CRN East Midlands Quarterly Board Update

Author: Prof. David Rowbotham Sponsor: Mr Andrew Furlong

Trust Board paper G

Purpose of report:

This paper is for:	Description	Select (X)
Decision	To formally receive a report and approve its recommendations OR a particular course of action	X
Discussion	To discuss, in depth, a report noting its implications without formally approving a recommendation or action	
Assurance	To assure the Board that systems and processes are in place, or to advise a gap along with treatment plan	
Noting	For noting without the need for discussion	

Previous consideration:

Meeting	Date	Please clarify the purpose of the paper to that meeting using the categories above
CMG Board (specify which CMG)		
Executive Board		
Trust Board Committee		
Trust Board		

It has been agreed that it is no longer a requirement for this paper to be presented to the Executive Performance Board (EPB) unless there are any specific issues that require EPB consideration. This report was reviewed by CRN East Midlands Executive Group on 23 September 2020.

Executive Summary

Context

University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute of Health Research (NIHR) Clinical Research Network East Midlands (CRN). UHL is contracted by the Department of Health and Social Care to take overall responsibility for the monitoring of governance and performance of the Network.

For the information of the Board, we have prepared this quarterly update on the recent progress and current priorities of CRN East Midlands. Appended to the report is a letter from the NIHR CRN Coordinating Centre with feedback on our year-end (2019/20) performance review meeting. Also appended is our annually updated Governance Framework, which requires Trust Board approval.

Questions

1. Since our July report, what have been the key areas of progress for CRN East Midlands and do the Board require any further information or assurance in relation to this?

2. Does the annual update to our Governance Framework provide satisfactory assurance to the Board?

Conclusion

1. This report provides an update on the progress of CRN East Midlands in supporting COVID-19 Urgent Public Health (UPH) research and an update on developing our regional readiness in contributing to a UK wide effort to deliver the forthcoming pipeline of COVID-19 vaccine research studies. The report also provides information on the restarting of paused NIHR Portfolio research, the new CRN Performance Managements Standards for this current year and feedback from the NIHR CRN Coordinating Centre following our year-end (2019/20) review meeting in July.

2. CRN East Midlands Governance Framework (Appendix 2) describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system and escalation process for the management of the LCRN. In this annual update, there are no fundamental changes to the framework, however, it has been updated with some minor governance and administrative changes. The sections where changes have been made are highlighted yellow for information.

Input Sought

We would welcome the Trust Board's input regarding the following:

(i) Review our report providing any comments or feedback you might have.
(ii) Review and approve CRN East Midlands Governance Framework v 7.0 – annual update (Appendix 2).

For Reference

This report relates to the following UHL quality and supporting priorities:

1. Quality priorities

Safe, surgery and procedures	Not applicable
Safely and timely discharge	Not applicable
Improved Cancer pathways	Not applicable
Streamlined emergency care	Not applicable
Better care pathways	Not applicable
Ward accreditation	Not applicable

2. Supporting priorities:

People strategy implementation	Not applicable
Estate investment and reconfiguration	Not applicable
e-Hospital	Not applicable
More embedded research	Yes
Better corporate services	Not applicable
Quality strategy development	Not applicable

3. Equality Impact Assessment and Patient and Public Involvement considerations:

- What was the outcome of your Equality Impact Assessment (EIA)? N/A - This report does not relate to a business case/business decision making process.

- Briefly describe the Patient and Public Involvement (PPI) activities undertaken in relation to this report, or confirm that none were required - N/A

- How did the outcome of the EIA influence your Patient and Public Involvement ? - N/A as this report provides an update on the CRN and does not relate to a UHL business case/decision making.

- If an EIA was not carried out, what was the rationale for this decision?

4. Risk and Assurance

Risk Reference:

Does this paper reference a risk event?	**Select (X)**	**Risk Description:**
Strategic: Does this link to a ***Principal Risk*** on the BAF?	N/A	
Organisational: Does this link to an ***Operational/Corporate Risk*** on Datix Register	N/A	
New Risk identified in paper: What ***type*** and ***description***?		
None		

5. Scheduled date for the **next paper** on this topic: January 2021

6. Executive Summaries should not exceed **5 sides** My paper does comply

NIHR | Clinical Research Network East Midlands

CRN East Midlands - Board Update 21 Sept 2020

For the information of the Board, this report provides an update on recent progress and the current priorities of CRN East Midlands.

1. **Urgent Public Health (COVID-19) research**

   As of 11th September, we have supported the delivery of 22 Urgent Public Health (UPH) research studies, which have in total, recruited almost 12,450 participants in the East Midlands; across the UK, around 160,000 participants have been recruited into these UPH studies. This has been achieved through a collaborative regional response and although we have been asked not to formally publish comparison figures with other regions or trusts, have performed very strongly as a region. Our rate of recruitment into interventional COVID-19 studies is 205.5 per 1,000 admissions, which is above the national average for England of 173.4. Due to the decline in COVID-19 hospital admissions over recent months, there has been a shift from recruiting research participants in the acute phase of the disease to broader research addressing some of the longer term effects of COVID-19 across health and social care. In the East Midlands there are a further eight UPH badged studies currently in set-up across a range of settings.

2. **COVID-19 vaccine research studies**

   Since our last report, we have made significant progress in developing our regional readiness to deliver the forthcoming pipeline of COVID-19 vaccine research studies. Over the next six months we anticipate to be delivering 6-8 studies, which are supported by the national Vaccine Task Force (VTF), with the first study expected to open to recruitment in late September. We have received an additional £0.5M (from the VTF) as enabling infrastructure, as these trials commence will be on a full cost recovery, commercial basis.

   We intend to run these studies across the East Midlands, with planning and set up activities being coordinated through our regional vaccine research delivery group. We are establishing a 5 county model with collaboration across a range of healthcare systems. In Nottinghamshire the Cripps Practice has been delivering the COV002 (Oxford) study for some months very successfully, and will continue as an important regional site. In Leicestershire, our approach is to use the NIHR Patient Recruitment Centre (PRC) based at UHL, blending acute, primary care and community infrastructure. In Northamptonshire a large primary care site will be involved in leading and delivering COVID-19 vaccine studies in collaboration with acute partners, and in Lincolnshire and Derbyshire the models have a community-wide focus.

We are working very closely with many partners across the health economy, with lots of learning from these large scale COVID-19 vaccine studies likely to be useful as a wider expanded flu program and later COVID-19 vaccination program are rolled out.

3. **Restart of NIHR research**

The NIHR published the Restart Framework in late May, to support sites in restarting the many studies which were paused during the pandemic. As of 9 September, 45% of studies (2,676) are open to recruitment, with a further 17% in the set-up / follow-up stage of activity and proceeding as planned. Of the 2,676 studies that are open, 36% have recruited since 1 June - 24% of commercial studies and 42% of non-commercial studies.

In the region, we have continued to support trusts and other partners with the restart of paused non-COVID-19 research, although we are mindful it is an organisation level decision. The main challenges around restarting research have been around staff resources, reduction in participant numbers and services not running or at capacity. Other common challenges included clinical backlog, protocol amendments, R&D delays and sponsor delays.

