NHS
The Leeds
Teaching Hospitals
NHS Trust

Research and Innovation Development

Audit Committee

Thursday 9 September 2021

Presented for:	Information and Assurance
Presented by:	Dr Phil Wood, Chief Medical Officer
Author:	Ai-Lyn Tan - Associate Medical Director, Research and Innovation Christopher Herbert - Director of Operations: Research and Innovation Julie Evans - Head of Nursing: Research and Innovation Claire Gaunt - Associate Director of Finance
Previous Committees:	None

Trust Goals	
The best for patient safety, quality and experience	✓
The best place to work	✓
A centre for excellence for research, education and innovation	✓
Seamless integrated care across organisational boundaries	
Financial sustainability	✓

Risk Appetite Framework				
Level 1 Risk	**(✓)**	**Level 2 Risks**	**(Risk Appetite Scale)**	**Risk**
Workforce Risk	✓	Workforce Deployment Risk - We will deliver safe and effective patient care through the deployment of resources with the right mix of skills and capacity to do what is required.	Cautious	↔ (same)
Operational Risk	✓	Business Continuity Risk - We will develop and maintain stable and resilient services, operating to consistently high levels of performance.	Cautious	↔ (same)
Clinical Risk	✓	Research, Innovation & Development Risk - We will deliver agreed minimum research and innovation priorities with health, social care, voluntary, education and private sectors	Cautious	↔ (same)
Financial Risk	✓	Financial Management & Waste Reduction Risk - We will deliver sound financial management and reporting for the Trust	Cautious	↔ (same)

		with no material misstatements or variances to forecast.		
External Risk	✓	Partnership Working Risk - We will maintain well-established stakeholder partnerships which will mitigate the threats to the achievement of the organisation's strategic goals.	Open	↔ (same)

Key points	
1. This paper sets out the controls and forums that are in place that enable the safe and effective management of research and innovation across the Trust.	Information

1. Summary

This management of research and innovation activities can be complex due to the time-limited funding for many initiatives, the large amount of collaborative working with partners and the highly individual nature of many projects and programmes. This paper sets out at a high level the Trust's approach to control processes, monitoring and assurance for all activities associated with research and innovation within the purview of the Research and Innovation department that are taking place across the Trust.

2. Background

This paper sets out the processes that are in place to ensure that research and innovation programmes that are sponsored or hosted by the Trust are appropriately governed and that all risks are identified and managed. This includes:

- Operational management of research activities
- Research Governance
- Business Development and Innovation
- National Pathology Imaging Co-operative
- Use of routinely collected clinical data for research purposes
- Financial management

A number of the hosted infrastructure programmes are run jointly with the University of Leeds and historically the operational management of these has sat outwith the Research and Innovation department, often with staff employed by the University rather than the Trust. These include

- NIHR Surgical Medtech Co-operative
- NIHR Leeds In Vitro Diagnostic Co-operative
- NIHR Leeds Biomedical Research Centre

These joint arrangements have sometimes resulted in challenges but as we work with partners on bids to renew these infrastructure programmes, we are looking at how the operational management of these can be more seamlessly integrated within Research and Innovation whilst respecting the academic leadership associated with these.

The ultimate responsibility for management of the Department falls to the R&I Triumvirate (Associate Medical Director, Director of Operations, Head of Nursing) and they are supported by a Senior Management team who have responsibility for dedicated areas. A monthly senior management meeting brings together this team to discuss issues, progress

against Key Performance Indicators (as set out in the 2020-25 R&I Strategy) and to manage risks associated with Research and Innovation.

As a result of the programme of work that has seen all the research delivery staff and research budgets in the Trust centralised within R&I over the last 3 years, many processes are now being reviewed and streamlined to allow consistency of process and oversight. All hosted infrastructure programmes and other major initiatives also report to the R&I Committee which then reports directly to the Trust board.

