

**Annual Report Research and Innovation Committee  
Audit Committee - 6 May 2021/ Board Workshop 20 May 2021**

<b>Presented for:</b>	Information and Assurance
<b>Presented by:</b>	Phil Wood, Chief Medical Officer
<b>Author:</b>	Donna Johnstone, Research and Innovation Manager Christopher Herbert, Director of Operations: Research and Innovation

<b>Trust Goals</b>	
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	✓
<b>Key points</b>	
1. <b>Terms of Reference</b> - The Committee Chair, along with the Committee has reviewed the Terms of Reference on a line by line basis, to ensure that the Committee is fit for purpose and carries out its duties as delegated by the Board of Directors. The committee has discharged its duties in line with the ToR subject to the following amendments set out in appendix A (shown in track changes)	Approval
2. <b>Reporting Requirements</b> - The Terms of reference for the Research and Innovation Committee state; The Committee will report annually on the delivery of its work programme which focuses on. <ul style="list-style-type: none"> <li>○ Overseeing the development and implementation of strategies to promote LTHT as a global hub for research and innovation and to establish conditions for increasing participation in research, promoting and supporting innovation and continuing development opportunities.</li> <li>○ Overseeing the establishment of partnerships with higher</li> </ul>	Assurance

<p>education institutes, industry, NHS organisations, and charities across the UK and internationally to increase participation in research, the clinical innovation pathway and continuing development opportunities.</p> <ul style="list-style-type: none"> <li>○ Keeping under review the performance management for the delivery of the research and innovation strategy.</li> <li>○ Providing assurance that opportunities to develop the research and clinical innovation portfolio are aligned with the Trust Board’s strategy and that high- quality bids are submitted.</li> <li>○ Providing assurance that the research workforce is developed and replenished in sufficient numbers to meet LTHT’s long-term strategic and clinical aspirations.</li> <li>○ Overseeing the development and implementation of highly-effective controls for research and innovation governance.</li> </ul>	
<p><b>3. Work Plans</b></p> <ol style="list-style-type: none"> <li>I. The Board of Directors approved the Committees Work Plan for 2020/21 (Appendix B), and reports assurance against items received during the year</li> <li>II. The Committee sets out its draft Work Plan for the coming year (Appendix C), seeking approval from the Board.</li> </ol>	Assurance

### 1. Purpose

The purpose of this paper is to provide assurance to the Audit Committee that the Research and Innovation Committee has discharged its duties in accordance with its Terms of Reference, completed its work plan for 2020/21 and to propose its draft work plan for 2021/22.

*The Committee shall review annually the Committee’s terms of reference and its own effectiveness and recommend any necessary changes arising therefrom.*

*To report to the Board on matters set out in its terms of reference and how the Committee has discharges responsibilities.*

*The Chair of the Committee shall provide an annual letter of assurance to the Chair of the Audit Committee confirming the effectiveness of the Committee and fulfilment of its objectives, and to the effect that the committee has reported to the board financial or operational performance which would adversely affect achievement of corporate objectives.*

### 2. Committee Members and Effectiveness

Dr Phil Wood is the appointed Chair of the Committee. The Committee Members/Attendees are set out below:

Chair:	Phil Wood	Chief Medical Officer
	Helen Christodoulides	Deputy Chief Nurse
Research:	Christopher Herbert	Director of Operations, R&I

	Julie Evans	Deputy Head of Nursing, R&I
	Gordon Cook	Director, NIHR Leeds MIC
	Charlotte Harden	Chief Operating Officer, NIHR Leeds MIC
	David Jayne	Director, NIHR Surgical MIC
	Vee Mapunde	Director of Operations, NIHR Surgical MIC
	Chris Twelves	Director, Leeds CRF & Interim R&I Director
	Helen Radford	Deputy Director, Leeds CRF
	Paul Emery	Director, NIHR Leeds BRC
	Medina Inamdar	Operations Manager, NIHR Leeds BRC
	Sinisa Savic	Director, NIHR Bioresource
	Claire Gaunt	Senior Finance Business Partner
	Matthew Callister	CI for Yorkshire Lung Screening Study
	Heidi Siddle	Consultant Podiatrist, NIHR Senior Clinical
	Rory O'Connor	Pro-Dean for Research UoL FMH
	Anne-Maree Keenan	Deputy Pro-Dean for Research UoL FMH
	Peter McWilliam	Chair of the Leeds Cares Research & Innovation Committee
Innovation:	James Goodyear	Director of Strategy
	David Brettle	Chief Clinical Scientist; Innovation Lead
	Darren Treanor	Consultant Histopathologist (Digital Pathology)
	Geoff Hall	Chief Clinical Information Officer
	Roy Charlton	Head of Commercial
	Nisha Sharma	Director of Breast Screening
	Ceri Williams	Director of Research & Innovation Development (UoL)
Trust Chair (Observer)	Linda Pollard	Trust Chair
Non-Executive Director(s) (Observer)	Chris Schofield	Non-Executive Director
In routine attendance	Donna Johnstone	R&I Manager

The Committee has met 4 times during this financial year, with meetings scheduled quarterly and all have been quorate and well attended. However, at the start of the year the meetings were disrupted due to COVID 19 and have since taken place on-line using the Zoom and TEAMS platforms.

The committee has been effective at discharging its duties.