A further challenge with restarting paused studies is the balance between delivering UPH studies, including the emerging large scale vaccines research, re-starting paused research where viable and considering an increase in coronavirus cases we are beginning to see across the country. This is a challenge we all see across the country, and in the East Midlands are maintaining close relationships with partners to understand local pressures, and best advise on how resources are best targeted.

4. **CRN Performance Managements Standards**

Confirmation has recently been received that the CRN High Level Objectives (HLOs) will not be applied to LCRNs this year, as many are not appropriate or reflective of our priorities at this time. Core priorities for this year have thus been incorporated into a set of slimmed down Performance Management Standards for 2020/21. A final paper is soon to be published to describe this, however we have been advised these will include UPH study set-up (local), UPH study recruitment (nationally) and study delivery efficiency (locally/nationally). Once this has been shared we will further work up our regional position and advise of a likely year-end position, although presently based on our understanding of these measures, we have no specific concerns.

5. **NIHR CRN Coordinating Centre Feedback - CRN East Midlands year-end performance review meeting**

Our Year-End Review Meeting with the NIHR CRN Coordinating Centre took place on 7 July 2020 and feedback was received on 20 August. Overall, the CRNCC was content with

our performance and progress. This letter also provided confirmation of the CRNCC's approval of our Annual Report for 2019/20.

Feedback from the CRNCC recognised excellent support from the Host and an established stable senior leadership team, underpinned by a supporting divisional team.

Further details can be found in the letter at Appendix 1.

6. **LCRN Governance Framework**

CRN East Midlands Governance Framework (Appendix 2) describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system and escalation process for the management of the LCRN. This framework is updated on an annual basis in order to reflect any changes in governance, assurance and escalation processes. In this annual update, there are no fundamental changes to the framework, however, it has been updated with some minor governance and administrative changes. The sections where changes have been made are highlighted yellow for information. This document has been reviewed by CRN East Midlands Executive Group and is provided to this Trust Board for formal approval.

If you have any questions or require any further information, please contact:

- Elizabeth Moss, Chief Operating Officer, elizabeth.moss@nihr.ac.uk or
- Professor David Rowbotham, Clinical Director, david.rowbotham@nihr.ac.uk or
- Carl Sheppard, Host Project Manager, carl.sheppard@nihr.ac.uk

Appendix 1

NIHR | National Institute for Health Research

CLINICAL RESEARCH NETWORK
COORDINATING CENTRE
21 Queen Street
Leeds
LS1 2TW

Tel: 0113 343 2314
Fax: 0113 343 0336
Email: crn@nihr.ac.uk
www.nihr.ac.uk

Professor David Rowbotham
NIHR CRN East Midlands
Knighton Street Outpatients
1st Floor
Leicester Royal Infirmary
LE1 5WW

20 August 2020

Dear David

NIHR CRN East Midlands Year-End Performance Review Meeting, 7 July 2020

Thank you to you and your team for attending the Year-End Performance Review Meeting between CRN East Midlands ('the LCRN') and the CRN Coordinating Centre ('CRNCC') chaired by William van't Hoff, Chief Executive Officer, and attended by the following colleagues:

LCRN attendees: David Rowbotham (DR) - Clinical Director, Steve Ryder (SR) - Co-Clinical Director, Elizabeth Moss (BM) - Chief Operating Officer, Andrew Furlong (AF) - Medical Director, University Hospitals of Leicester NHS Trust (Host Nominated Executive Director), Richard Mitchell (RM) - Chief Executive Officer, Sherwood Forest Hospitals NHS Foundation Trust (Partnership Group Chair)

CRNCC attendees: William van't Hoff (WvH) - Chief Executive Officer, Nick Lemoine (NL) - Medical Director, John Sitzia (JS) - National Chief Operating Officer, Imogen Shillito (IS) - National Director of Stakeholder Engagement and Communications (Executive Team Link), Joanna Knee (JK) - Research Delivery Director (Interim), Sine Littlewood (SL) - Business Development and Marketing Director (Interim), Stephen Lock (SLo) - CRN Chief Information and Technology Officer (Interim) (Senior Management Team Link), Anthea Mould (AM) - Workforce, Learning and Organisational Development Director (Interim), Lynn Clayton (LCl) - LCRN Support Coordinator (Secretariat), Jackie Wilson (JW) - LCRN Planning and Reporting Manager (Secretariat)

Thank you to you and your team for providing the documents and presentation to support discussions at the meeting.

Please also accept this letter as confirmation of the CRNCC's approval of your Annual Report for 2019/20. Additional feedback on the 2019/20 year-end finance return will be provided separately.

Actions and matters arising from last Performance Review Meeting
All actions from the previous annual review meeting were noted as complete, BM confirmed that the actions were closed and there was nothing further to raise.

Distinguishing features of the LCRN
Excellent support from the Host and an established stable senior leadership team, underpinned by a supporting divisional team.

The group discussed the large geographic area of the network, which covers a diverse population with notable socio-economic differences. This includes Leicester's Black, Asian and Minority Ethnic (BAME) community, the rural landscape of Lincolnshire with relatively high populations of Eastern Europeans in some areas, and the contrasting affluent county of Rutland. The bordering town of Corby in Northamptonshire is associated with notably low life expectancy. BM suggested it would be helpful to recognise some further nuances under the term BAME and agreed to share a breakdown of the network's geographical area and communities (**See Action EM39**).

The group discussed implementation of succession planning, AF confirmed that SR had been brought into post as Deputy Clinical Director, working in partnership with DR, with Kathryn Fairbrother (KF) as Deputy Chief Operating Officer providing cohesive support to BM. AF confirmed appropriate training is being provided.

Delivery in 2019/20
The LCRN Balanced Scorecard (Meeting Paper 3) was introduced as a new, continually improving, resource. The Balanced Scorecard enables a visual comparison across LCRNs within a single year, and year on year comparisons within a single year across all domains of LCRN performance.

Satisfaction
BM advised the group that the LCRN's 2020 Partner Satisfaction Survey results were shared with the network on 4 March and circulated immediately ahead of the Partnership Group meeting on 6 March. However, it was considered that there had not been enough time to review the results and so they would be discussed in due course.

DR was disappointed with the 43% Overall Customer Satisfaction Score and had opened discussions with selected Partners. DR and BM confirmed they had a targeted action plan in place to improve this metric over the next 12 months.

BM queried the timings for the release of the surveys citing that the Customer Satisfaction Survey had been opened to Chief Investigators around the time of embedding of the Schedule of Events Cost Attribution Template (SoECAT), which may have negatively impacted the responses. JK suggested that as the Research Delivery Directorate (RDD) are starting to think about the next survey, JK and BM could have a separate conversation regarding timings and audience(s) (**See Action EM40**).

BM noted a significant improvement in the response to the Patient Research Experience Survey (PRES). IS was pleased to see a notable improvement in Communications and Engagement.

