CRN East Midlands Quarterly Board Report

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	X
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	X	Assurance
Trust Board Committee		
Trust Board		

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. The purpose of this regular update paper is to summarise our performance, major achievements, challenges and actions. This report has been taken to the CRN East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive Lead for the CRN) in September 2019. It has been considered by UHL Executive Quality & Performance Board, and is submitted for review by UHL Trust Board on 3 October 2019. Appended to this written report is a dashboard displaying performance figures, Executive Group finance report, recent feedback letters from the NIHR CRN Coordinating Centre, updated Governance Framework (requires Trust Board approval) and current risk register. This report also provides an update on some of our patient engagement work in response to a request at the Trust Board meeting on 4 July 2019.

Questions

1. In order to provide assurance to the Host, what are the major achievements and challenges of the Network, and performance from 1 April 2019 up to 6 September 2019?

2. What are the current risks affecting the LCRN and are the Board assured of measures in place to address these?

Conclusion

1. This report presents a mixed picture of our performance across the High Level Objectives to date. Some areas are performing well, however, we have concerns for a number of HLOs, particularly those relating to our commercial metrics. Within our risk register, we have set out a number of actions to improve performance and will monitor progress closely. These include: reconfiguring some the team to re-focus efforts to attain these commercial targets; closer working with NUH and UHL, especially around oncology commercial research; targeting studies to specific community/mental health trusts and better use of the Research Support Team (RST) to support challenging studies. For some studies, we will not see an instant turn-around, some of this may take 12-18 months and thus there is a risk some of the commercial HLOs will not be met this year, but due to the budget focus, we will prioritise HLO2A.

2. In relation to current challenges and risks, the HR issues with NUH employed members of the core team have improved, however, this still remains a risk. Delays in the payment of invoices have improved but will continue to be monitored as a risk. The risk around visibility of performance data has also improved, although there are still some areas of concern to address and monitor. We have added new risks in relation to several HLOs with mitigating action plans in place.

Input Sought

We would welcome the Trust Board's input regarding:

(i) Review our performance and progress to date providing any comments or feedback you might have.

(ii) Review our current challenges, risks and mitigating actions, providing any comments or feedback you might have.

(iii) Review and approve CRN East Midlands Governance Framework –annual update (Appendix 5).

(iv) Provide any comments or further actions required in response to the update on our patient engagement work (Section 3 of the report).

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
- If an EIA was not carried out, what was the rationale for this decision? - N/A as this report provides an update on the performance of the CRN and does not relate to a UHL business case/decision making.

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 2019
6. Executive Summaries should not exceed **5 sides** My paper does comply

NIHR | Clinical Research Network East Midlands

CRN East Midlands Quarterly Board Report

Progress, Challenges and Performance

DATE: 19 September 2019

AUTHORS: Elizabeth Moss - Chief Operating Officer & Carl Sheppard - Project Manager

EXECUTIVE EDITOR: Professor David Rowbotham - Clinical Director

1. INTRODUCTION

1.1 University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute for 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.

1.2 This report provides a summary of 2019-20 year to date performance for CRN East Midlands and an update on current challenges and risks. Appended to this written report is a dashboard displaying performance figures, Executive Group finance report, recent feedback letters from the NIHR CRN Coordinating Centre, updated Governance Framework (requires Trust Board approval) and current risk register. This report also provides an update on some of our patient engagement work in response to a request at the Trust Board meeting on 4 July 2019.

1.3 This report will be taken to the CRN East Midlands Executive Group in September 2019. It will then be considered by the UHL Executive Performance Board and submitted to UHL Trust Board for review in October 2019.

2. CURRENT PERFORMANCE 2019-20

2.1 Appendix 1 presents data extracted on 6 September 2019 reflecting year to date performance for 2019-20. This shows the various NIHR High Level Objectives (HLOs) which the CRN is managed against. We wish to highlight the following for the Board's specific attention:

i. Our overall participant recruitment (HLO1A) is currently at 94% of our year to date target with 19,083 participants recruited; our year end target is 54,000. We are currently in seventh position out of the 15 regional networks in the national league table. Due to fluctuations in study pipeline, at this stage, it is it is difficult to forecast accurately the year end position, however our current analysis suggests we are on track to achieve this target, and we continue to monitor performance closely.

ii. HLO1B is a new objective to measure participant recruitment into commercial studies. We are currently at 66% of our year to date target with 511 participants recruited and we are in 13th position out of 15 regional networks. This is a cause for concern and there are a number of factors which have contributed to our current performance level. Our initial target, which was set in line with a realistic forecast, has been increased to 2,044 due to a national shortfall. This uplift reflects a significant stretch from our 2018/19 output of 1,627 and we are currently not confident of achieving this target.

Historical data indicates that we have always been towards the lower third of LRCNs for total recruitment into commercial studies and last year we would have finished 12th out of the 15 LCRNs, however this was not previously actively managed as an HLO. As such, our current position is not representative of a downturn in performance; our focus has always been on the national priority of ensuring studies recruit to time and target (HLO2A, where we have a strong performance record).