### 3. Delivery Against Terms of Reference

The terms of reference were reviewed by the committee in the February 2021 meeting, updated and will be approved at the next meeting on 11<sup>th</sup> May 2021.

#### **4. Amendments to Terms of Reference**

A full ToR is attached as Appendix A and changes made for 2021/22 are shown as track changes.

#### **5. 2020/21 Work Plan**

##### **Assurance of delivery of work plan**

The workplan for 2020/21 (as set out in Appendix B) allowed scrutiny of the KPI's as set out in the Trust's Research and Innovation Strategy (2020-25) along with a range of other national performance metrics against which the Trust is measured. The committee was assured that, despite the COVID pandemic, KPI's were largely being met. The committee also received reports on the impact of the COVID-19 pandemic on research, with the pause and restart process associated with the established research portfolio as well as the Trust's research response to the COVID pandemic. The annual reports from the NIHR infrastructure programmes (NIHR Biomedical Research Centre, NIHR Clinical Research Facility, NIHR Leeds Medtech and In Vitro Diagnostic Co-operative, NIHR Surgical Medtech and in Vitro Diagnostic Cooperative and NIHR Bioresource) and the associated feedback was shared. In addition, the committee also received regular reports from the National Pathology Imaging Co-operative. Reports on R&I finances were also received.

A summary of the reports received is in Appendices D, E and F.

#### **6. Other Issues addressed by the Committee in year**

A breach of IRMER regulations associated with a small number of Oncology trials that was reported to the CQC was addressed by the committee in February 2021. Assurance was received that the matter was being dealt with and measures put in place to minimise the risk of this happening again.

To further strengthen governance and control of risk the Research Governance Group will now provide a monthly assurance report to the Quality and Safety Assurance Group (Formerly Quality Management Group), which reports to the Quality Assurance Committee of the Board.

The committee was appraised of the potential financial challenges for Research and Innovation associated with the COVID pandemic as a proportion of R&I income is earned based on activity delivered. The pause on non-COVID research and the impact of the COVID pandemic on clinical services (from which patients are recruited) was likely to cause financial pressures both in this year and also in future years due to the impact on the portfolio. Assurance was received that the financial position was being monitored and measures put in place to minimise the impact.

#### **7. Risk Management**

The Committee has reviewed and commented on the risk register held by Research and Innovation and has assurance that risks associated with R&I and monitored and mitigated as far as possible. Further work has looked at how R&I risks should be included on the corporate risk register and how R&I risks can be aligned to the Trust's risk framework.

#### **8. Internal control environment**

No internal audits were received by the committee.

### **9. Proposed 2021/22 Work Plan**

The proposed 2021/22 work plan (Appendix C) builds on the 2020/21 workplan, but includes more detailed updates from hosted NIHR infrastructure programmes. The workplan also includes greater oversight of innovation functions within the Trust including the hosted NIHR MIC programmes and updates on work around the Innovation district. Planned presentations to the committee include the Sunflower programme, research into AI in Breast Cancer diagnostics, a case study from a partner in the Innovation pop-up and the Hospital Charity Research and Innovation strategy.

### **10. Publication Under Freedom of Information Act**

This paper has been made available under the Freedom of Information Act 2000

### **11. Recommendation**

The Research and Innovation Committee has delivered the agreed delegated activities by the Board as set out in its Work Plan and gained assurance as defined by the Committee Terms of Reference. The Terms of Reference have been amended for 2021/22 as shown in Appendix A and these are presented for approval along with the workplan for 2021/22.

### **12. Supporting Information**

The following papers make up this report:

- Summary of Research reports (Appendix D)
- Summary of Innovation reports (Appendix E)
- Summary of Finance reports (Appendix F)

Christopher Herbert

**Director of Operations: Research and Innovation**

April 2021

## Appendix A: Terms of Reference

### 1. Main Authority / Limitations

- 1.1 The Board hereby resolves to establish a management committee to be known as the Research and Innovation Committee ('the Committee'). The Committee is an executive-led management committee accountable to the Trust Board and shall have executive responsibilities, powers, authorities and discretion as set out in these terms of reference.
- 1.2 The Committee is authorised by the Board to oversee the development, implementation and performance management of the research and innovation strategy, to foster commercial opportunities that may arise, and to monitor, investigate and address any activity within its terms of reference. It is authorised to seek a range of views, expertise, transparency and openness in meeting its objective. The Committee is authorised to request the attendance of individuals and advisors with relevant experience and expertise where necessary.
- 1.3 The Committee Chair provides the Trust Board with a brief summary of the Committee's work at the first available Trust Board meeting opportunity after each Committee meeting. Approved minutes of the Committee are circulated to the Trust Board for information at the first formal meeting of the Trust Board after approval. The minutes are also circulated to those regularly in attendance. The Chair of the Committee will escalate matters in the first instance to the Chief Executive and Executive Management Team, and thereafter to the Trust Board as deemed appropriate.
- 1.4 Trust Standing Orders and Standing Financial Instructions apply to the operation of this Committee.

### 2. Objective

- 2.1 The Committee shall be accountable to the Trust Board and through its work focus on: (i) positioning LTHT in partnership with the University of Leeds and other academic organisations, as a global research and innovation powerhouse and as a catalyst for commercial opportunities that may emerge; or individually, compete for and win research grants or funds that underpin the Board's long-term clinical aspirations; ~~(ivii)~~ patient benefit from research participation and utilisation; ~~(viii)~~ linking research participation to quality and service improvement; and (iv) having oversight of commercial opportunities that arise from research and innovation programmes as well as related business engagement activities that seek to exploit Trust-owned resources.