Targeting Health
WvH expected Targeting Health would be a key focus for the future. BM asked if issues such as BAME population needs, liver and alcohol related disease, or rurality may be introduced as categories as these are important issues for the network. WvH felt it was important to consider how these might also be factored-in although they may be more difficult measures to capture.

HLOs
BM was pleased with HLO 1A performance in 2019/20, exceeding the target.
The group was pleased to hear that non-commercial recruitment to time and target (HLO 2B) exceeded the target for the fourth consecutive year. This was supported by weekly delivery meetings with COO, RDMs, IOM and Workforce leads enabling regular review, discussion and problem solving issues with studies.
The group acknowledged achievement of exceeding the national CRN ambition of 45% General Medical Practices participating in CRN Portfolio research (HLO 6C).

Financial Performance
DR was pleased to confirm previous delays in the Host's payment of invoices have been overcome. The Host Organisation Board Chairman has taken an interest and supported an improved process. Whilst monitoring of progress is ongoing, the last seven or eight months have frequently seen a 100% payment rate.

JS was content with the network's financial management despite a small underspend of £9,864 for the 2019/20 financial year, arising from funds allocated towards events that were subsequently cancelled late in the 2019/20 financial year due to COVID-19.

Challenges
BM felt the challenges to the network lay in attracting commercial research and large sample size studies, HLO 1B and HLO 2A. BM acknowledged recruitment into commercial studies is an area for improvement.

Supra-network activities
BM shared the numerous Supra-network activities, which include: alignment of continuous improvement projects across the Supra-network, such as an 'Awesome Table' visible to all staff, which collates improvement projects and impact stories; and close working relations with CRN West Midlands on Primary Care, including Super Practices, Primary Care Network (PCN) models and RESTART. Joint working in Workforce development has resulted in plans for a future joint Clinical Research Practitioners (CRP) event and webinar training across the Supra-network.

COVID-19
BM advised the network had provided a collaborative regional response to COVID-19, which had allowed R&D collaborative working across Trusts and exceptional recruitment into Urgent Public Health (UPH) studies (recruitment per 1000 admissions of 237.8 locally, compared to 178.3 nationally).

DR was pleased to share the continued collaborative working with Northampton General Hospital NHS Trust's R&D department and timely set up of UPH studies, e.g. the Trust completed study set-up and recruited to the RECOVERY trial within ten days, and has since recruited over 240 patients into the study.

RM noted that the COVID-19 national emergency had a unifying impact on CRN East Midlands, and the challenge would be sustaining the response in the absence of a single focus, alongside the challenge and workload of RESTART and the vaccines work. The network is positive about the opportunities.

Vaccines
The group acknowledged BM's shared role as Business Lead on the Vaccine Research Delivery Group.

BM shared the additional challenges brought on by simultaneously working on UPH, RESTART and Vaccines studies. DR noted that the workforce are experiencing fatigue and a second peak in COVID-19 has to be factored into delivery.

Restarting paused research and plans for delivery in 2020/21 (RESTART)
BM felt that COVID-19 and the work to deliver UPH studies has brought their workforce out of silo working and was keen to carry the ethos over into RESTART. DR hoped that the joint ways of working could be translated into all research and not just COVID-19. BM hopes to have the opportunity to consider lessons learnt in order to apply these to RESTART and the vaccines work.

Networking beyond organisational and regional boundaries
WvH emphasised the importance of the 15 LCRNs retaining a strong regional focus, supporting research that addresses the biggest needs in their localities, whilst working as part of a national network. The national network has enabled a global leading response to COVID-19.

Additional Items
WvH thanked the network for fantastic partnership working and demonstrating the delivery of research at the highest standard. Additional thanks to RM and AF for assisting and supporting the network to function so effectively.

BM shared the 2019/20 Digital Workstream Timeline, which is supporting four workstreams, including two Digital Showcases. This work underpins the network's delivery, and aligns strongly with the NIHR's current digital work.

The Executive team also thanked the network for leading the collaboration with the Centre for Black and Minority Ethnic (BME) Health in Leicester.

Risks
The Risk and Issues Log was discussed and BM explained that as HLOs were not the primary focus for the time being, these were not included, hence the Risks and Issues Log was not particularly full. COVID-19 risks were ongoing but the HR risk was much reduced and would likely be closed during Quarter 2 of 2019/20. NL commented that completion of the risk page was exemplary and the risks recorded are appropriate, and requested issues be added to the log (see Action EM41).

As noted at the meeting, we shall follow up in due course with all LCRNs to highlight any reflections or matters arising from this series of meetings.

I would like to thank you formally for the continuing leadership you provide for the LCRN and I look forward to our next meeting with you and your team.

Yours sincerely

Dr. William van't Hoff
Chief Executive Officer
NIHR Clinical Research Network (CRN)

Cc: Andrew Furlong, Medical Director, University Hospitals of Leicester NHS Trust and Host Nominated Executive Director, CRN East Midlands
Steve Ryder, Co-Clinical Director, CRN East Midlands
Elizabeth Moss, Chief Operating Officer, CRN East Midlands
Richard Mitchell, Chief Executive Officer, Sherwood Forest Hospitals NHS Foundation Trust and Partnership Group Chair
John Sitzia, National Chief Operating Officer
Nick Lemoine, Medical Director
Imogen Shillito, Stakeholder Engagement and Communications Director and Executive Team Link
Joanna Knee, Research Delivery Director (Interim)
Sine Littlewood, Business Development and Marketing Director (Interim)
Stephen Lock, CRN Chief Information and Technology Officer (Interim) and Senior Management Team Link
Anthea Mould, CRN Director of Workforce, Learning and Organisational Development (Interim)
CRNCC Senior Management Team
Andrew Walker, Head of Performance Management

Actions

Item	Action	Owner
EM39	BM to share a breakdown of the network's geographical area and communities	Beth Moss
EM40	JK agreed to discuss with BM the timing of the release of the Customer Satisfaction Survey	Joanna Knee / Beth Moss
EM41	BM to add issues to the network's Risk and Issues Log	Beth Moss

Appendix 2

NIHR | Clinical Research Network East Midlands

NIHR Clinical Research Network East Midlands

GOVERNANCE FRAMEWORK

Host Organisation:

University Hospitals of Leicester NHS Trust

Change Control

Version	Date	Changes made
1.0	01.04.14	Original document – approved by UHL Executive Strategic Board
1.1	08.04.14	More detail on roles of the Clinical Research Divisional Leads and additions to section 7.1.
1.2	22.09.14	Changes to risk management process (section 10)
2.0	13.03.15	Annual review (2015/16) with the addition of Financial Management section (8)
2.1	02.07.15	Update to Executive Director, removal of Business Delivery Manager post
3.0	29.01.16	Annual Review (2016/17) – added reference to Study Support Service (section 5), Clinical Leadership Group included within Operational Management Group (section 5), listed Working Groups (section 6), updated Executive Group details (section 6), updated reporting assurance to quarterly Board Report (section 7), updated staff responsible for operational management of Service Support budget (section 8), updated table for LCRN financial cost codes and delegated authorisation allowances (section 8), updated resolution to audit findings (section 9).
4.0	07.03.17	Annual review (2017/18) – removed historic reference to transition of Network (section 1), updated Executive Leadership Team (section 4), updated LCRN Leadership Team (section 5), Lead RM&G Manager post removed (section 5), clarified Divisional Clinical Research Leads (section 5), defined details of Clinical Leads Group (section 6), updated Governance Structure (section 6), updated details of Working Groups (section 6), added Senior Leadership Team Meeting which fulfils requirements of OMG (section 6), updated frequency of Executive Group to every 3 months (section 6), removed reference to RM&G and included SSS (section 6), updated Finance Support Structure (section 8), updated financial cost codes and delegated authorisation allowances (section 8), updated details to confirm audit due this year (section 9).
5.0	22.06.18	Annual review (2018/19) – added new Co-Clinical Director post (section 4), new Deputy COO post (section 5), added reference to Financial Operating Procedure (section 8) updated responsibility for operational management of the SSC budget (section 8), reported 2017/18 audit findings (section 9) , updated risk scoring matrix in line with national template (section 11).
6.0	06.09.19	Annual review (2019/20) – added reference to new Portfolio eligibility criteria (section 1), added new Clinical Leads Recruitment SOP (section 5), updated Working Groups, new Chair of Partnership Group and updated number of Operations Managers (section 6), added new Financial SOPs (section 8), added reference to LCRN Contract Compliance Assurance Framework (section 9), and Issue Resolution Procedure (section 12), updated branding.

7.0	22.09.20	Annual review (2020/21) - updated introduction (section 1.1 and 1.2), updated Trust's Acting Chief Executive Officer (section 4.1), updated description of Industry Delivery Manager role (section 5.1), updated list of Working/Steering groups (section 6.1), clarified title of Communications and Engagement Lead (section 6.3), updated reporting format (section 6.5), updated funding description (section 8.2), updated LCRN Host Finance Lead role description, (section 8.8), updated costing and financial management arrangements (section 8.11 and 8.12), updated CRNEM Finance Support Structure (section 8.13), updated financial cost codes table (section 8.15), added reference to issue log (section 9.9), updated Trust's Acting Chief Executive Officer (section 12.2).

NIHR CLINICAL RESEARCH NETWORK EAST MIDLANDS

Governance Framework

CONTENTS

1. INTRODUCTION

1.1 The National Institute for Health Research Clinical Research Network (NIHR CRN) supports patients, the public and health and care organisations across England to participate in high-quality research, advancing knowledge and improving care. The CRN is comprised of 15 Local Clinical Research Networks (LCRNs) and 30 Specialties who coordinate and support the delivery of high-quality research both by geography and therapy area. National leadership and coordination is provided through the CRN Coordinating Centre. In January 2018 the NIHR CRN Portfolio eligibility criteria were expanded to include research taking place outside traditional NHS settings. This change in policy was introduced to better reflect the environment and services that people access and live in today. This means that the CRN also supports the delivery of funded health and care research taking place in settings such as care homes, hospices, schools, prisons, or other social care and public health environments.

1.2 The formal name of the LCRN in the East Midlands is NIHR CRN East Midlands (the LCRN). University Hospitals of Leicester NHS Trust (the Trust) hosts the Network on behalf of the NIHR and partner organisations in the East Midlands (Derbyshire, Nottinghamshire, Lincolnshire, Leicestershire, Rutland and Northamptonshire).

1.3 The Trust is committed to providing safe high quality care and has developed a range of policies, systems and processes which together comprise robust and integrated Financial Management, Assurance and Escalation, and Risk Management Frameworks. The principles of which have informed this document to ensure high-level, informed accountability of the Trust Board for the good governance of the LCRN.

1.4 The LCRN was launched on 1 April 2014. This document describes the processes and controls established by the LCRN to ensure good governance. This document provides governance assurances for delivery of the Department of Health and Social Care (DHSC) issued Contract and NIHR CRN Performance and Operating Framework.

2. PURPOSE

2.1 This framework describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system and escalation process for the management of the LCRN.

2.2 This framework will be reviewed by the LCRN Executive Group and the Trust Board on an annual basis in order to reflect any changes in governance, assurance and escalation processes.

3. GENERAL PRINCIPLES

3.1. The Trust Board is accountable for the good governance of the LCRN. The Board should apply, in a proportionate and appropriate way, the principles of good governance and thereby promote:

- Robust, transparent and accountable LCRN governance;
- Effective and supportive LCRN hosting arrangements;
- Effective and proportionate contracts with Partners and other organisations in receipt of LCRN funding or resources;
- Responsible financial management including budgetary control and the production of financial reports;
- A structure that ensures effective local performance management;
- Partner participation and engagement, research delivery and value for money.

3.2. The Trust, along with the LCRN leadership, are responsible for developing governing structures, systems, terms of reference and local working practices for working for the LCRN. The specific governance requirements required are detailed in this framework and in respect of:

- The Accountable Officer;
- The nominated Executive Director;
- Scheme of delegation and Host Board controls and assurances;
- Financial management;
- Assurance framework and risk management system;
- Escalation process;
- LCRN Leadership and Management Groups.

3.3. NHS patients and the public are the key stakeholders in NIHR CRN research, and are to be included in LCRN governance arrangements. Patient or public representatives have been included in the agreed membership of the LCRN Partnership Group.

3.4. LCRN governance arrangements are required to be formally signed off by the Trust Board and by the national CRN Coordinating Centre.

4. EXECUTIVE LEADERSHIP TEAM

4.1 The **LCRN Accountable Officer** is the Trust's Acting Chief Executive Officer, Rebecca Brown.

4.2 The Nominated **Executive Director** for the LCRN is the Trust's Medical Director, Mr Andrew Furlong.

4.3 The Trust has appointed Professor David Rowbotham as the **LCRN Clinical Director**. The Clinical Director has local overall responsibility for the LCRN reporting to the Nominated Executive Director and the national CRN Coordinating Centre. The Trust has appointed Professor Stephen Ryder as the **LCRN Co-Clinical Director**. The LCRN Clinical Director and Co-Clinical Director will lead in the engagement of the regional clinical and research community, promoting research and building clinical research capacity.

4.4 The Trust has appointed Elizabeth Moss as the **LCRN Chief Operating Officer** who is responsible for the operational delivery of the contract and overall operational management of the network. The Chief Operating Officer reports to the LCRN Clinical Director and the national CRN Coordinating Centre. The Board understands that it is a contractual obligation to ensure that the Chief Operating Officer is a Trust employee.