3. Operational Management

The operational management of research at the Trust comprises a number of different elements so that research active staff and research teams are provided with the necessary support. These elements include:

- Oversight of processes that ensure only studies that are safe to open, have the resource available to deliver them and that are likely to recruit patients open at site (study set-up)
- Support for researchers developing grant applications
- Review and negotiation of contracts that allow research to happen
- Business management

3.1 Study set-up

A key component of the Trust's Research Governance is ensuring that we have the ability and capacity to deliver research safely within the organisation following a detailed review of study protocols and other accompanying information (e.g. Pharmacy manual, Laboratory manual, Finances). This requires cross-organisational working with a number of teams and can be complex. Only once all necessary approvals have been received is local Confirmation of Capacity and Capability (CCC) issued and a study able to start. Setup of studies across the organisation is supported by a central team within R&I and following the completion of the integration programme work is underway to streamline the processes and bring in standardised ways of working across the organisation.

Nationally there is a target for 75% of studies being opened within 70 days of an organisation being selected as a site. Local setup times are monitored through EDGE (a research management system) and the NIHR's Portfolio Management System and overall performance is reviewed on a monthly basis at the Senior Management Team meeting. Performance and any issues hindering progress are also reviewed at weekly study setup meetings which is chaired by the Research and Innovation Manager (Research Operations) which brings together the central support team with the contracts manager, representatives from research support services in Pharmacy, Pathology, Radiology and Medical Physics, with any major issues escalated to the R&I Triumvirate for information or action where these can't be resolved.

3.2 Grant application support

The majority of research programmes are funded through specific grants awarded to individuals/the organisation from a wide variety of sources. A dedicated Grant Funding Development Manager within R&I supports researchers with the development of such grants to ensure that submitted applications are of a high quality, that researchers have worked with the R&I finance team to ensure that all costs are included, and that links have been made as necessary to other parts of the research support and delivery infrastructure. This dedicated support also means that we can identify where any capital costs are being

included in grant applications and how this is managed through the Trust's capital processes (see finance section). A Grant application tracker is shared for information at the Senior Management Team meeting so all are aware of bids that are in development or pending decision.

3.3 Contract negotiation
Research contracts fall into 2 categories:
   a. Contracts that use unmodified templates that have been negotiated at a national level
   b. Custom contracts that require bespoke drafting and negotiation

For contracts that use unmodified national templates, a simple review process is undertaken following local SOP's to ensure that the correct information for the project is included (PI name, finance and invoicing details, recruitment target, protocol reference) prior to final review and signature by one of the Senior Management team. This process is overseen and managed by the study setup team under the leadership of the Research and Innovation Manager (Research Operations).

A research contracts manager is employed to manage the drafting and negotiation of bespoke research agreements. These can be for situations where the Trust is participating in a project (either as lead or as a partner) where a multi-partner collaboration agreement is required or where a modified version of a national template. Regular review meetings with the Director of Operations: Research and Innovation ensure that the bespoke contract workflow is being actively managed, that any issues or major negotiation challenges are highlighted and that assurance is in place that agreements are fit for purpose.

4. Research Delivery Workforce Management
Workforce delivery staff (research nurses and Clinical Trials Assistants) previously employed and managed within CSU's have been brought into R&I along with research cost centres over the last 2 years, with this integration process completing in August 2021. This has allowed improved oversight of staff, improved training, improved governance, better career opportunities, better budgetary oversight and the use of more streamlined processes. It has also enabled us to identify potential capacity gaps and support plans for further actions to be undertaken.

The delivery workforce is overseen and managed by the Head of Nursing with four Lead Nurses. A monthly meeting with Team Leaders as a forum and on an individual basis allows monitoring and assurance to manage areas of staffing pressures and patient acuity.

Work steams for standardising practice are now being implemented involving all teams and form part of the Nursing & Midwifery Strategy. These include
   • The Senior Nursing team working with corporate nursing through attendance at Nurse Director and Head of Nursing meetings to ensure Governance assurance is covered in all clinical areas that solely deliver research activities. This includes the principles for a Perfect Ward where applicable. This is achieved by in conjunction with the Clinical Research Facility Senior Leadership Team.
   • Working with the finance team and R&I business mangers to ensure workforce gaps are identified and vacancy control processes implemented to ensure adequate workforce within allocated budgets and identification of areas where investment is required to meet demand.

