment programme) in which a Consultant in the Trust was named as Chief Investigator. This application was submitted with the collaboration and support of the NIHR Research Design Service. Although the application was unsuccessful, the submission of such a major research funding application is a step forward for the Trust.

YTHFT continues to have a well developed research management and governance infrastructure including a tried and tested system for managing Standard Operating Procedures for research. The Trust has demonstrated that it has the capability to run good quality trials that meet the regulatory requirements and this was reinforced by a successful statutory inspection by the Medicine and Healthcare products Regulatory Agency (MHRA) in May 2012.

We currently have two part time CLRN funded research management and governance staff (0.8 and 0.9 wte respectively) based in the R&D Unit. The objective for the Trust to have benchmark measures in place to demonstrate the effectiveness of our procedures has been overtaken by the implementation of performance measures by the NIHR, notably their high level objective that all NIHR Portfolio studies should receive NHS permission from an NHS research site within 30 days of that site receiving a valid application.

A process for ensuring correct categorisation of investigative projects has been implemented in the Trust with medical input provided by the Clinical Lead for Research (Mr Andy Coatesworth).

Two Lead Research Nurse Co-ordinators have been appointed to ensure that research nurses and clinical trial assistants are provided with appropriate management and support. They have been in post since 2010.

The Unit has maintained a good working relationship with colleagues at the University of York and continues to share the expertise of the R&D Unit in order to facilitate co-sponsorship of some clinical trials of investigational medicinal products (CTIMPs). There has been renewed interest amongst local NHS Trusts in collaborating on research management and governance procedures and, to this end, a Memorandum of Understanding has recently been signed between ourselves and two other NHS Trusts: Hull and East Yorkshire Hospitals NHS Trust and North Lincolnshire and Goole Hospitals NHS Trust. This recent development will be taken forward in the strategy for 2014 - 16.

The HYMS Experimental Medicine Unit, now known as the York Clinical Research Facility, (CRF) is well established and generating research income in its own right. It is successfully running, and has already run, a number of early phase studies including a 'First in man' study of a treatment vaccine for Leishmaniasis; a study funded by the Wellcome Trust and co-sponsored by YTHFT and the University of York.

York CRF was successful in applying for and being allocated a Pharmaceutical Graduate Management trainee for nine months. Her project looked at promoting the CRF's services and increasing commercial activity. As a result of this work the CRF was relaunched in October 2013 with a new name and new website. The University of York has entered into a risk sharing strategy with the Trust in order to secure the future funding of the CRF for the next five years.

Following the Trust's acquisition of Scarborough and North East Yorkshire Healthcare NHS Trust (SNEY) in July 2012 the R&D Unit has been responsible for all research activity taking place within the services that were previously part of SNEY. The transition of research governance services has

been relatively straightforward with all new research projects since July 2012 being approved through the R&D Unit. There have been some delays to the alignment of the research Standard Operating Procedures (SOPs) in the combined organisation due to ongoing issues with integration of some of the Trust's core services (e.g. adverse incident reporting and use of CPD).

Scarborough and its associated hospitals share many clinical services with Hull and East Yorkshire Hospitals NHS Trust and any potential collaborative ways of working with Hull would be particularly beneficial to them.

## 2.2 The Changing Landscape

The R&D strategy is being updated against a backdrop of significant change within the NHS. Changes to the commissioning of health services in England and to the education and training of the health workforce have recently been implemented. We are also on the cusp of changes to the national research infrastructure. The details of these latter changes are not yet finalised and therefore their likely impact nationally, regionally, and locally is difficult to gauge.

The recent and upcoming changes to the national research infrastructure include:

- The creation of nine 'Collaboration in Leadership for Applied Health Research and Care' networks (CLAHRCs)
- The creation of 15 Academic Health Science Networks (AHSNs).
- The reconfiguration of the existing topic specific and comprehensive local research networks (currently 102 in total) into 15 local Clinical Research Networks (LCRNs). The LCRNs will map onto the geographical footprint of the AHSNs.