## 2.2 Primary Duties and Responsibilities

2.2.1 Oversee the development and implementation of strategies to promote LTHT as a global hub for research and innovation and to establish conditions for increasing participation in research, promoting and supporting innovation and continuing development opportunities.

2.2.2 Oversee the establishment of partnerships with higher education institutes, industry, NHS organisations, and charities across the UK and internationally to increase participation in research, the clinical innovation pathway and continuing development opportunities.

2.2.22.2.3 Be alert and encourage the development of commercial opportunities that may arise from research and innovation activities and from the networks that develop with partners and other organisations through the course of that work. When necessary be prepared to draw upon external advice and expertise to explore and exploit commercial opportunities.

2.2.32.2.4 Keep under review the performance management for the delivery of the research and innovation strategy.

2.2.42.2.5 Provide assurance that opportunities to develop the research and clinical innovation portfolio are aligned with the Trust Board's strategy and that high quality bids are submitted.

2.2.52.2.6 Provide assurance that the research workforce is developed and replenished in sufficient numbers to meet LTHT's long-term strategic and clinical aspirations

2.2.62.2.7 Oversee the development and implementation of highly-effective controls for research and innovation governance.

2.2.72.2.8 Oversee the rapid resolution of any significant weaknesses found in the Trust's research, innovation, endeavors by reviewing decisions to halt research and innovation activity and apply whatever learning is necessary to: (i) ensure safe, high-quality and compliance research and innovation practices at all times; and (ii) the success fulfillment of research obligations to which the Trust is committed. Ensure material concerns are addressed to the satisfaction of all concerned and properly declared to the Trust Board of Directors.

2.2.82.2.9 Provide assurance to the Chair of Audit Committee confirming the effectiveness of the Committee and fulfillment of its objective, and to the effect that the Committee has disclosed to the Audit Chair all significant deficiencies and material weaknesses in the design or operation of internal controls which could adversely affect the Trust's ability to achieve research, innovation, education or training objectives.

2.2.92.2.10 To undertake or consider on behalf of the Trust Chair or the Trust Board such other related tasks or topics as the Trust Chair or the Board may from to time entrust to the Committee.

### 3. Duties and Behaviours

- 3.1 The duties of the Chairperson of the Committee shall be to:
- keep the Board informed regularly of any material matters which have come to the Committee's attention;
  - ensure that minutes of the Committee are an accurate reflection of discussion;
  - attend or designate another member of the Committee to attend public meetings of the Trust to answer any questions related to the work of the Committee;
  - submit an annual report on the work of the Committee to the Audit Committee;
  - and ensure that all significant risks are discussed and escalated in line with LTHT's Risk Management Policy.
- 3.2 The duties of members and attendees shall be to:
- attend and contribute
  - have read the papers and materials in advance and be ready to work with them
  - actively participate in discussions pertaining to Committee business ensuring that solutions and action plans have multidisciplinary perspectives and have considered the impact Trust-wide;
  - disseminate the learning and actions from the meetings; and
  - to attend at least 75% of meetings of the R&I Committee.

### 4. Constitution

- 4.1 The Committee shall meet as often as required but not less than four times each year.
- 4.2 The quorum for meetings shall be two Members, one of whom should be the Committee Chair, unless he or she is unable to attend due to exceptional circumstances. In the absence of both the Committee Chair and Vice Chair a decision will be taken in advance of the meeting as to which member of the committee shall Chair that particular meeting.

### 5. Membership and attendance

- 5.1 Members of the Committee shall be appointed at the discretion of the Chief Medical Officer. The Trust Chair and Non-Executive Directors shall have the right of attendance but not as members of the Committee. *In extremis*, any member of the Committee who is able to speak and be heard by each of the other members shall be deemed to be present in person and shall count towards the quorum. The core membership shall be:
- (i) Chief Medical Officer (Chair)
  - (ii) Chief Nurse (Vice Chair)
  - (iii) Director of Research & Innovation
  - (iv) Head of Nursing for Research & Innovation
  - (v) Director of Operations for Research & Innovation
  - (vi) University of Leeds representative(s)
  - (vii) Assistant Director of Finance (amended)
  - (viii) Directors of the NIHR funded programmes (these will be invited in rotation)
  - (ix) Operations Directors/Managers of the NIHR funded programmes
  - (x) Director of Strategy (amended)
  - (xi) Head of Commercial

- (xii) Representative clinicians with experience of research and the clinical innovation pathway.

In routine attendance:

- (i) Non-Executive Director
- (ii) Research & Innovation Manager (Serving Officer)
- (iii) Minutes Secretary

- 5.2 Where ever possible members must send deputies to represent them in their absence. The Chair may invite specific colleagues to address the Committee where appropriate.
- 5.3 The Committee is serviced by the Trust's Research & Innovation Manager who shall organise meetings, prepare the annual work plan and record proceedings. Papers shall be available at least five clear days before each meeting. Papers shall not be tabled unless it is essential and only with the Committee Chair's prior agreement.
- 5.4 Terms of reference are reviewed annually or in the light of changes in practice or national/local guidance. The Board will initiate the mechanism to review performance, which shall include the extent to which the Committee has operated in satisfaction of its terms of reference, and in particular compliance with reporting arrangements to the Board.