- Working with Human Resources and Workforce to streamline the recruitment process and provide a more agile workforce within Research Delivery. This is monitored through monthly Lead Nurse meetings.
- Establishing the "Research Academy" to deliver training and development for LTHT research staff. The success of this initiative is shown by its expansion across the Yorkshire & Humber area through the Clinical Research Network. Feedback is obtained from all courses delivered to allow monitoring of the effectiveness of the training provided and continuous improvement.
- The Lead Nurse for Education is working on core competencies for all research staff to comply with as a minimum standard framework. This will ensure all research is delivered to the same expected high standards across the Trust.

Any issues or risks associated with Research Delivery are raised at weekly Triumvirate meetings, discussed at monthly Senior Management meetings and highlighted in the Quarterly report for the Trust's R&I Committee.

5. Research Governance

The Research Governance team ensures that the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality in the UK are adhered to in the Trust. These regulations set standards to improve research quality and safeguard the patients and public, enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents, ensuring lessons are learned and preventing poor performance and misconduct.

The Research Governance function provides advice and guidance for researchers around regulatory and governance approvals required for their proposed studies as well as advice for all ongoing studies. This includes oversight of study sponsorship for chief investigators who are based in the LTHT, supporting applications to the Health Research Authority to ensure compliance with NHS research governance standards and practice. The LTHT Research Governance team works closely with the Quality Assurance team from the University of Leeds who ensure that locally sponsored trials using an medicinal product (CTIMP) meet regulatory thresholds in their conduct. The QA team also support the Trust in MHRA inspections of the Trust and University which take place every 3 years or so.

This joint approach to Research Governance is managed through a joint research governance group that meets monthly to review any issues with the sponsored research portfolio, any research incidents identified either through management structures or reported on DATIX, reports from monitoring activities carried out on sponsored trials and progress against any corrective action plans that are in place with either sponsors or the MHRA in relation to issues. The minutes from this meeting are shared at the R&I Senior Management team meeting and with the R&I Committee and any identified risks are included on the overall R&I Risk Register. Any major issues identified are escalated to the R&I Triumvirate for information or action via the Director of Operations.

6. NIHR Clinical Research Facility

The Clinical Research Facility team within R&I manages the delivery of early phase and experimental medicine clinical trials. Partially funded by an NIHR grant its operational structure utilises core functions within R&I (delivery staff management, setup, governance, performance management, finance) as well as having its own specialist oversight related to these complex trials and the management of the estate in which they are carried out across

all Trust sites. The CRF Operations team meets weekly and the CRF Manager is part of the R&I Senior Management team and any issues and risks associated with the CRF are discussed in that forum. The CRF has its own oversight board which is chaired by the Chief Medical Officer and which contains representation from senior teams at both the University of Leeds and Leeds Teaching Hospitals. It also provides a quarterly update to the R&I Committee.

7.   Performance Management

Our overall performance in research delivery is monitored through data captured in EDGE that is entered by research delivery and research management staff. A number of dashboards that are available on the Trust intranet allow key performance statistics to be viewed in real-time by anyone working in the Trust. Many of the metrics captured locally are fed into national reporting systems and analyses of these allow us to benchmark our performance against other organisations nationally in a wide range of categories. Many of the dashboards are used internally to ensure that national targets are being met.

This performance data is reviewed on a monthly basis at the R&I Senior Management meeting and key metrics are shared quarterly with the R&I Committee.