CLAHRCs are a relatively new initiative designed to 'bridge the gap' between health research and clinical practice as nationally we do not currently have systematic ways to ensure research is effectively translated to frontline NHS services. Each CLAHRC is a partnership between relevant organisations such as NHS trusts, councils and universities. Our local CLAHRC covers Leeds, York and Bradford.

AHSNs have been created with the following aims in mind:

- To improve health and reduce inequalities in population health by focusing on the chronic diseases which make the biggest impact on mortality in a particular region
- To transform the quality and efficiency of health services in the network through supporting the development, testing and rapid adoption of effective service innovations whether developed internally or outside the NHS
- To generate wealth in regions by developing a wealth creation system

York Teaching Hospital NHS Foundation Trust sits within the Yorkshire and Humber AHSN.

The new Clinical Research Networks will be structured around 30 specialties that will be grouped into 12 themes. The themes are:

- Cancer
- Diabetes, metabolic and endocrine disorders, renal disorders
- Stroke and cardiovascular disease
- Children
- Reproductive health and childbirth, genetics, haematology
- Dementias and neurodegeneration (DeNDRoN), neurological disorders
- Mental health
- Primary care, ageing, oral and dental health, health services and research delivery, public health
- Dermatology and musculoskeletal disorders
- Anaesthesia peri-operative medicine and pain management, critical care, injuries and emergencies, surgery
- Ear nose and throat, infectious diseases and microbiology, ophthalmology, respiratory

- Gastroenterology, hepatology

Each LCRN will determine how to configure its local specialty groups. Those groups will report to the relevant CRN National Specialty Leads at the National Institute for Health Research (NIHR).

York Teaching Hospital NHS Foundation Trust will sit within the Yorkshire and Humber LCRN. The host organisation of our LCRN will be Sheffield Teaching Hospital NHS Foundation Trust. The latter will have responsibility, amongst other things, for distributing funding for research delivery across the member organisations of the LCRN.

The new LCRNs come into place formally in April 2014 and a transition process to take us from the old to the new structure is currently in place. However it is expected that the delivery of research at the coal face will remain much the same for the next financial year. The move to the new LCRN is a major undertaking and we will need to be flexible and respond appropriately to the opportunities and challenges this brings during the lifetime of the 2014 -16 strategy.

### **2.3 Aims and Objectives 2014 – 2016**

In order to realise our strategic aims for R&D we will focus on the following key areas:

- Research leadership
- Research capability and capacity
- Research partnerships

#### **2.3.1 Research leadership**

This strategy will strive to foster a positive culture of research throughout the Trust. To achieve this it will be important that research activity is appropriately supported, valued, rewarded and encouraged. This will require active support at all levels of the organisation from Trust Board through to clinical services. The leadership for R&D in the Trust is headed by the Director of Applied Learning and Research supported by a Clinical Lead for Research, an R&D Group and an established R&D Unit all of whom are accountable to the Trust Board. In addition we will seek to create a number of research champions who will take a role in providing leadership for research in their particular clinical area and develop a mentorship scheme for new researchers.

In the last few years much has been gained from the professional leadership that has been put in place for research staff, especially for research nurses and clinical trials assistants. Such leadership will become ever more important as we move to the new LCRN structure and have to enable, and support, our research staff to work flexibly.

#### **2.3.2 Research capability and capacity**

In strengthening the research culture within the Trust we will seek to expand the number of clinical areas that are involved in delivering research. The appointment of some new consultants with an interest in research has resulted in a revival of research in a number of clinical areas where we have not previously had a strong research portfolio and we intend to build on this impetus. We will also actively seek opportunities to be involved in research which is led by nurses and allied health professionals.

In striving to extend the reach of our research activity, and in order to respond flexibly to the impending changes in national research infrastructure, we will manage centrally all the research income we generate so this can be directed to where it is most required. We expect any excess income to be used primarily to address issues that impact on our capacity to host research studies.

One of our key objectives is to support and develop high quality research that is initiated by Trust staff. The main focus of support for Trust generated research will be in the areas where we have acknowledged activity and expertise and / or where there are clear opportunities for development. Collaboration with the University of York is also an important factor in this.