#### **Document Owner**

The Trust Board Secretary is the owner of this document and of any Board minute authorising any amendment.

## Appendix B: 2020/21 Workplan

Agenda Item	1	2	3	4
	May	Aug	Nov	Feb
	2020	2020	2020	2021
<b>Strategy Update</b>				
<ul style="list-style-type: none"> <li>Review of objectives/KPIs</li> </ul>	◆	◆	◆	◆
<b>Performance/Metrics</b>				
<ul style="list-style-type: none"> <li>Performance in Initiation and Delivery (PID)</li> <li>Recruitment to time and target (NIHR Clinical Research Network High Level Objective)</li> <li>Participant portfolio recruitment against target</li> <li>Number of portfolio studies recruiting participants</li> </ul>	◆	◆	◆	◆
<b>Workforce Integration Project</b>				
<ul style="list-style-type: none"> <li>Update on current programme</li> </ul>	◆	◆	◆	◆
<b>Supporting research in the NHS</b>				
<ul style="list-style-type: none"> <li>R&amp;I Operations</li> <li>NHS Researchers</li> </ul>	◆		◆	
<b>Supporting innovation in the NHS</b>				
<ul style="list-style-type: none"> <li>Clinical Innovation System update</li> </ul>	◆		◆	
<b>Presentations</b>				
<ul style="list-style-type: none"> <li>Research</li> </ul>			Leeds Children's Hospital (General overview, CRF Update, Patient Rep)	NIHR Research Grant recipient (Alabama or Sunflower study)
<ul style="list-style-type: none"> <li>Innovation</li> </ul>		Academic Health Science Network		

<b>Finance Report</b>	◆	◆	◆	◆
<b>Chair's Items</b>	◆	◆	◆	◆
<b>Items for Information</b>				
<ul style="list-style-type: none"> <li>• UoL/LTHT Joint Research Governance Committee</li> </ul>	◆	◆	◆	◆
<ul style="list-style-type: none"> <li>• NIHR Annual Reports &amp; Feedback</li> </ul>			◆	◆
<b>Board/Assurance Reports</b>				
<ul style="list-style-type: none"> <li>• Annual Report &amp; Work Plan</li> </ul>				◆
<ul style="list-style-type: none"> <li>• Audit Committee Assurance</li> </ul>				◆
<ul style="list-style-type: none"> <li>• Terms of Reference review</li> </ul>				◆
<ul style="list-style-type: none"> <li>• Committee objectives review</li> </ul>				◆

## Appendix C: Proposed 2021/22 Workplan

Agenda Item	1	2	3	4
	May	Aug	Nov	Feb
	2021	2021	2021	2022
<b>Strategy Update</b>				
<ul style="list-style-type: none"> <li>Review of objectives/KPIs</li> </ul>	◆	◆	◆	◆
<b>Performance/Metrics</b>				
<ul style="list-style-type: none"> <li>Performance in Initiation and Delivery (PID)</li> <li>Recruitment to time and target (NIHR Clinical Research Network High Level Objective)</li> <li>Participant portfolio recruitment against target</li> <li>Number of portfolio studies recruiting participants</li> </ul>	◆	◆	◆	◆
<b>Workforce Integration Project</b>				
<ul style="list-style-type: none"> <li>Update on programme</li> </ul>	◆			
<b>Supporting research delivery in the NHS</b>				
<ul style="list-style-type: none"> <li>R&amp;I Operations</li> <li>Real World Data update</li> </ul>	◆ ◆	◆ ◆	◆ ◆	◆ ◆
<b>Research infrastructure update</b>				
<ul style="list-style-type: none"> <li>Biomedical Research Centre update</li> <li>Clinical Research Facility update</li> <li>National Pathology Imaging co-operative update</li> </ul>	◆ ◆ ◆	◆ ◆ ◆	◆ ◆ ◆	◆ ◆ ◆
<b>Supporting innovation in the NHS</b>				
<ul style="list-style-type: none"> <li>Innovation update</li> <li></li> </ul>	◆	◆	◆	◆

<ul style="list-style-type: none"> <li>Innovation District update</li> <li>NIHR Surgical MIC update</li> <li>NIHR Leeds MIC update</li> </ul>	◆	◆	◆	◆
<b>Presentations</b>				
<ul style="list-style-type: none"> <li>Research</li> </ul>	NIHR Research Grant recipient (Alabama or Sunflower study)		Leeds Hospital Charity Research and Innovation Strategy	
<ul style="list-style-type: none"> <li>Innovation</li> </ul>		Use of AI in Breast Cancer imaging diagnostics  (Nisha Sharma)		Innovation Pop-up partner case study
<b>Finance Report</b>	◆	◆	◆	◆
<b>Risk Review</b>	◆	◆	◆	◆
<b>Chair's Items</b>	◆	◆	◆	◆
<b>Items for Information</b>				
<ul style="list-style-type: none"> <li>UoL/LTHT Joint Research Governance Group minutes</li> </ul>	◆	◆	◆	◆
<ul style="list-style-type: none"> <li>NIHR Annual Reports &amp; Feedback</li> </ul>			◆	◆
<b>Board/Assurance Reports</b>				
<ul style="list-style-type: none"> <li>Annual Report &amp; Work Plan</li> </ul>				◆
<ul style="list-style-type: none"> <li>Audit Committee Assurance</li> </ul>				◆
<ul style="list-style-type: none"> <li>Terms of Reference review</li> </ul>				◆
<ul style="list-style-type: none"> <li>Committee objectives review</li> </ul>				◆