We have set out a number of actions (as recorded on our risk register) seeking to improve our performance this year and some longer term plans to ensure we achieve this objective in future years. We have analysed the data and can clearly see that the attainment of this new HLO relies heavily on a small number of high recruiting studies, of which we have only a few open, when compared to other regions. We are seeking opportunities to open commercial studies with higher targets, however many are confined to pre-selected sites or only one LCRN. We are working closely with partners to raise the profile of ths new HLO, and are looking to reconfigure some of our teams to prioritise our commercial objectives. We should, however, advise that at present the performance of this HLO does not directly impact upon future income, and that HLO2A and B remain of high priority at this time.

iii. For the proportion of closed commercial studies recruiting to time and target (HLO2A), we are currently at 79% against a target of 80% and in sixth position out of the 15 regional networks. Only a small number of studies have closed at this stage of the year and based on current forecasting, we have some concerns our performance may decline. We are conducting regular review meetings with NUH and UHL in relation to their commercial portfolios, where the biggest impact is seen on HLO2A. In addition to understanding reasons for underperformance, we are also considering how we manage this, and may look to develop a post to support this work, as with HLO2B.

iv. For the proportion of closed non-commercial studies recruiting to time and target, where the lead site is in the East Midlands (HLO2B), we are currently at 100% against a target of 80% and in first place out of the 15 LCRNs. Whilst this performance is encouraging, it only captures a small proportion of closed studies at this point of the year. We have some concerns around recruitment for a number of studies likely to close before year end, which could cause our performance to fall below target. We are monitoring these studies closely and will implement action plans for recovery where possible. As with HLO2A, we hold regular performance meetings and continue to engage with our Partner organisations. Both HLO2A and 2B will have an impact on our future budget so it is important for us to take actions to address this now.

v. The next group of HLOs (HLO6) are intended to measure local engagement across the regional health economy.

- We are pleased to report that we have already achieved our objective for the proportion of NHS Trusts recruiting into NIHR studies (HLO6A) with 100% of trusts recruiting.

- For the proportion of NHS Trusts recruiting into commercial studies (HLO6B), we are currently at 56% against a year end target of 70%. We are forecasting it is possible we may not achieve this and have set out a number of actions to improve performance. We have conducted some analysis to identify key areas within our less experienced Trusts where commercial research could be targeted. We will provide support to increase the likelihood of these sites being selected for studies by commercial partners. Also, our Senior Team Links (STLs) continue to engage with our Partners to discuss the development of their commercial research plans.

- The proportion of GP sites recruiting into NIHR studies (HLO6C) is currently at 37% against a target of 45%. We have always done well with this measure and have very well engaged GPs in the region, however there is some uncertainty around measurement of this as the service delivery models in primary care change, such as the development of Primary Care Networks (PCNs) and clustering of practices. We are currently seeking to understand the impact of this, as earlier in the year we were reporting at 44%.

- We are also being measured against a new objective for the number of non-NHS sites recruiting into NIHR CRN Portfolio studies (HLO6D). We are currently seeking clarification around cohort studies and how sites will be managed in these types of trials, as this will impact the achievement of this at both regional and national level.

vi. For recruitment into Dementia and Neurodegenerative studies (HLO7), we are currently at 128% of our year to date target with 641 participants recruited against a year end target of 1,300. We are expecting some of the high recruiting studies to close before the end of the year, which will slow down our recruitment rate. We are focussing attention on maximising recruitment into these studies, however, based on the current pipeline we have modest confidence that we can meet this by year end.

vii. HLO8 is a new objective which measures the number of NIHR CRN Portfolio study participants responding to the Patient Research Experience Survey. We are currently at 197% of our year to date target with 854 participant responses. We are confident we will exceed our year end target of 1,000 responses. Further information regarding this new HLO is provided in section 3 below.

viii. HLO9A & 9B are new objectives to reduce study site set-up times for NIHR CRN Portfolio studies; these have replaced HLO4&5. We are currently on target for both metrics. For commercial studies (9A), we are currently at 50 days against a target of 80 days and for non-commercial studies (9B), we are currently at 57 days against a target of 62 days.

2.2 Our latest Executive Group Finance Report is included as Appendix 2. We have previously reported to the Board our concerns in respect of timely payments to LCRN stakeholders by UHL as the Host for CRN East Midlands and an update is included in this Finance report. An update on the risk score is provided in section 6 below (risk #46).

3. FEEDBACK FROM JULY TRUST BOARD: PATIENT INVOLVEMENT & ENGAGEMENT

3.1 At the Trust Board meeting on 4 July 2019, a request was made for us to review opportunities to improve the way that feedback is provided to patients who had participated in research studies. This section has been included to respond to the Board's request and provide an update on some of our recent patient engagement work.

The NIHR CRN is keen to look for ways to meaningfully engage with patients, carers and members of the public in the delivery of research. As of 2019-20, a new CRN High Level Objective (HLO8) has been introduced which measures the number of responses to the Patient Research Experience Survey (PRES) each year, as delivered by LCRNs. HLO8 has a national target of 10,000 responses with LCRNs expected to generate PRES responses from 1% of total recruitment. For the region this would equate to approx. 500-600 responses, however CRN East Midlands has set an initial target of 1,000 responses, with a stretch target to 1,500. As of 6/9/2019, we have received 854 responses from across the region.

CRN East Midlands is working with a wide range of partners to deliver PRES to research participants, including 11 Trusts, 1 non-NHS provider (LOROS Hospice), and a series of primary care research sites. CRN East Midlands develops localised versions of the PRES with partners and provides all materials for partners to share with research participants. This utilises both paper and digital surveys, and the data is collated and displayed at both partner and regional level on our PRES website, so it can be accessed by both professionals and members of the public.

CRN East Midlands also coordinates the Patient Research Ambassador (PRA) programme in the East Midlands, working with partners to support PRAs to encourage more people to take part in research. This includes supporting partners by providing resources, guidance about the programme and developing case studies and communications materials to raise the profile of PRAs. The PRA programme is promoted on the CRN East Midlands website, and will be a key feature of the forthcoming CRN East Midlands Engagement website which is currently under

development. We also work with partner organisations to create and disseminate materials aimed at increasing both engagement and participation to ensure that more people are given the opportunity to participate in, and shape, research.