4.5 The governance responsibilities of the LCRN Executive Leadership Team are to:

- Deliver the core activities of the LCRN, in line with the agreed governance requirements within the Host Contract and Performance and Operating Framework;
- Ensure any activities are carried out as may be necessary for the proper governance of the LCRN;
- Ensure that a proper and auditable process is developed and executed for the fair and effective distribution of LCRN funding;
- Be available for regular meetings as a core Leadership Team;
- Support scrutiny and transparency, for example by providing any information as required for the internal auditors, and attending the audit committee of the Trust as requested;
- Ensure the timely delivery of performance and other reports;
- Support the Trust by adhering to any local governance requirements, such as the local standing financial instructions and all relevant national NHS requirements;
- Convene regular Partnership Group meetings;
- Make freely available to the Trust and all Partner organisations, as requested,

any information that is not commercial and/or in confidence and in line with national NHS policies;

- Manage the LCRN so as not to compromise either the Host Organisation or Partner organisations through reasons of conflicting issues such as competition law or data protection.

5. LCRN LEADERSHIP TEAM

5.1 The Trust has appointed a LCRN Leadership team consisting of:

- **LCRN Clinical Director** (supported by the **Co-Clinical Director**) has local overall responsibility for the LCRN reporting to the Nominated Executive Director and the national CRN Coordinating Centre;

- **LCRN Chief Operating Officer** who is responsible for the operational delivery of the contract and overall operational management of the network;

- **LCRN Deputy Chief Operating Officer** who is responsible for deputising for the Chief Operating Officer and for monitoring budget expenditure and LCRN overall performance;

- **LCRN Divisional Research Delivery Managers** who provide day-to-day operational management of research activity in each of the six operational divisions;

- **Industry Delivery Manager** who is responsible for supporting and enabling the effective delivery of commercial research within the LCRN.

5.2 The governance responsibilities of the LCRN Leadership team are to:

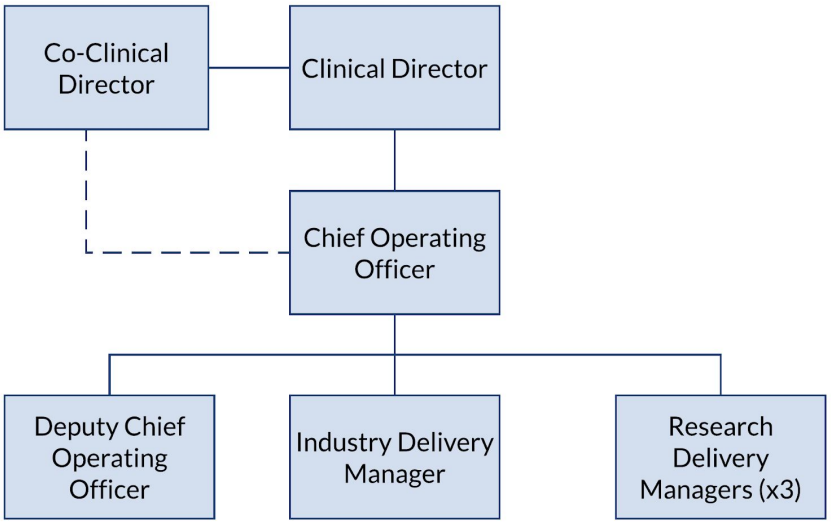
- Deliver the management and operational (i.e. non-clinical) activities of the LCRNs, in line with any agreed governance requirements;

- Support the LCRN Executive Leadership team to ensure that activities are carried out as may be necessary for the proper governance of the LCRN;

- Ensure delivery of NIHR CRN Portfolio studies, including life sciences industry research, are delivered in accordance with any agreed governance requirements.

5.3 Figure 1, illustrating the LCRN leadership structure, is included below:

Figure 1 - CRN East Midlands Leadership Structure



LCRN Divisional Clinical Research Leads

5.4 The LCRN has appointed six **LCRN Clinical Research Leads**, one for each research delivery division. These clinicians represent the clinical activity interests of all specialties within their research delivery division, liaising closely with the Clinical Research Specialty Leads. They work closely with their Divisional Research Delivery Managers (see below).

5.5 The governance responsibilities of the LCRN Divisional Clinical Research Leads are:

- Address resource allocations and the balance of the LCRN portfolio across specialties, sites, trusts, care settings, patient groups and study composition;
- Provide clinical intelligence and advice to support research delivery within the division, including a view of the clinical implications of national policy locally;
- Support Clinical Research Specialty Leads with the identification and development of research communities within the LCRN area, across all NHS partners.

LCRN Clinical Research Specialties

5.6 The NIHR CRN has adopted a framework of 30 Clinical Research Specialties for the purposes of engagement with clinical research communities and to enable clinical leadership and oversight of the NIHR CRN research portfolio.

5.7 The 30 Clinical Research Specialties are grouped into 6 Divisions for operational management purposes:

- Division 1: Cancer
- Division 2: Cardiovascular disease; Diabetes; Metabolic and endocrine disorders; Renal disorders; Stroke;

- Division 3: Children; Genetics; Haematology; Reproductive health & childbirth;
- Division 4: Dementias and neurodegeneration; Mental health; Neurological disorders;
- Division 5: Ageing; Dermatology; Health services and delivery research; Oral and dental health; Musculoskeletal disorders; Primary care; Public health;
- Division 6: Anaesthesia, perioperative medicine and pain management; Critical care; Ear, nose and throat; Gastroenterology; Hepatology; Infectious diseases and microbiology; Injuries and emergencies; Ophthalmology; Respiratory disorders; Surgery.

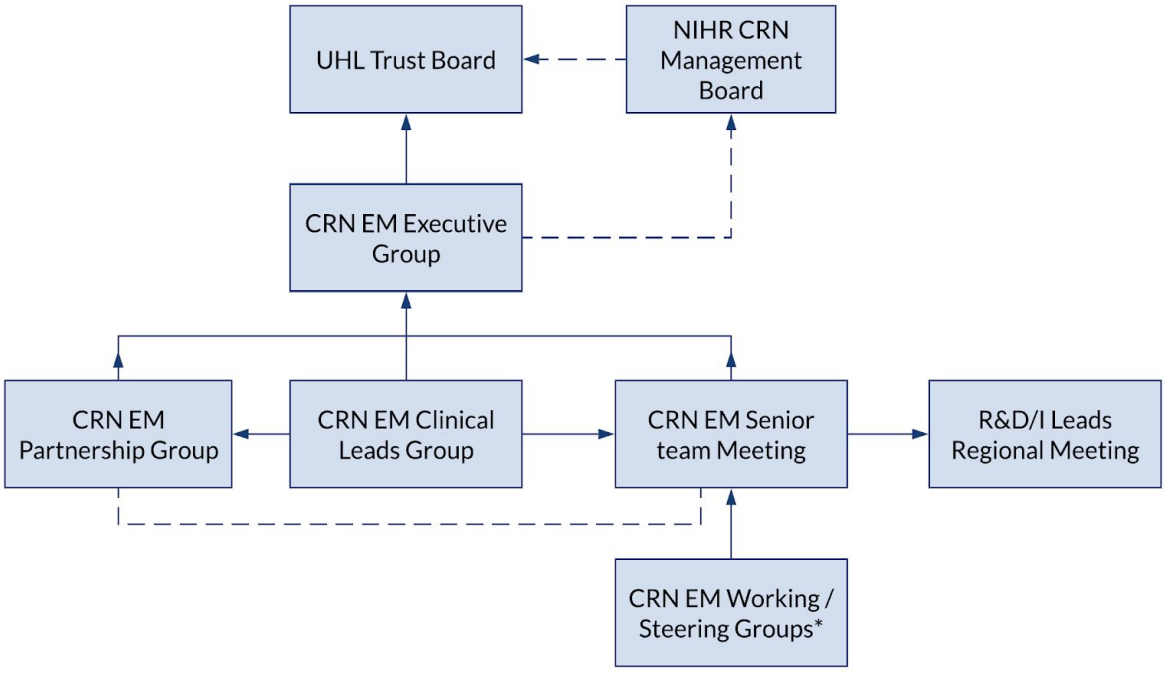
5.8 The LCRN has appointed local Clinical Research Specialty Leads for all 30 specialties. The LCRN Clinical Research Specialty Leads report to the LCRN Divisional Clinical Research Lead responsible for that Specialty. Local Clinical Research Specialty Leads will be responsible for the clinical leadership of their research communities within the LCRN area, development of local Clinical Research Specialty Groups and clinical oversight of the performance of the Specialty portfolio of studies.