## Appendix D: Research Report Summary

### **National Institute for Health Research (NIHR) awards.**

The Trust hosts a number of major NIHR infrastructure awards:

- Leeds Clinical Research Facility (CRF)
- Leeds Bioresource
- Leeds Musculoskeletal Biomedical Research Centre (BRC)
- Leeds Invitro Diagnostics Co-operative (Leeds MIC)
- Leeds Medical Technology Co-operative (Surgical MIC)

Progress and annual reports for these awards are reported to the R&I Committee and the following reports have been submitted for review and information:

- Annual and finance returns to the NIHR

### **NIHR Bioresource.**

It was noted that two additional themes for the NIHR Bioresource received funding and that Leeds had an opportunity to use the samples collected to support COVID 19 research.

The BioResource clinical team were re-deployed to the COVID 19 Research team to support the ISARIC, COVACTA, RECOVERY trials but they have also been recruiting to the COVID 19 BioResource Cohort.

### **NIHR Leeds Clinical Research Facility (LCRF)**

Following the retirement of Ms Debbie Beirne, LCRF Manager, there was a change in Senior Leadership with Dr Helen Radford commencing in April 2020 as her successor. During the first wave of the pandemic, the LCRF supported a small number of studies that were deemed lifesaving or life enhancing and were delivered through the Jubilee and Bexsley CRF Units. The Children's and Dental CRF Units remained closed during the first COVID 19 wave. Clinical Staff were deployed the COVID 19 Research Delivery Team

Since the start of the pandemic, the LCRF have collaborated closely with R&I and the BRC to support the operational set-up and delivery of identified prioritised Urgent Public Health England COVID 19 studies. Professor Christopher Twelves (LCRF Clinical Director) provided academic oversight for all COVID 19 studies.

Bexley CRF supported the Trust COVID 19 response by hosting several non-COVID departments that were displaced to provide extra clinical space. This included relocating the CRF team to the old CRF space on J86 to facilitate hosting the Surgical Assessment Unit in the new CRF unit estate.

Jubilee CRF supported the Trust response by hosting the Psychology Department, who were providing a staff drop in service. In addition the CRF hosted the COVID 19 Research Delivery Team at the LGI site and now support the delivery of ongoing participant follow up visits.

Children's CRF was closed at the start of the first COVID lockdown but supported the Children's CSU by hosting clinical services on the Unit several times a week.

DenTCRU was also closed at the start of the lockdown, but re-opened once all safety measures were addressed.

## **Pausing and Re-opening non-COVID-19 research across the Trust**

In March 2020 it was necessary to pause activities associated with a significant proportion of the 800+ research projects that were live in the Trust at that time. As the impact of the April wave of COVID cases subsided and the Trust started to re-open clinical services, so R&I put in place a process to support the re-opening of these projects in the organisation. This process needed central co-ordination because of the limited resource available initially for research in Pathology, Pharmacy and Radiology.

An important feature of this process was that it was the researchers themselves who determined which studies they wanted to re-open - and there has been strong engagement with research leads and Chief/Principal Investigators throughout this process. Research teams were asked to consider the feasibility of re-opening research against the principles of:

- Only research that is feasible i.e. safe, relevant and viable should restart.
- Research should only restart when safe to do so.
- Restart' pace should be commensurate with capacity and readiness in local research and CSU teams

The re-start was released in waves, with the first two allowing approximately 50% of previously open studies to restart; the third wave has taken this figure to approximately 75%, with some areas now having up to 90% of their original portfolio re-opened. However, the ability to recruit patients into studies is being limited by the ongoing pandemic due to issues such decreased patient throughput and the use of telephone clinics. Some planned or previously open studies have also been closed or cancelled by sponsors.

As the COVID situation developed moving into Autumn/Winter the decision was taken to leave studies that have already been restarted open and to allow local teams to assess whether they can be delivered safely and balance portfolio delivery against available resource. It should be noted it will take time to rebuild research activity to pre-pandemic levels.

## **COVID-19 Research**

Since March 2020 the R&I Department have sought to develop and enable a wide portfolio of Urgent Public Health (UPH) badged COVID-19 research within LTHT to help with the global fight against the pandemic and also to enable patients with COVID-19 at LTHT to receive potentially beneficial therapeutics. A specific COVID 19 research delivery team was established, based at both the LGI and SJUH. However more recently the COVID 19 research delivery team have been based in J34 at SJUH only. Through collaborative working the team has increased and decreased in size to adapt to the needs through the use of secondments and drafting in of staff from other areas where capacity exists.

## **COVID 19 Vaccine Studies**

An effective vaccine against the coronavirus is a key strategy to end the devastating health and social costs caused by the pandemic. The UK government has set up the Vaccines Delivery Task Force to run at least 10 - 12 COVID-19 vaccine trials at pace and scale, supported by the NIHR Clinical Research Network.

Together with partners across the city (Leeds Community Health NHS Trust, Leeds CCG, Leeds and York Partnership NHS Foundation Trust) as well as the Harrogate and District NHS Foundation Trust R&D function, Leeds Teaching Hospitals NHS Trust R&I set up a

multidisciplinary team involving the research functions in these partners to plan for large scale vaccine trial delivery.