We are planning to design some 'thank you cards' to distribute to our stakeholders, to allow them to send to participants at the end of their active participation in a trial. We are also designing a template 'lay person' study results document, for local Investigators to send to participants, once the trial results are published. The intention is to pilot this with some local lead Investigators and if successful to open to wider stakeholders. The expectation is that the local study team will complete this and send out to their participants. We expect that both of these will contribute to showing participants are valued and their contribution is recognised

In addition to these local plans, at a national level, the NIHR CRN are further developing a patient app "NIHR Be Part of Research", which was piloted last year under the name 'Our Research'. One of the main purposes of the app is to say thank you to patients. At the moment, this is a generic thank you message, however as the app continues to develop, the intention is to allow the use of the NHS Login to link this 'thank you' message to specific studies that patients have taken part in. Phase 2 of the app development work is progressing well, and it should be launched on the App Store and Google Play over the next few weeks.

4. NIHR CRN COORDINATING CENTRE FEEDBACK

4.1 Feedback was provided on 18 July 2019 in relation to our 2018-19 Annual Report and 2019-20 Annual Plan. Both the Report and the Plan have been formally approved and feedback was positive on the whole. Some follow up actions have been addressed and we have submitted our response. Further details can be found in the letter at Appendix 3.

4.2 Our Year-End Review Meeting with the NIHR CRN Coordinating Centre took place on 12 July 2019 and feedback was received on 6 September. Overall, the CRNCC was content with our performance and delivery against plans for 2018-19. Other than the ongoing issue of delays in the Host payment of invoices (Risk #46), there were no major concerns or issues identified. A number of actions are required and feedback/input requested into national work, a response is currently being prepared. Further details can be found in the letter at Appendix 4.

5. LCRN GOVERNANCE FRAMEWORK

5.1 CRN East Midlands Governance Framework (Appendix 5) 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. This document has been reviewed by CRN East Midlands Executive Group and is provided to this Trust Board for formal approval.

6. RISK REGISTER & CURRENT CHALLENGES

6.1 Risks and issues are discussed through the CRN Executive Group chaired by Andrew Furlong. A risk register (Appendix 6) is maintained with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Coordinating Centre (CRN CC).

6.2 Risks are recorded on the register as follows:

- Risk #45 - Ongoing issues with NUH employed members of the core team which have not been well supported. A number of meetings and discussions have taken place between the CRN COO, UHL HR and NUH HR to address this risk. Some progress has been made, although currently the risk score is unchanged. Further actions are planned, and this will require ongoing monitoring and review prior to making any changes to the overall risk score.
- Risk #46 - Ongoing delays to payment of invoices from suppliers and partners could negatively impact the reputation of CRN & UHL, and impact on the delivery of some contractual elements. Over the last two quarters we have observed a significant improvement in the proportion of invoices being paid on time in comparison to 2018, however, some elements have not yet improved (i.e. BACS payment). The risk probability has reduced slightly, although overall this remains medium risk and ongoing active monitoring is still required. We are assured that the payment process seems to be working well, however would like to see a further quarter of data to be confident to further reduce the risk, and thus reduce the reputational impact for the Host.
- Risk #47 - CRN EM will not deliver against HLO7 target for 2019-20. Our performance has improved, however, it is still possible we may not achieve our target at year end. Overall the risk score is unchanged and this remains relatively low risk.
- Risk #48 - Lack of visibility of performance data for all studies making it difficult to manage key HLOs. Since the latest phase of the national data integration project has gone live we have greater assurances around the data quality, although there are still some areas of concern. Research data confirmation is a new step in the process and we are seeing some issues with data transfer and missing data, which needs constant monitoring and action. The probability of this risk has reduced from likely to possible and overall this remains medium risk .

- Risks #49, 50, 51 and 52 have been added as new risks which correspond to concerns that we may not achieve our targets for HLO 1B, 2A, 2B and 6B respectively (as described in section 2 of this report). Notably, HLO1B and HLO2A have been scored as high risk as it is likely we will not achieve these targets. We have plans in place to address these performance concerns and mitigating actions have been set out on the risk register.

7. SUMMARY

7.1 This report presents a mixed picture of our performance across the High Level Objectives to date. Some areas are performing well, however, we have concerns for a number of HLOs, particularly those relating to our commercial metrics. Within the risk register, we have set out a number of actions to improve performance and will monitor progress closely. These include: reconfiguring some the team to re-focus efforts to attain these commercial targets; closer working with NUH and UHL, especially around oncology commercial research; targeting studies to specific community/mental health trusts and better use of the Research Support Team (RST) to support challenging studies. For some studies, we will not see an instant turn-around, some of this may take 12-18 months and thus there is a risk some of the commercial HLOs will not be met this year, but due to the budget focus, we will prioritise HLO2A.

7.2 In relation to current challenges and risks, the HR issues with NUH employed members of the core team have improved, however, this still remains a risk. Delays in the payment of invoices have improved but will continue to be monitored as a risk. The risk around visibility of performance data has also improved, although there are still some areas of concern to address and monitor. We have added new risks in relation to several HLOs with mitigating action plans in place.

8. RECOMMENDATIONS

8.1 UHL Trust Board is asked to:

(i) Review our performance and progress to date providing any comments or feedback you might have.

(ii) Review our current challenges, risks and mitigating actions, providing any comments or feedback you might have.

(iii) Review and approve CRN East Midlands Governance Framework (annual update).