5.9 The LCRN has produced a Standard Operating Procedure for the recruitment of Clinical Research Divisional Leads, Specialty Leads and Sub-specialty Leads.

6. LCRN GOVERNANCE STRUCTURE

6.1 A diagram of the LCRN governance structure is included as Figure 2.

Figure 2 – CRN East Midlands Governance Structure



* Dementia Challenge Steering Group, EnRICH Advisory Group, Engagement Working Group & Finance Working Group (ad hoc groups to be convened as needed, e.g. Public Health/pandemic related)

6.2 The Trust has established the **LCRN Partnership Group**. The Group is a formal forum of LCRN partners and key stakeholders. Its role is to provide active oversight and constructive mutual challenge on LCRN plans, activities, performance and reports in order to support the LCRN to achieve its objectives and raise the ambitions for clinical research of the LCRN Partners. The Trust has appointed an independent Chair (Richard Mitchell, Chief Executive, Sherwood Forest Hospitals NHS Foundation Trust) and the group will be attended by the Trusts' Nominated Executive Director, LCRN Clinical Director and LCRN Chief Operating Officer. The Group meets three times per year.

6.3 The Trust has established a **LCRN Executive Group** chaired by the Nominated Executive Director reporting to the Trust Board. Membership includes LCRN Clinical Director, LCRN Chief Operating Officer, LCRN Deputy Chief Operating Officer, LCRN Project Manager, LCRN Host Financial Lead, and LCRN Communications and Engagement Lead. Its purpose is to oversee and deliver good governance of the LCRN as defined by the Host contract and LCRN Operating Framework. The Group will meet every 3 months.

6.4 The Trust has established a **Senior Team Meeting** chaired by the Chief Operating Officer and reporting to the LCRN Executive Group. This group fulfils the expectations of the **LCRN Operational Management Group**. Membership includes Clinical Director, Chief Operating Officer, Deputy Chief Operating Officer, Research Delivery Managers (3), Industry Delivery Manager, with the next management tier of Operations Managers (5), Workforce Development Lead and Senior Nurse to inform business need. Its purpose is to maintain oversight of overall management of the LCRN and be the forum to address cross-divisional and cross-cutting needs for support and intervention. The Group will liaise with the Clinical Leads Group. The Senior Team will meet formally every 4-6 weeks. In addition, the LCRN Leadership Team will convene a weekly teleconference to discuss ongoing operational matters.

6.5 A verbal report will be provided at the Regional R&D/I Leads meeting every 8 weeks to provide updates on LCRN business. The Clinical Director or Chief Operating Officer plus a member of the LCRN Senior Team will attend the meeting to discuss LCRN business as required.

6.6 The Trust has appointed a Clinical Leads Group, described as the Clinical Cabinet, consisting of the Clinical Director, Co-Clinical Director, Chief Operating Officer, Deputy COO and LCRN Divisional Leads. The Clinical Leadership Group will work closely with the Senior Leadership Team; its role includes providing: (i) advice on clinical implications of national policy at the local level; (ii) intelligence to determine resource allocations and (iii) clinical intelligence and advice to support LCRN research delivery.

7. HOST BOARD CONTROLS AND ASSURANCES

7.1 The Trust Board will agree to review and/or sign off the following LCRN activities:

- Receipt of the LCRN Annual and Finance Plans, from the Executive Director, for approval;

- Receipt of an LCRN Annual Report, from the Executive Director, for approval;
- Submission of the Annual Plan, Finance Plan and Annual Report to the national CRN Coordinating Centre for approval;
- Provision of the approved Annual Plan and Annual Report to all the members of the LCRN Partnership Group;
- Report to Trust Board quarterly on the work of the LCRN alongside the quarterly report on UHL R&D;
- Inclusion of LCRN key performance indicators in the quarterly Trust Board Report.

7.2 The Trust, as Host Organisation, has an obligation to ensure the proper management of the LCRN in terms of compliance with the governance framework and processes of the Host, including human resources, standing financial, audit and standards of business conduct instructions. The Trust shall ensure that internal policies and standing financial instructions, as they affect the LCRN, do not unreasonably diminish the efficient management of the LCRN.

7.3 The Trust, as Host Organisation, shall ensure that the LCRN is run in accordance with relevant laws and regulatory requirements, relevant national NHS policies and requirements, and the NHS Constitution.

8. FINANCIAL MANAGEMENT

8.1 The Trust, as Host Organisation, receives, manages and distributes the allocated funding with the LCRN via the Department of Health and Social Care (DHSC) approved standard template sub-contracts, or other forms of agreement with DHSC approved text.

8.2 The Trust, as Host Organisation, has an obligation to use the funding solely for development and delivery of LCRN activities as set out in the contract between DHSC and the Trust. Along with any other purposes, as described in executed contract variations (e.g. Excess Treatment Cost distribution). Measures will be developed to provide assurance that LCRN funding provided to partner organisations is used solely for these purposes.

8.3 The Trust, as Host Organisation, through the LCRN Executive Group, will draw up an annual financial plan for the LCRN, as part of the LCRN Annual Plan. This plan will be reviewed by the LCRN Partnership Group prior to submission. The plan will be approved by the Trust Board and then submitted for approval to the national CRN Coordinating Centre.

8.4 The Trust, as Host Organisation, reports to the National CRN Coordinating Centre on financial expenditure including forecast outturn for the financial year, via the NIHR CRN Finance Tool, on a quarterly basis.

8.5 The Trust, as Host Organisation, is required to submit an end-of-year financial return

to the National CRN Coordinating Centre in respect of LCRN funding received. The financial return reports on all LCRN funding and expenditure, for all organisations in receipt of that funding and agrees the year-end figures for respective Partner Organisations.