Work included launching a major campaign to persuade people in Leeds to sign up to the vaccine trial registry which was done via articles in local press and coverage on BBC Look North, BBC local radio stations and ITV regional news. The impact of this was that Leeds had the highest number of potential participants signed up to national registry across the UK (>6,000; 2% of the national total), with the impact of the campaign also spilling over neighbouring areas.

The Patient and Public Involvement and Engagement (PPIE) work has also been of note and particularly focused on engaging with BAME groups and other under-represented populations in research. One of the outputs from this work was the development of a set of 'frequently asked questions' (FAQs) about vaccine research. These have been pulled together following eight 'question and answer' sessions, which involved a total of 82 people representative of different communities, as well as discussions with voluntary sector organisations who support people who are often under-represented in research.

LTHT was selected to participate in the Novavax vaccine trial on the 23<sup>rd</sup> September 2020 and commenced recruitment in Leeds on 13<sup>th</sup> October with 600 participants recruited by 30<sup>th</sup> October. The trial took place in the EDGE sports hall at the University of Leeds which had sufficient space to deliver at pace and scale, and so that we are not bringing healthy volunteers onto hospital estate. Over 800 participants took part and LTHT had the highest number of patients attending/screened in the UK. The Novavax study data has been released and is considered 89.3% effective and is currently being reviewed for use by the Medicines and Healthcare Products Regulatory Agency (MHRA).

### **Performance update**

Official recruitment targets as set out by the Clinical Research Network were put on hold due to COVID 19, however we have continued to monitor our own recruitment performance. At the end of January our participant recruitment into research at the Trust was significantly lower than 2019/20 which is due almost to all non-COVID research being paused in the organisation at the start of the year. Research delivery has gradually increased across the organisation with strong recruitment to COVID vaccine trial and other COVID research studies.

### **R&I Strategy 2020-2025**

The new R&I Strategy 2020-25 was launched in June 2020, with a vision by 2025 that every patient cared for by LTHT and every member of staff to have the opportunity to participate in research in some way, making research an "always event" for the organisation. The vision is underpinned by the following ambitions:

#### 1. To be the best NHS Trust to deliver high quality clinical research

To ensure that all patients can participate in research we need to ensure that our research delivery teams receive the right training, are fair, empowered, accountable, collaborative and patient centred. We will ensure that every member of LTHT staff has access to high quality research training through the Research Academy and that support and career development pathways are available for all professions and at every career stage.

#### 2. To be the best NHS Trust to champion research (staff/patients/public)

Research cannot be delivered in isolation; it requires buy-in from our staff, our patients and members of the public. We will ensure that research activities within LTHT are visible to all staff and patients and through a proactive communications and PPIE strategy reach

out to members of the public across Leeds, West Yorkshire and the UK to engage them in research programmes being carried out at LTHT

### 3. To maintain and grow world-class clinical infrastructure and assets for research and innovation

High quality research and innovation requires high quality infrastructure, both physical and digital. Working in collaboration with other teams in the Trust, our academic partners, industrial partners, charity partners and NIHR we will further develop the world class infrastructure required within the organisation so that programmes can be delivered at pace and scale.

#### **Joint University of Leeds (UoL/LTHT research strategy**

Following the news that the AHSC bid was unsuccessful, a decision through the Joint Partnership Board to develop a joint UoL/LTHT research strategy 2020-2030. The strategy was developed over a 3 month period with wide consultation and has a strong positive alignment with some of the wider strategic ambitions for the Trust. There are also further opportunities included to support the Innovation District and the strengths in working together for economic growth.

#### **Research Workforce - Delivery Integration Programme**

R&I continues to make good progress with the integration programme that brings all research delivery teams and associated budgets together within R&I. The following CSU research teams have now completed the integration:

- Chapel Allerton
- Oncology (except Haematology)
- Cardiorespiratory
- Leeds Children's Hospital
- Women's
- Trauma and Related Services
- Neurosciences
- Emergency and Specialty Medicine

R&I has worked with CSU Triumvirates to manage this change process and have received positive feedback about how this will be beneficial for both research staff (by allowing them to be part of a dedicated, specialist function managed by peers) and for closer working between R&I and the CSU's.

#### **Research Academy**

The Research Academy supported the delivery of COVID-19 Clinical Research, including induction, learning bursts, clinical skills were successfully developed, delivered, and evaluated. This included a rolling Clinical Skills program to up skill the Clinical Research Nurses, these were facilitated by the clinical education team and covered venepuncture, cannulation and intravenous pump training. There were 100 attendees overall over a ten-week period.

Overall, the COVID-19 research education programme was very well received. Evaluative data showed that 90% liked the organisation of the training and felt that it was successful. 85% said that the information gained will be useful in their new role. The team have supported over twenty-three clinical trials and LTHT have also highlighted as being one of the best recruiting sites in Europe and top 10 globally for COVID-19 studies. The Research Academy also shared its experience of COVID-19 research regionally through delivering training for the volunteer staff for the Yorkshire and Humber Nightingale Hospital and NIHR Local Clinical Research Network, providing training for the cohort of nursing staff from across the region identified to support delivery of research at the Nightingale site.