8.   National Pathology Imaging Co-operative (NPIC)

The National Pathology Imaging Co-operative is a £47m programme made up of 2 major grants alongside additional contributions from the industry partners involved.
- £10m Innovate UK (Wave 1) - Centre of Excellence for Artificial Intelligence
- £20m Innovate UK/OLS Centre Scale-up (Wave 2)

NPIC is managed by a Project Director, supported by an Operations Director and Deployment Director. A monthly Project Executive Management team meeting oversees the progress of the project; this team includes individuals who are not directly involved in the day-to-day running of the project to give independent oversight. Into this Executive Management meeting reports 2 subcommittees - one subcommittee that manages programme finances and another subcommittee that has been supporting the IT infrastructure needs of the project. A programme steering board meets quarterly that has representation from the programme funders and all 27 partners involved to ensure that any major issues that affect all partners are managed, the overall progress of the programme is monitored and visible to all partners and that the funders have assurance that the individual projects are on target to meet their objectives.

An NPIC update is provided at the monthly R&I Senior Management meeting and a paper highlighting progress is presented at the R&I Committee.

9.   Financial Management

The financial management of R&I activities is supported by primarily dedicated R&I Finance staff. The team is headed by an Assistant Director of Finance (ADF) and there is a lead R&I Accountant supported by a senior finance officer aligned to each of the clinical areas such as Oncology. The finance staff supporting R&I are part of a wider management accounting team managed by the ADF and resources are used flexibly.

The financial management of R&I is subject to the same standard work around financial reporting, control and forecasting as non-research activity and the Trust's financial

performance framework is applied. There are specific arrangements for research approvals set out in the Trust's Standing Financial Instructions and Schemes of Delegation. R&I is subject to audit scrutiny both internal and external; some of the claims to the specific funding bodies such as Innovate UK have to have external audit scrutiny every time they are submitted, so audit requirements are a key consideration.

The ADF is a member of and provides a standard report to the Trust's R&I Committee which provides a general update, reports on key actions and highlights issues and risks. The ADF is a member of the various NIHR Infrastructure Boards and Executives and as appropriate chairs specific finance meetings such as the "Finance Strategy Group" which has been constituted to provide sound financial governance around the new NPIC development. The ADF is also an active member of a number of research related groups with the Leeds Hospitals Charity.

Over the years there has to been an evolving and significant development agenda in R&I both nationally and internally which has involved complex and varied financial issues and funding methodologies. The move to managing research under one centralised CSU has further required historical practices to be reviewed and amended, to ensure that they are fit for purpose and support the ambitions for the future. The impact of COVID has also obviously had a real bearing on what has been required in terms of support.

In response to this, each year the R&I Finance Team identifies a set of development objectives which incorporates areas and issues which they feel need to be the focus of attention for the coming year; this is informed by stakeholder feedback, internal service needs including the need for continuous improvement and national requirements. A detailed action plan is set out and agreed which incorporates a number of key work streams; some of which are purely financial but some require joint working with non-financial colleagues both internal and external. The Leeds Improvement Method is embedded in taking forward the action plan and a report on progress is included in each R&I Committee report.

As a result there has been over recent years much progress and strengthening of financial management arrangements. A new development for 21/22 has been the creation of a "Working together Group" which is chaired by the ADF and which is designed to provide a forum to bring together the finance team and the R&I Operations Manager and Business Managers as the financial aspects and general research processes are so inextricably linked.

There are clear research governance frameworks for the different elements of research both in terms of what is established in LTHT and what is required by funding bodies/Sponsors; the current development plan does however include workstreams to further develop and strengthen governance. One work steam underway is assessing whether there needs to be greater links at times to the other trust committees including the Capital Planning Group and the Finance and Performance Committee and when and if prospective research bids should be subject to the normal business case route and format.

The NPIC development due to its complexity has been invaluable in highlighting what additional arrangements could helpfully be formally set out to reflect the fact that LTHT in pursuing its Research Strategy, is entering into more and more ambitious high value, multi-partner activities which involve varied funding bodies, have links to wider service developments and which can involve both capital and revenue implications. The NPIC arrangements are currently being reviewed by an external Audit provider and this will

helpfully provide a check as to the robustness and appropriateness of what is being put in place both now and proposed for the future; for both NPIC and research activity in general.

There is a clear monthly finance reporting process and consistent reporting template that allows the positions both within the individual business segments within R&I to be assessed as well as the overall position for R&I. Monthly financial reviews are carried out with individual research areas and the financial position is assessed each month at the senior management meeting.