8.6 The Trust, as Host Organisation, has produced a Financial Operating Procedure, which provides guidance to budget holders on the best practice for budget setting and monitoring. This helps to ensure that the Clinical Research Network East Midlands (CRN EM) financial matters are managed to the highest professional standards and in accordance with NHS accounting standards.

8.7 In order to meet the NIHR LCRN Minimum Financial Controls, the Trust, as Host Organisation, has produced a Standard Operating Procedure for the Monitoring of Partner organisations to ensure that LCRN funding provided to Partners is used solely to deliver NIHR portfolio research activities as per the LCRN Partner Organisation contracts. It has also produced a Standard Operating Procedure and Guidance for CRN Portfolio Commercial Contract Research Income to provide guidance in relation to income generated from NIHR CRN portfolio commercial contract research.

Financial Scheme of Delegation

8.8 The Trust, as Host Organisation, has appointed Martin Maynes as **LCRN Host Finance Lead** who is responsible for providing financial support and specialist technical accounting knowledge to the LCRN leadership team. Martin produces LCRN financial reports for review by the LCRN Executive Group, Host Board and LCRN Partnership Group.

8.9 Elizabeth Moss, **LCRN Chief Operating Officer**, is responsible for overall LCRN budget oversight and strategic decision making.

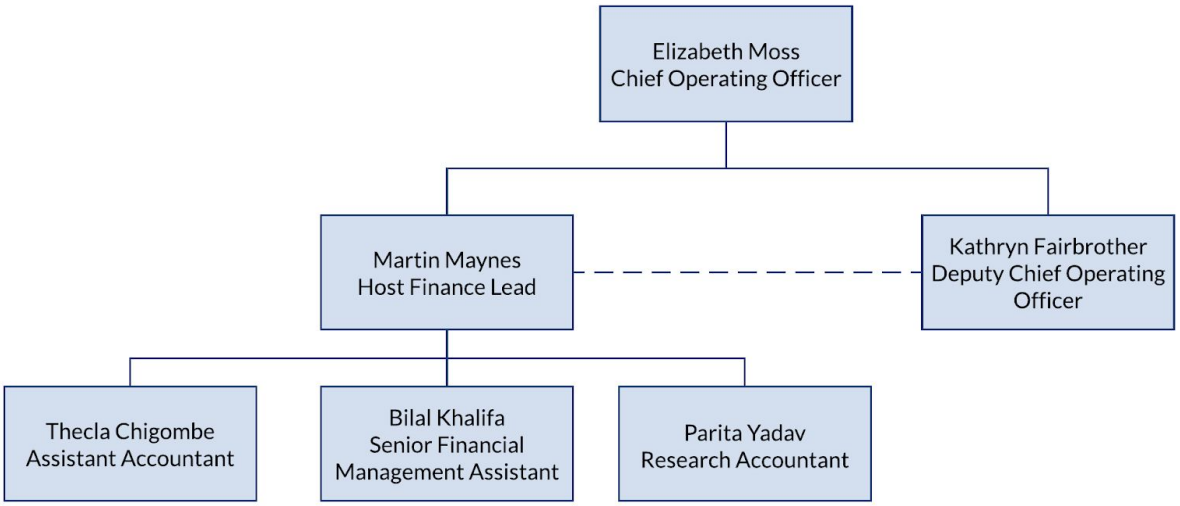
8.10 The Trust, as Host Organisation, has appointed Kathryn Fairbrother as **LCRN Deputy Chief Operating Officer** who is responsible and accountable for operational management for the infrastructure and central budgets

8.11 Kiran Mistry, Chris Siewierksi, Marie Thompson, Bryony Berridge (**Study Support Service Managers**) are responsible for the cost attribution for all non-commercial NIHR portfolio studies led in the East Midlands via the Schedule of Events Cost Attribution Template (SoECAT) - these are authorised on behalf of the Network by Divisional Managers, Compliance and Assurance Manager, Deputy COO/COO. Unmet Service Support Costs provided to Primary Care and non-NHS organisations are managed by the Study Support Service team. Kathryn Fairbrother (**Deputy Chief Operating Officer**) is responsible for the operational management of the Service Support Costs budget.

8.12 The Trust has appointed a qualified and experienced finance team to monitor the budget on a day to day basis. The finance team work closely with research finance staff within partner organisations. All members of the finance team are line managed by the LCRN Host Finance Lead, with day to day operational management by the Deputy Chief Operating Officer.

8.13 Figure 3, which presents the structure of the finance team, is set out below.

Figure 3 – CRN East Midlands Finance Support Structure



8.14 The table below provides the LCRN financial cost codes and delegated authorisation allowances.

Table 1

		Authorisers					
		LCRN Chief Operating Officer	LCRN Deputy Chief Operating Officer	Workforce Development Lead	RST Team Leader	Senior Nurse (NUH)	Business Delivery Operations Manager
Cost Code	Description	Up to £600,000	Up to £100,000	Up to £5,000	Up to £5,000	Up to £5,000	Up to £5,000
O11	CRN EM Vaccine Delivery Fund	Y	Y	N	N	N	Y
S18	CRN EM RSI	Y	Y	N	N	N	N
S19	CRN EM Clinical and Specialty Leads	Y	Y	N	N	N	N
S89	CRN EM Primary Care Service Support Costs	Y	Y	N	N	N	N
S90	CRN EM General Infrastructure	Y	Y	N	N	N	N
S97	CRN EM UHL Infrastructure	Y	Y	N	N	N	N
S98	CRN EM Non pay Non staff	Y	Y	N	N	N	N
U08	CRN EM RST	Y	Y	Y	Y	N	N
U14	CRN EM SSS	Y	Y	N	N	N	N
U89	CRN EM Management Team	Y	Y	N	N	N	N
U96	CRN EM Host Services	Y	Y	N	N	N	N
U97	CRN EM Network Wider Team	Y	Y	N	N	N	N
COR014	Central Network Funding (NUH)	Y	Y	N	N	Y	N

9 ASSURANCE FRAMEWORK

9.1 The LCRN is committed to supporting safe high quality research and has developed a range of policies, systems and processes to clarify how issues or concerns which may detrimentally impact upon the LCRN are escalated throughout the organisation.

9.2 This section describes the structure and systems through which the LCRN Leadership and Management Groups, and the Trust board receive assurance.

9.3 The assurance framework describes how the LCRN is able to identify, monitor, escalate and manage issues in a timely fashion and at an appropriate level.

Issue Management and Control

9.4 An issue is defined as a relevant event that has happened, was not planned, and requires management action.

9.5 The LCRN has an open and learning culture encouraging monitoring and comments and concerns to be communicated relating to issues that impact on LCRN delivery. The table below provides examples of both internal and external sources of identified issues.

Table 2

Internal Sources	External Sources
Staff and management	Patients, carers and the public
Staff surveys	External audit
Risk register	CRN Coordinating Centre
Executive Group	Partner feedback and complaints
Partnership Group	Partner and public surveys
Senior Team Meeting	

9.6 It is important that the LCRN has the capability to respond to issues or concerns in a timely fashion. In practice the response required varies considerably according to the nature of the issue or concern. In some cases, immediate action may be required. In other cases, and particularly with more complex or longstanding issues, the commissioning of a full report may be an appropriate response. However the response must always be:

- timely
- proportionate
- comprehensive
- inclusive
- effective.