Appendix 1 - HLO Dashboard

NIHR | Clinical Research Network East Midlands

2019/20 High Level Objectives

Data cut from 6th September, 2019

HLO	Objective	Metric	Goal	YTD Achievement	YTD Performance / Year End RAG Assurance	
HLO1a	Deliver significant levels of participation in NIHR CRN Portfolio studies	Overall number of participants recruited to NIHR CRN Portfolio studies	54,000	19,083	94%	
HLO1b		Number of participants recruited to commercial contract NIHR CRN Portfolio studies (Subset of HLO1a)	2,044	511	66%	
HLO2a	Deliver NIHR CRN Portfolio studies to recruitment target within the planned recruitment period	Proportion of **commercial** studies achieving or surpassing their recruitment target during their planned recruitment period	80%	79%	-	
HLO2b		Proportion of **non-commercial** studies achieving or surpassing their recruitment target during their planned recruitment period	80%	100%	-	
HLO6a	Widen participation in research by enabling the involvement of a range of health and social care providers	Proportion of NHS Trusts recruiting into NIHR CRN Portfolio studies	100%	100%	-	
HLO6b		Proportion of NHS Trusts recruiting into NIHR CRN Portfolio commercial studies	70%	56%	-	
HLO6c		Proportion of General Medical Practices recruiting into NIHR CRN Portfolio studies	45%	37%	-	
HLO6d		Number of non-NHS sites recruiting into NIHR CRN Portfolio studies	TBC	TBC	TBC	
HLO7	Deliver significant levels of participation in NIHR CRN Portfolio Dementias and Neurodegeneration	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR	1,300	641	128%	
HLO8	Demonstrate to people taking part in health and social care research studies that their contribution is valued	Number of NIHR CRN Portfolio study participants responding to the Research Participant Experience Survey	1,000	854	197%	
HLO9a	Reduce study site set-up times for NIHR CRN Portfolio studies by 5%	Median study site set-up time for commercial studies	80 days	50 days	-	
HLO9b		Median study site set-up time for non-commercial studies	62 days	57 days	-	

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: CRN EM EXECUTIVE COMMITTEE

DATE: 18th SEPTEMBER 2019

REPORT FROM: MARTIN MAYNES – HOST FINANCE LEAD

SUBJECT: CRN EM FINANCE UPDATE

1. Purpose

This report provides an update on the following issues:

- 19/20 financial forecast
- Accounts Payable

2 2019/20 Finance Forecast

The table below summarises the 19/20 year to date and forecast position to 31st March 2020.

	Annual Plan	April to August	Forecast Expenditure	Forecast Variance
	£'000	£'000	£'000	£'000
Income				
NIHR Allocation	20,979	8,865	21,103	124
Expenditure				
Network Wider Team	541	218	507	-34
Host Services	325	132	325	0
Management Team	827	327	803	-24
Study Support Service (SSS) Team	578	190	502	-75
Research Study Team (RST)	555	135	401	-154
Clinical & SG Leads	143	34	104	-38
Research Site Initiative	664	277	664	0
Primary Care Service Support Costs	200	83	200	0
NON - Primary Care SSC	200	83	200	0
Partner Organisation Infrastructure	16,569	6,844	16,456	-113
ETC	0	124	124	124
CRN EM Non Pay Non Staff	194	63	200	6
Innovation Fund	400	4	413	13
Vacancy Factor	-217	350	0	217
To be allocated			203	203
Total	**20,979**	**8,865**	**21,103**	**124**

The main points to note are as follows.

Income
The favourable variance is due to receiving more income for ETC QTR 4 than accrued at the year end. Accrual information was provided by NHS England for ETC payment. Additional income received was passed onto to relevant partners as shown in the table.

Network Wider Team
There is a favourable pay variance of £29k due to an Information Administrator leaving the post. This post is not being replaced. Also, the Business Support officer sucessfully obtained a post within SSS team. This post is being replaced but there is slippage as a

replacement candidate started and then left within a short period of time. In addition, there is a non pay favourable variance of £5k due to savings in overheads for vacant posts.

Management Team
The underspend is largely due to savings in non pay.

Study Support Team
There is a favourable pay variance is due to starters and leavers within SSS Team. Also Network related ETC funds have not been fully utilised.

Research Support Team
Overall underspend is due to facing several challenges in expanding the RST team, i.e. sourcing and negotiating accommodation for posts, recruiting the right candidates, readvertising vacancies etc.

Clinical & SG Leads
The favourable pay variance with associated non pay and overhead is £16k. There are also savings related to slippage in recruiting to posts.

Partner Organisation Infrastructure
Favourable variance is due to a combination of factors:

Infrastructure budget is underspent by £78k, largely due to budget allocated to non NHS organisations has not materialised as quickly as anticipated.

Primary Care - Based on the budget setting, currently there is a pressure of £49k as net effect of staff leaving and additional allocation for Super Practice pilot scheme.

Network - budget is underspent by £84k largely due to leavers and retirement.

Excess Treatment Costs
£124k expenditure allocated to POs to match additional income received.

3. Accounts Payable

We have observed an improvement in the last two quarters in comparison to the performance in 2018, where only 10% of invoices had been paid within 30 days. In Q1 of this year 83% of invoices have been paid in 30 days and in Q2 to date 81%. The average payment time YTD is 31 days in Q1 and 25 days in Q2, which is a significant improvement on 85 days on average in 2018.

There still appears to be a perceived issue with payments made via BACS, on average in 2018/19 the number of days for payment were 37 days and since the introduction of Excess Treatment Cost Payments on October 2018, we have had significant delays in payments via BACS for which we have to report to NHS England and give reasons why this occurred and in the majority of cases this was to due to Host Payment delays. We are instigating a monitoring process for these payments akin to the invoice monitoring process and they will be included in the weekly report to the Host identifying what payments are required.

Overall, there has been significant improvement but will continue the monitoring process as we have been here before where there is a temporary improvement and this then slips.