At York Hospital the departments of Anaesthesia / Critical Care, Gastroenterology, Ophthalmology, Renal Medicine and Sexual Health have all been active in initiating and successfully completing research projects during the lifetime of the previous strategy. At Scarborough Hospital, the Combined Gastroenterology Unit in the Department of Surgery also has a successful track record in generating its own research.

With regard to other departments where new opportunities may lie, the Trust's increasing collaboration with the Centre for Infection and Immunology at the University of York and the immunological basis of many rheumatological conditions make Rheumatology a speciality where we will look to generate collaborative research. Gastroenterology is another speciality where we will actively explore opportunities for such collaboration. This list is not exhaustive and we will continue to support other clinical specialties and actively work with other departments who wish to develop their research potential.

During the period of this strategy we will strive to secure funding from a national research funding body for a project generated by a member of Trust staff.

### 2.3.3 Research partnerships

Partnerships and collaborative working will be vital in allowing us to move forward and realise our research ambitions.

We will continue to foster existing research partnerships with departments at the University of York, including the Hull York Medical School, but we will also actively seek new collaborations with other staff and departments at the University. The creation of credible clinical academic posts based within the Trust would be a significant step forward and this possibility will be explored during the lifetime of this strategy. Potential collaborations with other local academic institutions, such as York St John University, will also be actively explored.

Developing relationships with commercial partners, such as pharmaceutical and medical device companies, will also continue to be an integral part of our activity over the next two years; this will ensure that the Trust benefits from external funding and will also enable our research portfolio to be expanded.

York Teaching Hospital NHS Foundation Trust will seek to establish greater involvement in the local CLAHRC and to be actively engaged in the Yorkshire and Humber AHSN. As a member organisation of Yorkshire and Humber LCRN it will play a significant role in helping the LCRN to achieve the NIHR's objectives.

The York CRF intends to develop further its activity in facilitating early phase trials for commercial as well as non-commercial sponsors. There are also opportunities to extend its reach into other types of studies. The Trust has invested in the environment to ensure that the facility is commercially viable and ready to exploit any business opportunities which are aligned to the Trust's values and objectives.

Patient and public involvement (PPI) continues to be high on the national research agenda. We have already made progress in this area by having significant lay representation on our R & D group however there is more we could do to advance this aspect of PPI within the Trust. We will increase the opportunities for patients and their families to be informed about, and involved in, our research and research processes.

## 3. Conclusion

This strategy intends to outline the Trust’s aspirations for the next two years. An annual report will be presented to the Executive Board outlining progress made against plan.

The attached implementation plan outlines the actions and activity which we consider will enable the Trust to progress the Research and Development agenda in a considered and pragmatic manner.

**4. Recommendation**

The Trust Board is asked to ratify the R&D Strategy for 2014 - 2016

**5. References and further reading**

<b>Author</b>	Dr Christine Davey, Research Adviser, R&D Unit
<b>Owner</b>	Mrs Sue Holden, Director Applied Learning and Research
<b>Date</b>	8 <sup>th</sup> May 2014