9.7 The LCRN will follow a five step procedure for issue management and control (table 3). This procedure will be followed by the LCRN Senior Management who comprises the Operational Management Group.

Table 3

Procedure	Description	Delegation
1. Capture	Determine severity/ priority	
2. Examine	Assess impact on LCRN strategic and operational objectives	Request for advice (Executive or Partnership Groups)
3. Propose	Identify options Evaluate options Create recommended options	
4. Decide	Escalate (if beyond delegated authority) Approve, reject or defer recommended option	Request for advice (Executive or Partnership Groups)
5. Implement	Take corrective action or Continue to monitor	

Internal and External Sources of Assurance

9.8 Internal and external sources of assessment/assurance cover the range of the LCRN's activities and include:

Table 4

Internal Sources of Assurance	External Sources of Assurance
Performance review meetings	Patients, carers and the public
Performance reports – Summary, Partner, Division/Specialty, CCG	UHL Audit Programme
Internal audit (review of internal systems and processes)	CRN Coordinating Centre
Executive Group	Partner feedback and engagement
Partnership Group	Partner and public survey results
Senior Team Meeting	
Staff surveys and exit interviews	
UHL Board feedback	
Executive Performance Board reporting	
LCRN Performance Dashboard	

9.9 The LCRN has implemented an issues register to record and manage key issues currently impacting on LCRN business. Each issue is assigned an owner and scores based on the severity and priority of the issue to the LCRN. The issues are reviewed regularly in parallel with the risk register, primarily via the Executive Group.

9.10 The LCRN has produced an Issue Resolution Procedure so that stakeholders have a

route to raise any matters of concern which may arise in relation to CRN East Midlands business.

LCRN Host Organisation Annual Review

9.11 The Trust may be requested, on an annual basis, to review its role in discharging the Department of Health and Social Care contract for hosting the LCRN and provide a report on this within the LCRN Annual Report. This report must be shared with the LCRN Partnership Group.

LCRN Auditing Arrangements

9.12 The Trust is obliged to ensure that LCRN activity is included in the local internal audit programme of work. The LCRN should be audited at least once every three years. The LCRN Clinical Director has instigated these arrangements with the Trust's Interim Director of Finance and PwC UK.

9.13 The LCRN was audited in December 2017 and was provided a low risk rating. There were four findings (3 minor, 1 medium) and the LCRN have implemented an action plan to ensure all findings will be resolved. The next audit will be due in 2020/21.

LCRN Contract Compliance Assurance Framework

9.14 From 2018/19, the NIHR CRNCC will monitor compliance of LCRN Host Organisations in respect of the Performance and Operating Framework (POF) via the LCRN Contract Compliance Assurance Framework (CCAF). The LCRN is required to submit documents evidencing assurance against a sample of indicators from the POF over a three year schedule. The evidence will be reviewed by the CRNCC annually and feedback will be provided with follow up actions to address any areas of non-compliance. It should be noted that the LCRN Contract Compliance Assurance Framework is additional to, and does not replace, LCRN Annual Plans, LCRN Annual Reports, nor any activities covered by the NIHR CRN Performance Management Framework or routinely requested by CRNCC Directorates.

10 BUSINESS CONTINUITY ARRANGEMENTS

10.1 The Trust has a responsibility to ensure that robust local business continuity arrangements are in place for the LCRN, to ensure continuity of service in the event of an emergency.

10.2 The LCRN has developed a Business Continuity plan. This is to enable the LCRN to respond to a disruptive incident, including a public health outbreak e.g. pandemic or other related event, maintain the delivery of critical activities/services and return to "business as usual". Business continuity arrangements have been developed in line with the guidance set out by the national CRN Coordinating Centre.

10.3 The LCRN has developed an Urgent Public Health Research plan to enable the Trust and the LCRN to support the rapid delivery of urgent public health research, which may be in a pandemic or related situation. The Urgent Public Health Research plan will be immediately activated in the event that the Department of Health and Social

Care requests expedited urgent public health research.

11 RISK MANAGEMENT PROCESS

11.1 The Trust operates within a clear risk management framework which sets out how risk is identified, assimilated into the risk register, reported, monitored and escalated through the Trust's governance structures. The framework is set out in the Risk Management Policy and is supported by relevant policies, including the Risk Assessment Policy and Policy for reporting and management of incidents including the investigation of Serious Untoward incidents.

11.2 The LCRN has implemented a risk management framework, which includes a risk register. The risk register is updated regularly and reviewed every 3 months by the LCRN Executive Group.

11.3 Both strategic and operational risks are captured within the LCRN risk register. Each risk is assigned a risk owner and a score based on the likelihood of occurrence and the impact to the LCRN. Risk scores take into consideration any mitigating actions and are reviewed regularly. The risk matrix is shown below:

	IMPACT				
PROBABILITY	**Insignificant (1)**	**Minor (2)**	**Moderate (3)**	**Major (4)**	**Catastrophic (5)**
Highly Likely (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Highly Unlikely (1)	1	2	3	4	5

1-5 GREEN = LOW*	***Only risks with an Inherent Risk of 6 or above are recorded on this Risk Register**
6-11 YELLOW = MEDIUM	
12-19 AMBER = HIGH	**Risks with a scoring of 12 and above should be monitored and escalated**
20-25 RED = EXTREME	

12 ESCALATION PROCESS

12.1 This process describes the escalation route of issues or concerns or risks which could threaten the delivery of the Trust's obligations with regard to the delivery of the Department of Health contract and Performance and Operating Framework.

12.2 There are identified points of contact within LCRN management, the Host Organisation, and the national CRN Coordinating Centre for concerns and issues to be escalated. Agreed escalation routes and levels are:

1. LCRN Clinical Director – Professor David Rowbotham or LCRN Co-Clinical Director – Professor Stephen Ryder

2. Nominated Executive Director – Mr Andrew Furlong

3. The Trust Acting Chief Executive Officer – Rebecca Brown

4. National CRN Coordinating Centre

12.3 The level of the organisation at which an issue should be addressed also varies considerably. The principle of subsidiarity is generally followed i.e. the lowest level consistent with providing an effective response. If one level finds that it cannot provide an effective response, it has a duty to escalate to the next level. However, escalation should not be used simply to pass on a problem.

13 MONITORING OF ACTION PLANS

13.1 The Trust has developed a common action plan template. Action plans developed by the LCRN that are to be monitored by the LCRN Executive Group are in accordance with this model.

13.2 The LCRN Executive Group will continue to monitor any new action plans created in 2020/21 that develop from the Annual Plan or are required as routine or extraordinary plans throughout the year.

14 REVIEW

14.1 The Governance Framework will be reviewed on an annual basis by the LCRN Executive Group and by the Host Organisation Trust Board.

David Rowbotham
Clinical Director, CRN East Midlands