4. Recommendations

The CRN Executive Committee is asked to:

- Note the 19/20 forecast
- Note the current Accounts Payable performance

NIHR | National Institute for Health Research

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Mr Andrew Furlong
Medical Director
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18 July 2019

Dear Mr Furlong,

LCRN Annual Report 2018/19 and LCRN Annual Plan 2019/20

Thank you for submitting CRN East Midlands' Annual Report, including the Q4 finance return for 2018/19 and Annual Plan including the Annual Financial Plan for 2019/20. I am pleased to confirm that the CRN Coordinating Centre (CRNCC) review group recommended the approval of your Annual Report and Annual Plan.

General feedback to all LCRNs
The review group would like to share some general points on LCRN Annual Reports and Plans:

- Demonstration of supra-regional working is clearly evident from LCRN Reports and Plans and we encourage LCRNs to continue to learn from each other
- We encourage LCRNs to use the Research Targeting Tool to identify where study sites may be located in addition to the Disease Mapping dashboard to identify diseases of high prevalence in their local populations
- We ask that all LCRNs ensure implementation of the improvement actions arising from the 2018/19 National Improvement Plan (i.e. new effective study start up process for commercial studies and new performance monitoring process) and provide continued support for phase 2 of this national project in 2019/20
- We note there have been some changes to ways of resourcing leadership for CRN specialties and will monitor this during the course of the year
- In relation to support for CRN specialties and delivery against the Specialty Objectives, many LCRN Annual Reports and Plans would have benefited from additional detail. Medical and Research Delivery Directorate colleagues will be in touch to discuss further with relevant LCRNs
- Further discussions have taken place in a number of LCRN Performance Review meetings in relation to recording of age to satisfy the requirements of Specialty Objective 5 (2019/20 Performance and Operating Framework section B.4.Table 2). This can be met through LCRNs recording Date of Birth, Year of Birth or Age at recruitment (or in 2019/20, working towards a system for recording of age). CRNCC's preference would be for Date of Birth to be recorded as this is unambiguous, however networks will satisfy requirements by the other methods listed. Should there be any further guidance, we will advise accordingly

- A number of LCRN Plans noted the intention to bid for one of the five purpose designed centres dedicated to late-phase commercial research, referenced in the Life Sciences Industrial Strategy. Further details will be announced in due course but in the meantime we thought it helpful to clarify that the bidding process will be open to, and led by, NHS trusts rather than LCRNs
- The use of social media channels in promoting research is clearly evident in many LCRN Reports and Plans. As you may be aware, a review of NIHR use of social media channels is underway, and we ask LCRNs to look out for the outcomes of the review and if necessary, adjust their plans accordingly

Specific feedback on CRN East Midlands' Annual Report 2018/19

Annual Report Section	**CRNCC Feedback**	**Action required**
Report overall including Executive Summary	Excellent report. We commend the strong collaboration with CRN West Midlands in areas including continuous improvement and working across specialties such as in Primary care and Musculoskeletal Disorders	No action required
High Level Objectives / Specialty Objectives	Excellent HLO 1 performance at 67,826 compared with the local target of 52,000 and HLO 2b performance at 91% (2/15 LCRNs) We note good performance overall against the majority of Specialty Objectives. We recognise exceptional performance in Renal Disorders (1/15 LCRNs for recruitment) and the roll-out of a hub and spoke model across the region as well as being the top recruiting LCRN for Hepatology and Oral and Dental Health We commend strong links to Gastroenterology trainee networks and the adoption of a trainee network study onto the NIHR CRN Portfolio We note your First Global patient in Respiratory Disorders (CPMS ID: 35847)	We note HLO 2b performance was underpinned by excellent ways of working and encourage you to share your experience and learning across the CRN
Key Projects	Well written and detailed section. We note the LCRN completed 90% of planned projects Thank you for your contributions to national projects, particularly Beth Moss's support for the Research Activity national project and the LCRN's support for the Accelerating Digital project	No action required

Contract Compliance	We note the ongoing issue of non-compliance in relation to payment of invoices by the Host, which has been escalated to the Host Board and is now included on the network risk register We note partial compliance with the High Level Objectives, Specialty Objectives, LCRN Operating Framework Indicators and partial compliance with clause C6.2.1 of the Performance and Operating Framework (POF) Following the 2018/19 Contract Compliance Assurance Framework, the CRNCC is satisfied with the LCRN's Contract Compliance for 2018/19	An update on how the Host intends to resolve this issue would be appreciated We note plans for 2019/20, and look forward to receiving details in due course of your new Lead for Health Services Research We will revisit the wording of clause C6.2.1 as part of the review of the POF for 2020/21 No further action required
Q4 finance return	No specific comments	No action required
Overall commentary	We note good delivery overall against your locally identified priorities We note targeted work and relationship building in readiness for Research Activity (RA) integration We commend your proactive engagement and collaborations with NIHR infrastructure in the region and the Urgent Public Health plan, which is an exemplar nationally We note zero non-supported non-commercial studies reported	We look forward to the results of the formal evaluation of your innovation fund in due course

Specific feedback on CRN East Midlands' Annual Plan 2019/20 including High Level Objectives ambition values 2019/20

As part of the process of CRNCC review of LCRN Annual Plans we have reviewed the forecasts for HLOs 1a, 1b and 7. The collated performance estimates for all LCRNs indicate there will be a shortfall from the ambition values for HLO 1a and 1b of 10,057 and 5,009 respectively. There was no shortfall for HLO 7.

We have undertaken an analysis looking at LCRN forecasts for 2019/20, average LCRN performance over the last five years and taking into account any funding increase in 2019/20. A methodology has been adopted for HLO 1a and 1b that aims to meet the ambition values for these measures, as set out below.