<b>REALISING OUR STRATEGIC OBJECTIVES – IMPLEMENTATION PLAN</b>			
<b>Objective</b>	<b>Action</b>	<b>Timescale</b>	<b><u>Lead Person and Contributors</u></b>
1. Strengthen the research culture within the Trust	1.1 Give due recognition to research experience in new Consultant appointments 1.2 Raise awareness of research to new starters within the Trust 1.3. Develop the role of research champions in clinical areas 1.4 Publicise research activity to Trust Board and members of Trust staff 1.5 Publicise research publications authored by Trust staff	1.1 By 2/02/2015 1.2 Process in place by 4/08/2014 1.3 By 2/02/2015 1.4 Ongoing; formal process in place by 4/08/2014 1.5 Process in place by 4/08/2014	1.1 <b><u>S.Holden</u></b> Medical Director, HR Director 1.2 <b><u>R&amp;D management team</u></b> 1.3 <b><u>R&amp;D management team</u></b> 1.4 <b><u>C.Davey</u></b> 1.5 <b><u>C.Davey</u></b>
2. Actively support and encourage Trust staff to pursue high quality research	2.1 Continue to support experienced researchers in developing investigator led studies 2.2 Actively support members of staff who are interested in, but new to, research 2.3 Actively encourage clinical nurses, allied health professionals and other non medical staff to become more involved in research 2.4 Provide active support through the development of a mentorship scheme 2.5 Ensure provision of effective research supervision 2.6 Support publication of Trust initiated research in good quality journals	2.1 Ongoing 2.2 Ongoing 2.3 Ongoing 2.4 Scheme in place by 2/02/2015 2.5 Ongoing 2.6 Ongoing	2.1 <b><u>C. Davey and D.Phillips</u></b> 2.2 <b><u>C. Davey and D. Phillips</u></b> 2.3 <b><u>R&amp;D management team</u></b> 2.4 <b><u>S.Holden, A. Coatesworth</u></b> 2.5 <b><u>A. Coatesworth</u></b> Medical Director, Senior managers of non-medical researchers 2.6 <b><u>C.Davey and D. Phillips</u></b> R&D Group
3. Secure funding from a national research funding programme for Trust generated research project(s)	3.1 Support researchers to develop collaborations and submit grant applications, particularly for NIHR portfolio-eligible funding; 3.1.1 Disseminate information about national grant awards to researchers within the Trust 3.1.2 Provide support of R&D Unit Research Advisers for project development 3.1.3 Collaborate with the NIHR's Research Design Service 3.1.4 Develop an internal peer review process	3.1 Ongoing; One substantial grant awarded by 1/11/2016	3.1 <b><u>C.Davey, D. Phillips, D.Foster</u></b> R&D Group

<p>4. Expand the work of the York Clinical Research Facility</p>	<p>4.1 Continue the safe conduct of early phase clinical trials and other forms of translational research</p> <p>4.2 Actively market the work of the CRF externally and identify studies to use the facilities and skills of the CRF team</p> <p>4.3 Work with colleagues at the University of York to identify further opportunities for collaboration e.g. translational research related to rheumatology</p>	<p>4.1 Ongoing</p> <p>4.2 Ongoing</p> <p>4.3 By 2/02/2015</p>	<p>4.1. <u><b>W.Rashid</b></u></p> <p>4.2 <u><b>W.Rashid</b></u></p> <p>4.3 <u><b>W.Rashid</b></u></p>
<p>5. Increase the income we generate through research activity</p>	<p>5.1 Maximise NIHR funding by meeting appropriate government initiation and delivery benchmarks for Portfolio studies</p> <p>5.2 Seek to develop further the consultancy arm of the R&amp;D Unit and offer services to academic and other partners</p> <p>5.3 Develop and provide fee paying research related course(s) nationally e.g. for clinical trial assistants</p> <p>5.4 Develop a marketing plan for attracting more device industry research</p>	<p>5.1 Ongoing</p> <p>5.2 By 2/02/2015</p> <p>5.3 By 2/02/2015</p> <p>5.4 By 2/02/2015</p>	<p>5.1 <u><b>D.Foster</b></u></p> <p>5.2 <u><b>C.Davey and D Phillips</b></u></p> <p>5.3 <u><b>C.Davey</b></u></p> <p>5.4 <u><b>W.Rashid</b></u></p> <p>C.Davey</p>
<p>6. Deliver robust and flexible financial management of our research income</p>	<p>6.1 Develop a process for managing research income centrally</p>	<p>6.1 Process in place by 31/03/2015</p>	<p>6.1 <u><b>S.Holden</b></u> R. Cooke, D. Foster</p>
<p>7. Streamline research management and governance services across the integrated organisation and our Clinical Alliance partners</p>	<p>7.1 Continue work on aligning research management and governance services at York and SNEY hospitals</p> <p>7.2 Work with the Health Research Authority, Yorkshire and Humber Academic Health Science Network and the Yorkshire and Humber LCRN to implement any proposed national changes to research management and governance procedures</p> <p>7.3 Align and share relevant research management and governance processes with Hull and East Yorkshire Hospitals NHS Trust and North Lincolnshire and Goole NHS Trust, as part of our existing Memorandum of Understanding</p>	<p>7.1 Ongoing; achieve by 2/02/2015</p> <p>7.2 As and when required</p> <p>7.3 Ongoing; achieve by 1/02/2016</p>	<p>7.1 <u><b>D.Foster</b></u> J.Holmes, R&amp;D Unit admin team</p> <p>7.2 <u><b>D.Foster</b></u> J. Holmes, R&amp;D Unit admin team</p> <p>7.3 <u><b>D.Foster</b></u> R&amp;D managers in HEY and NLAG</p>