Since the beginning of June 2020, the Academy curriculum and content has been updated and adapted to allow the content to be delivered on a virtual platform. System and processes have also been updated to facilitate online booking and administrative tasks (such as administering certificates electronically). These changes allow the continuation of local training for LTHT and University of Leeds staff, while facilitating the on-going NIHR project work. 10 courses on a variety of subjects such as the OneForm and EDGE new user training, informed consent, ACTT-2 Protocol (COVID-19 trial), Adverse Events reporting, and Clinical Research Protocols have been run virtually.

The Lead Nurse for Research & Innovation (Education) has also been selected and received additional training from the National Institute for Health Research (NIHR) National Co-ordinating centre in delivering training on virtual platforms such as MS Teams and Zoom. This has allowed the delivery of the NIHR programmes such as informed consent to continue to be available virtually on a local, regional, and national level.

## Appendix E: Innovation Report Summary

### Clinical Innovation System (CIS)

Work has continued to develop “Innovation” activity within LTHT as part of the CIS programme. The aim of the programme is to be an enabler through which staff within the organisation can be supported with Innovation programmes and whereby partner organisations can easily connect with expertise in the organisation by:

- (a) Identifying and understanding unmet needs within LTHT / services
- (b) Identifying opportunities for training to help create and support a culture of Innovation, to support ideation, entrepreneurship and adoption
- (c) Develop collaborative solutions to identified needs where no solutions exist
- (d) Access data (through the R-DIT team) for AI training and other data-related projects
- (e) Carry out product evaluations (using the research infrastructure)
- (f) Support adoption and generate real-world data on clinical impact from use of products in clinical services

Activities have focused on 5 main areas:

#### 1. Supporting the Hospitals of the Future programme

The Hospitals of the Future programme has clearly defined thematic areas for application of innovative technologies including:

- Wayfinding
- Self-Management
- Tracking
- Wearables

Using national and international networks LTHT is reaching out to identify technologies that are both ready now “off the shelf” for these purposes, but which may also need further development or adaptation to meet the needs. As an example, we are working with the UK/Israel Tech Hub within the British Embassy in Israel, The Foundation for Biomedical Research and Innovation at Kobe (Japan) and also the Biotechnology & Pharmaceutical Industries Promotion Office in Taiwan, looking cross-sectorally as well as using these opportunities to assess whether businesses could be attracted into the Leeds region based on the potential for working closely with the Hospitals of the Future programme. Further international relationships are also being established working in close alignment with the Department of International trade.

#### 2. Radiology Innovation programme

Working closely with the Radiology triumvirate to build a strategic innovation programme around the use of Artificial Intelligence in clinical services, building on work being led by Nisha Sharma and Andy Scarsbrook - and wider interests in others within the CSU. Based on initial discussions around high-level needs, we have worked with the AHSN and Knowledge Transfer Network (KTN) to identify potential solutions that could support the Radiology CSU. The programme of work with Radiology has a clear route forwards and strong buy-in from the CSU leadership team and a working group established to lead this activity within the CSU.

This is an exemplar of how we would like to work with other CSU’s across the organisation as we build the CIS team and programme of work further.

### 3. Development of “pop-up” Innovation Hub and associated services

Funding to support the development of the pop-up Innovation hub within the Gilbert Scott Building and the team that would support delivery of services has been included in the Leeds City Region ask to the government. Following a series of consultation meetings with Trust staff members and the University of Leeds, from which there was significant enthusiasm for this initiative, a working group to support the development of the services that would be offered through the Pop-up Innovation Hub has been put together.

The Leeds Regional Entrepreneurship Acceleration Program (REAP) is involved with the aim to ensure the programme is positioned distinctly (as well as non-competitively) within the regional innovation offering, and that any interventions that form part of the Leeds REAP offering can be utilised as part of the services offered by the hub / Clinical Innovation System.

### 4. Business Engagement and Opportunity Development

Despite the pandemic work continues to build a pipeline of innovation project opportunities. Key relationships include:

- a. Serenus AI: Throughout 2019 2020 LTHT R+I have been building up a project plan with Professor Hemant Pandit (NIHR Senior Investigator for Orthopaedic Surgery) working with Serenus AI. This project is focussing on triage of hip and knee replacement placements and whether they are suitable for surgery or not. This project is also aligned with the NIHR Surgical MIC.
- b. Scaled Insights: LTHT has an Memorandum of Understanding with Scaled Insights (signed July 2018) to identify opportunities where their Behavioural Science AI can be used in health application. On the back of this, multiple projects are now being initiated with Scaled Insights, including projects looking at adherence to medicines for CVD patients, potential for monitoring patient behaviour changes in those with neurological conditions (both diagnosed and undiagnosed) and for staff surveys within LTHT as requested by NHS England.
- c. Betalin: Development of a novel cell-seeded biomaterial for treatment of Type 1 diabetes. This programme of work links to each of the Surgical MIC, Clinical Research Facility (for evaluation) and Northern Alliance Advanced Therapies Treatment Centre (ATTC) programmes. Work has supported Betalin to understand what they need to do to bring this product to market in the UK (particularly the regulatory requirements) and develop the partnerships needed for them to do this in terms of manufacturing and preclinical trials support. Of note, Betalin have now set up an office and laboratory in NEXUS due to the support provided.
- d. 3D Lifeprints: 3D life prints have been engaged with LTHT R&I since the beginning of 2019 (including a small contract of work with Paediatric Cardiology). Further developments involve working with Orthopaedic Surgeons including Hemant Pandit, Jonathan Lockwood and Jiten Parmar at the Leeds Dental Institute and Asim Sheikh, Consultant Neurosurgeon at the LGI. Should the planned work with these teams proceed it is very likely that 3D Lifeprints will set up a facility in Leeds within the next 12 months.
- e. Kheiron Medical Technology: We have been working with Kheiron to support the development of their AI tool for breast cancer diagnosis via an InnovateUK Biomedical Catalyst award. This has been a successful project and further work is planned to evaluate their product in a real-life clinical environment and also to broaden the

relationship to include digital pathology.