HLO 1a - we will adopt either:
a) the LCRN's recruitment forecast or
b) assign the LCRN a target for 2019/20 which takes the LCRN's forecast plus an element of the HLO 1a shortfall. The shortfall allocation method is based on the LCRN's 2019/20 LCRN funding allocation (excluding Top-sliced elements) as a proportion of the total

HLO 1b
For HLO 1b we will adopt either:
a) the LCRN's recruitment forecast or
b) assign the LCRN a target for 2019/20 which takes the LCRN's forecast plus an element of the HLO 1b shortfall. The shortfall allocation method is based on the LCRN's 2019/20 funding allocation (excluding Top-sliced elements) as a proportion of the total, or
c) the LCRN's average recruitment in the previous 5 years

HLO 7
Individual LCRN forecasts for HLO 7 will be used as the LCRNs' local ambition value for HLO 7

The final values for each LCRN for HLO 1a, 1b and 7 are available at Appendix 1.

Annual Plan Section	**CRNCC Feedback**	**Action required**
Plan overall	Good plan. We appreciate the clear strategy and interesting work around digital improvement articulated in the Digital Maturity Proposition (Appendix 4). We are pleased to see the detailed breakdown of workforce activities, linked to long-term plans	We encourage you to consider more fully showcasing your excellent digital work when developing your annual plan for 2020/21
High Level Objectives	We ask you to work to achieve the following targets: • HLO 1a - 54,000 • HLO 1b - 2,044 • HLO 7 - 1,300	No action required
Specialty Objectives	Good plans. We note the LCRN's concern in relation to Specialty Objective 5 and the recording of age	See general point above
Key Projects	We are pleased to see clear intent to engage with non-NHS sites It would be helpful to understand more clearly how the 2019/20 POF Communications requirements will be met We are interested in the cross-Midlands approach to the implementation of the national improvement programme for the life sciences industry and providing feedback on non-selection	 CRNCC Communications team colleagues will be in touch to discuss and understand plans in more detail Please keep the CRNCC Business Development and Marketing Team informed of progress and learning

	of sites. We anticipate this will have both regional and national impact We expected to see a project to specifically address the identified potential drop in commercial performance (other than mention of development of a joint approach in the Business Development and Marketing Profile)	CRNCC Business Development and Marketing colleagues will be in contact to understand plans in more detail
Contract Compliance	We note four areas of partial compliance (Specialty Objectives, Financial Management, CRN Specialties and Information and Knowledge). Plans in place to mitigate noted	No action required
Annual Financial Plan (AFP)	We note the relatively high vacancy factors for some Partner organisations	We recommend the ongoing careful monitoring of vacant posts to ensure a break-even position. CRNCC Finance colleagues will monitor progress through the financial quarterly returns
Risks and Issues	Noted	No action required
Additional comments	It is positive to see plans for exploring approaches to increasing (Black, Asian and Minority Ethnic (BAME) volunteers for JDR sign up, and plans to expand study availability into prison, schools and community settings The involvement of 'super practices' within the continued rollout of the Primary Care Research Sites Initiative (RSI) is of interest	We encourage you to share learning across the CRN

We very much look forward to working with you in the coming year to support the implementation of your Plan. Please do not hesitate to escalate any performance issues or areas needing support from the CRNCC as they arise during the year via the CRN Performance Management team (crncc.performance@nihr.ac.uk), SMT Link or the lead responsible for the relevant function.

Yours sincerely

Amber O'Malley
Head of Performance Management
NIHR Clinical Research Network

Cc: Professor David Rowbotham, Clinical Director, CRN East Midlands
Professor Steve Ryder, Co-Clinical Director, CRN East Midlands

Elizabeth Moss, Chief Operating Officer, CRN East Midlands
Dr Jonathan P Sheffield, CRN Chief Executive Officer
John Sitzia, National Chief Operating Officer
Professor Nick Lemoine, Medical Director
Dr Matt Cooper, Business Development & Marketing Director
Dr Clare Morgan, Research Delivery Director
Imogen Shillito, Stakeholder Engagement & Communications Director
Dr Jonathan Gower, Assistant Specialty Cluster Lead for Cluster F (SMT Link)
CRNCC Senior Management Team

Appendix 1 (n.b. this appendix is an attachment to the above letter)

LCRN HLO 1a, 1b and HLO 7 targets for 2019/20

LCRN	LCRN HLO 1a forecast	LCRN HLO 1a target	LCRN HLO 1b forecast	LCRN HLO 1b target	LCRN HLO 7 target
East Midlands	54,000	54,000	1,550	2,044	1,300
Eastern	50,000	50,000	2,825	2,825	2,500
Greater Manchester	47,000	48,522	2,500	3,729	2,000
Kent, Surrey and Sussex	40,000	40,000	2,000	2,512	1,700
North East and North Cumbria	41,206	41,206	1,600	2,172	1,700
North Thames	64,400	66,776	4,800	4,800	2,500
North West Coast	35,000	35,000	2,200	2,200	2,400
North West London	22,122	23,298	583	1,105	550
South London	56,382	58,366	1,723	2,257	1,251
South West Peninsula	23,000	23,900	1,820	1,820	5,000
Thames Valley and South Midlands	50,000	50,000	2,000	2,553	1,550
Wessex	43,479	43,479	2,000	2,000	688
West Midlands	65,000	65,000	4,400	4,400	1,200
West of England	28,883	28,883	1,000	1,593	550
Yorkshire and Humber	66,725	68,824	4,000	4,000	2,080
Total	**687,197**	**697,254**	**35,001**	**40,010**	**26,969**
National CRN Ambition 2019/20		**697,254**		**40,010**	**25,000**
Shortfall	**10,057**		**5,009**		

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

5 September 2019

Dear Professor Rowbotham and Professor Ryder

NIHR CRN East Midlands Year-End Performance Review Meeting 12 July 2019

Thank you to you and your team for attending the Year-End Review Meeting between the CRN Coordinating Centre (CRNCC) and CRN East Midlands ("the LCRN") held on 12 July 2019 to discuss the LCRN's delivery and performance in 2018/19 and plans for 2019/20.