<p>8. Create opportunities for patients and their families to be informed about, and involved in, Trust research and our research processes</p>	<p>8.1 Maintain an up to date section about research on the Trust's website  8.2 Place posters about Trust research in wards and departments  8.3 Provide written information about research at key places e.g. Reception, PALS  8.4 Include reference to research in Trust outpatient appointment letters  8.5 Include information about research in booklets for Inpatients  8.6 Develop a process for involving patients in the development of Trust initiated studies</p>	<p>8.1 Ongoing; update every 3 months  8.2 By 4/08/2014  8.3 By 4/08/2014  8.4 By 3/02/2014  8.5 By 4/08/2014  8.6 By 2/02/2015</p>	<p>8.1 <b><u>C.Davey</u></b>  8.2 <b><u>H. Campbell, Sarah.Russell-Sharpe</u></b>  Research teams  8.3 <b><u>C.Davey</u></b>  8.4 <b><u>H.Campbell</u></b>  8.5 <b><u>C.Davey</u></b>  Communications Team  8.6 <b><u>C.Davey</u></b></p>
<p>9. Continue to work with the National Institute for Health Research (NIHR) and the Yorkshire and Humber LCRN to provide professional support for research</p>	<p>9.1 Develop a flexible workforce who can work within and across the themes that make up the new LCRN structure  9.2 Continue to provide robust management, appraisal and team support for Research Nurses and other research staff  9.3 Maintain robust systems during and after the transition from the current clinical networks to the new LCRNs  9.4 Ensure collaborative working across the new LCRN in relation to provision of training in research skills and Good Clinical Practice</p>	<p>9.1 Ongoing  9.2 As and when required  9.3 Ongoing  9.4 Agreed programme by 1/04/2015</p>	<p>9.1 <b><u>Hilary Campbell, Sarah Russell-Sharpe</u></b>  9.2 <b><u>Hilary Campbell, Sarah Russell-Sharpe</u></b>  9.3 <b><u>R&amp;D management team</u></b>  9.4 <b><u>C.Davey</u></b></p>
<p>10. Build and strengthen our research relationships with local universities, local NHS organisations and regional centres of national networks such as the AHSN and CLARHC</p>	<p>10.1 Continue to explore and develop opportunities with local academic institutions.  10.2 Work with academic partners to put in place credible clinical academic posts based in York  10.3 Maximise opportunities presented by the recent establishment of the York Tissue Bank  10.4 Develop joint strategy for R&amp;D with the University of York  10.4.1 Explore establishment of a joint R&amp;D office with the University of York  10.5 Investigate membership of the local CLAHRC  10.6 Exploit opportunities offered by the Yorkshire and Humber AHSN</p>	<p>10.1 Ongoing  10.2 By 1/11/2016  10.3 Ongoing  10.4 By 1/11/2016  10.5 By 4/08/2014  10.6 Ongoing; identify opportunities by 4/08/2014</p>	<p>10.1 <b><u>R&amp;D management team</u></b>  10.2 <b><u>S. Holden</u></b>  10.3 <b><u>W.Rashid</u></b>  S. Pollock  10.4 <b><u>D.Foster</u></b>  S.Holden  10.5 <b><u>C.Davey</u></b>  10.6 <b><u>C.Davey</u></b></p>