f. CAILTEC (Centre for Augmented Intelligence & Immersive technology in Emergency Care). Led by Taj Hassan and supported by the ESM CSU, we have been supporting the early stage development of this programme of work and supporting the development of programme activities and governance. A project manager has now been appointed to support this programme for the next 12 months; this individual will work as part of the CIS team and lead on the development of this initiative and collaborative projects that will form part of its delivery plan.

## 5. Governance and embedding

A common criticism of the NHS is that Innovation is not systematic, hard wired into organisations and is often invisible. Therefore an Innovation Operations Committee has been established with initial membership drawn from the Corporate Operations, Informatics, Kaysan Promotion Office, Quality Improvement, Procurement and Strategy functions. The purpose of this group will be to oversee the activities coming through the innovation system, help prioritise programmes of work, ensure individual programmes of work are connected to the wider Trust strategy and ensure connectivity into supporting corporate functions early on in individual project initiation so that hurdles relating to e.g. informatics integration or procurement can be dealt with early on.

### Real World Data

The use of real world data (data collected from routine clinical care) is increasing as a tool for research, particularly for data science projects and supporting the development of Artificial Intelligence tools. Strong governance has been put in place around real world data use over the last 2 years with every data request being reviewed by an access committee, and a Research Data Oversight Group (RDOG) established to oversee wider activities related to the secondary use of routinely collected clinical data as defined by GDPR.

Since the inception of the data access request process in April 2019, 140 requests to utilise real-world data in research projects have been received and reviewed by the Data Access Committee. These have ranged from straightforward requests which are easy to execute to more complex requests requiring many thousands of radiology or digital pathology images. Extracting and de-identifying these images from Trust systems has required a significant amount of work and innovation, but plans are now in place for how the developed processes can be done at scale, giving Leeds a unique capability in terms of creating large deidentified, linked datasets derived from routine clinical care. Work is also underway to create an interactive data directory to help researchers create richer requests and funding is being sought to allow conversion of the Trust's metadata to the internationally-recognised OMOP (Observational Medical Outcomes Partnership) model which will allow LTHT data fields to be assessed in a common way alongside data sources from other organisations, with benefits for Leeds partners participating in future major data science programmes.

A significant number of requests for data to be released for COVID-19 data projects under the COPI (Control of Patient Information) notice have been received, and the data access process has allowed the Trust to have an audit trail of all such requests. Many of these data projects have been poorly conceived with requests made for identifiable fields - and in some instances feedback from the data access group has helped reshape those projects. The R-DIT (data access) team that fulfil requests has also been very active in supporting 2 major data programmes that require large, complex linked datasets (NIHR Health Informatics Collaborative (NIHR-HIC)) and HDR-UK DeCOVID). Their work has strengthened Leeds profile in both those

national programmes, and the involvement in the NIHR HIC is particularly important with regards to the next NIHR Biomedical Research Centre (BRC) application.

## Appendix F: Finance Report Summary

### The financial impact of COVID

Additional costs which have been incurred due to COVID 19 for research have been reclaimed in line with the current Department of Health (DoH) guidance; to period 6 this is £741k. The finance arrangements changed in period 7 and COVID related expenditure has to be contained within the block funding which organisations have been given for the remainder of the year. In terms of non-NHS income generating activities there is a national expectation that these activities can recover and if this proves not to be the case, organisations will be expected to demonstrate that they have taken all reasonable steps to try and prevent this from occurring.

The close monitoring of the financial impact of COVID on research trials will continue.

### Non COVID related activities

The following is a summary of key activities completed this financial year:

- The NIHR annual statement of expenditure (ASTOX) submissions have been completed.
- The budgets for the CSUs completing the R&I integration were moved to the R&I CSU.
- Further actions have continued to ensure financial governance is in place for the Digital Pathology projects, including a business case submitted to the Trust Board for review and discussion.
- Producing proposals for the financial governance and reporting arrangements for all of the NIHR Infrastructure platforms to ensure consistency and appropriate reporting.
- Providing the finance support to the urgent COVID trials.
- Inputting into a national consultation exercise around COVID research funding.
- Improving the systems and processes for R&I finance review for new studies in line with the Leeds Improvement Method principles.

- Continue to work on improving how research studies should be handles in terms of normal business case processes to ensure appropriate levels of governance are taken into account. i.e. the management of capital expenditure for new research studies.
- Continue the work to scope and model the impact of potential income loss due to COVID and ensure that demonstrable efforts to recover non-NHS activity and income have been taken, one example is to show that all reasonable steps have been taken to address any nervousness of patients to participate in research activities due to COVID concerns.
- Continue to work with Chief Investigators where funding extensions might need to be secured or where spend might not be possible in line agreed budget profiles due to COVID.