The meeting was chaired by Matt Cooper and attended by the following colleagues:

LCRN attendees: David Rowbotham (DR) - Clinical Director, Steve Ryder (SR) - Co-Clinical Director, Elizabeth Moss (EM) - Chief Operating Officer, Martin Maynes (MM) - Head of Finance, Research and Innovation, University Hospitals of Leicester NHS Trust (on behalf of Andrew Furlong). **CRNCC attendees:** Jonathan Sheffield (JPS) - Chief Executive Officer, Matt Cooper (MC) - Business Development and Marketing Director, Nick Lemoine (NL) - Medical Director, Clare Morgan (CM) Research Delivery Director, Imogen Shillito (IS) - Stakeholder Engagement and Communications Director, Jackie Wilson (JW) - LCRN Planning and Reporting Manager (Secretariat)

LCRN apologies: Andrew Furlong (AF) - Medical Director, University Hospitals of Leicester NHS Trust (Host Nominated Executive Director). **CRNCC apologies**: John Sitzia (JS) - National Chief Operating Officer

We would like to thank your team for providing the documents and presentation materials to support discussions at the meeting.

Actions and matters arising from the last meeting
All actions from the previous review meeting were noted as complete, with the exception of:

- EM21- (relating to delay in Host payment of invoices) which remains open. Performance has improved although the 30 day payment target is not yet being met. The issue has been discussed by the Host Trust Board, and the Board Chair expects the matter to be addressed by the next meeting of the Board. The CRNCC will continue to monitor progress

Overall summary
Overall, we are content with the LCRN's performance and delivery against plans for 2018/19. We are pleased to see the network's best performance for HLO 1 with recruitment of 67,826 participants compared to 56,177 in 2017/18, and strong Recruitment to Time and Target for both commercial (HLO 2a) and non-commercial (HLO 2b) studies, at 79% and 91% respectively. We note strong primary care engagement (with HLO 6c above target at 51%) and commend the LCRN being the top recruiting network for Primary Care, Oral and Dental Health, Hepatology, and Renal Disorders. We thank you for your time and efforts locally and nationally on LPMS/CPMS integration.

Major issues to be addressed

- Other than the ongoing issue of delays in the Host payment of invoices, there were no major concerns or issues identified

Medium issues to be addressed

- A number of Specialties are struggling to deliver commercial studies to Time and Target, with Injuries and Emergencies and Metabolic and Endocrine red-rated in 2018/19. The network has a strong Lead for Metabolic and Endocrine and will explore the reasons for underperformance in this Specialty. However, it is acknowledged Injuries and Emergencies studies are relatively scarce, and the number of studies fluctuates, and the LCRN seeks to engage with studies where possible. There may be opportunities to learn from colleagues at Yorkshire Ambulance Service NHS Trust regarding pre-hospital studies **(see Action EM26)**

Minor issues to be addressed

- The network is one of two LCRNs to fall slightly short of the HLO 6b target (69% performance in 2018/19 against the 70% target). This was explained in part by challenges identifying appropriate studies and Trust configurations. CM suggested linking up with The Community Health Care Alliance of Research Trusts in England (CHART) (**see Action EM25**)
- We note variability in workload related to sign-off of the Schedule of Events Cost Attribution Templates (SoECATs), particularly if there are requests for support from researchers. The CRNCC hopes to have additional resource in 2019/20 to provide coordinated support and training to help researchers, and encouraged the network team to provide suggestions on support that would be of use **(see Action EM27)**
- We discussed ongoing partial-compliance with the Performance and Operating Framework (POF) linked to the turnover of local Clinical Research Specialty Leads (CRSLs). The CRNCC will consider the length of a local CRSL role being vacant in an operational year before the vacancy is regarded as a compliance issue **(see Action EM28)**

Progress on these issues may be sought at the next CRNCC / LCRN Performance Review meeting.

Additional points to note

- We discussed the considerable effort put into the implementation of Research Activity Integration between CPMS and LPMS, which the LCRN has managed as a project. We note good quality data from Research Sites Initiative (RSI) and non-RSI primary care

practices (with data entered centrally at a local level), regular engagement with Partners, and a local website to support this activity
- We note the increase in Cost Per Weighted Recruit (CPWR) from 2017/18 to 2018/19 (£69.93 to £78.98) which is likely attributable to a higher proportion of recruitment from interventional studies in 2018/19, or the impact of the activity-based funding element if this is relatively high in the local model (especially where this is based on retrospective data). We suggested it may be worth considering a prospective element in the local funding model **(see Actions EM29, EM30 and EM31)**
- We discussed the LCRN Partner Satisfaction Survey; the CRNCC will consider how the views of primary care may be sought when reviewing the survey questions, audience, and survey method for 2020 **(see Action EM32)**
- We note a good response overall to the Customer Satisfaction Survey and plans to reshape the Study Support Service, likely with a divisional structure to enable better support for researchers
- We note that to date there have been 539 responses (2019/20 target: 1,000) to the Research Participant Experience Survey and are interested in the associated dashboard created with Google Data Studio **(see Action EM33)**
- We discussed the recording of age (in the context of Specialty Objective 5) and the benefit of agreeing collectively how this should be achieved. We agreed strong representation to record date of birth will be made at the next Integrated Steering Group meeting **(see Action EM34)**
- There was a discussion on delivering cost-saving initiatives and the importance of LCRNs letting the CRNCC know the impact of any changes and issues arising, for example if there is a negative impact on geographical access to research
- We note no concerns with the current risk register, and the ongoing challenge around R045 relating to Nottingham University Hospitals NHS Trust-employed members of the core team. BM will review the register with the Host and update as required **(see Action EM35)**
- The November Strategic Summit will consider what the future Network should look like, prior to the retendering process for LCRNs and the CRNCC. LCRN Partnership Group Chairs will also be consulted **(see Actions EM36 and EM37)**