10. Use of routinely collected clinical data for research purposes

An increasing number of research projects rely on the use of large scale datasets that are collected as part of routine patient care, rather than specifically for research projects. Datasets for such projects are retrieved on a project-by-project basis from Trust IT systems and de-identified prior to release by a dedicated team working in Research and Innovation according to SOP's. Performance metrics for the team have recently been introduced and there is an ongoing programme of continuous improvement to improve the service offered.

Working with colleagues in Information Governance a strong oversight process has been developed to ensure that the risk of any potentially identifiable information being released is minimised, that there is a legal basis for data processing and that the datasets being requested are appropriate for the aims of the project. A "Data Access" group has been established by the Trust which meets monthly and reviews applications from researchers both from LTHT and who are working in collaboration with LTHT who wish to access large scale datasets for research projects, or share datasets with third party organisations where patient consent is not being sought. Lists of approved requests are shared at the R&I Senior Management meeting for information and at the R&I Committee meeting as part of the Real World Data Update paper.

The Data Access Committee has been meeting for the last 2 years and its effectiveness is continually reviewed. Processes associated with approval and release of real world datasets were audited by KPMG in December 2019. The recommendations from that Audit have been incorporated into our processes locally.

11. Business Development and Innovation

Business relationships with commercial partners are managed through the Business Development and Innovation team. Relationships broadly fall into 2 categories:
i.   where the Trust is a site for conducting commercially sponsored clinical trials
ii.   where the Trust is engaged with projects that are co-developing or evaluating a novel technology

For (i) many partnership opportunities come via the Clinical Research Network, however we have a strong relationship with many Contract Research Organisations (CRO's) and Pharmaceutical companies who bring multiple projects to the Trust each year. Each of these has a dedicated relationship manager (one of the Business Development and Innovation Managers) through whom issues can be addressed and there are 2-3 face to face meetings per year to monitor performance and get insights on the future portfolio of work so as to help shape workforce planning. The studies that are undertaken at the Trust are selected by research leaders in their specialty areas looking at available capacity, whether patient populations exist that can be recruited from and other factors. The setup, delivery and governance of selected projects then falls to other functions within R&I.

For (ii) many partnership opportunities are developed through introductions from external organisations (e.g. Academic Health Science Network) or from our own networking and business development activities. New opportunities are reviewed weekly and those that are felt to potentially address an unmet need, deliver patient benefit, be of interest to Trust staff, have a credible partner and add value to both the business and the Trust are taken forwards. Only where clinical partners who are interested in being involved in a project are then these filtered opportunities taken forwards. These are reviewed weekly to monitor progress and allow all members of the team to have an understanding of the wider portfolio. The Business Development and Innovation team manage the development of projects and then manage the ongoing relationship once a project is live. Given the growing number of commercial relationships that are being developed a Customer Relationship Management (CRM) system is currently being implemented to allow interactions to be tracked and managed.

Alongside the development of business relationships the Business Development and Innovation team also work to identify needs and challenges around which innovation projects can be built, develop innovation training and run innovation-focused events. Alongside the weekly review of new opportunities and developing projects there is a weekly operations meeting to track wider innovation activities and ensure the objectives and KPI's set out in the annual plan are being met.

The Business Development and Innovation team reports to the Director of Operations and updates are provided to the monthly R&I senior management meeting and an Innovation paper is presented at the R&I Committee.

12. Risk
This report has been provided for information and assurance purposes. All risks are within the Trust's risk appetite and risk mitigation is managed by the R&I Senior Management team.

13. Publication Under Freedom of Information Act
This paper has been made available under the Freedom of Information Act 2000

14. Recommendation
The audit committee are asked to receive this report and
  i)   Comment on the mechanisms in place for the management of research and innovation across the Trust
  ii)   Make any further recommendations it feels appropriate based on the information provided to further enhance management and oversight

<div align="right">
Ai-Lyn Tan
Christopher Herbert
Julie Evans
Claire Gaunt

26th August 2021
</div>