General points and themes for all LCRNs

I am pleased to confirm that all the LCRN Review meetings have now been completed and would like to share the following general points and themes that emerged from this series of meetings:

- The next Strategic Summit on 19 and 20 November will focus on the future of the Network; how this should look and how we will need to operate and the future research portfolio. We would like to emphasise the importance of the LCRNs and Partnership Group Chairs being involved in discussions regarding the retendering process
- It was helpful to understand the current collated national position on delivery of cost-saving initiatives through LCRN updates. We will share details at a future CRNCC / LCRN Liaison Meeting or via the LCRN Bulletin. As the next Comprehensive Spending review is unlikely to report prior to confirmation of the LCRN funding budget for 2020/21, we anticipate a similar financial position for the Network next year and ask all networks to plan on the basis of the same or similar levels of funding
- We discussed what LCRNs are doing to target research according to health needs. It was helpful to hear about local activities and support for the ten priority areas, and

details on additional local health priorities that are being explored and will be targeted, especially in light of regional system responses to the Long Term Plan. We encourage all LCRNs to consider ways in which the Network will be able to report and evidence the impact of this work both locally and nationally. LCRNs may find it helpful to explore the NHS Rightcare data (https://www.england.nhs.uk/rightcare/products/), amalgamated by Sustainability and Transformation Plans (STP) footprint

- At each meeting we discussed delivery of the Research Participant Experience Survey (RPES), plans for increasing response rates to deliver against the new High Level Objective (HLO 8), and the possibility of analysing the data differently for HLO 8 reporting purposes. It was interesting to hear plans for the administration of the Survey, and we will be in touch to collate information and share best practice across the course of the year
- Further discussions have taken place in a number of LCRN Performance Review meetings in relation to recording of age to satisfy the requirements of Specialty Objective 5 (2019/20 Performance and Operating Framework section B.4.Table 2). This can be met through LCRNs recording Date of Birth, Year of Birth or Age at recruitment (or in 2019/20, working towards a system for recording of age). CRNCC's preference would be for Date of Birth to be recorded as this is unambiguous, however networks will satisfy requirements by the other methods listed. Should there be any further guidance, we will advise accordingly

During the meeting challenges that would potentially impact on the ability of CRN East Midlands to deliver against the planned commitments set out in the LCRN Annual Plan 2019/20 were raised; however LCRN colleagues provided assurance that appropriate plans are in place to address these issues and challenges. Should you wish to discuss progress with colleagues in the CRNCC please do not hesitate to contact us for guidance or support, or speak with your SMT Link. Otherwise we will assume that the network remains on track to deliver against commitments documented in the Plan.

The CRNCC would like to thank you formally for the continuing leadership you provide for CRN East Midlands and we look forward to our next meeting with the team.

If there are any issues that you would like to discuss at this stage, please contact Amber O'Malley, Head of Performance Management (email: amber.o'malley@nihr.ac.uk, tel: 0113 3430313) in the first instance.

Yours sincerely

Jonathan Sheffield OBE, MBChB, FRCPath
Chief Executive Officer
NIHR Clinical Research Network

Cc: Andrew Furlong, Medical Director, University Hospitals of Leicester NHS Trust and Host Nominated Executive Director, CRN East Midlands
Martin Maynes, Head of Finance, Research and Innovation, University Hospitals of Leicester NHS Trust and Host representative, CRN East Midlands
Elizabeth Moss, Chief Operating Officer, CRN East Midlands
John Sitzia, National Chief Operating Officer

Nick Lemoine, Medical Director
Matt Cooper, Business Development and Marketing Director
Clare Morgan, Research Delivery Director
Imogen Shillito, Stakeholder Engagement and Communications Director
Amber O'Malley, Head of Performance Management
CRNCC Senior Management Team

Actions

Item	Action	Owner
EM25	CM to introduce EM to Christine Burt, Portfolio Research Manager at Birmingham Community Healthcare NHS Trust in relation to The Community Healthcare Alliance of Research Trusts (CHART) in relation to HLO 6b performance	Clare Morgan
EM26	CM to put EM in contact with Dr Fiona Bell, Research & Development Manager at Yorkshire Ambulance Service NHS Trust, to discuss delivering pre-hospital studies	Clare Morgan
EM27	EM to send CM suggestions for nationally provided support and training to assist with completion of Schedule of Events Cost Attribution Templates (SoECATs)	Elizabeth Moss
EM28	CRNCC Performance Management team to consider the length of a Local Specialty Lead role being vacant in an operational year before the vacancy is regarded as an issue of non-compliance with the Performance and Operating Framework (POF) when refreshing the POF for 2020/21	CRNCC Performance Management team
EM29	EM to provide an explanation for the increase in CRN East Midlands' CPWR in 2018/19	Elizabeth Moss
EM30	CRNCC Performance Management team to consider including the breakdown of participants recruited to interventional versus observational studies in the LCRN fact sheet	CRNCC Performance Management team
EM31	EM, DR and SR to consider including a prospective element in the local funding model	Elizabeth Moss, David Rowbotham and Steve Ryder
EM32	EM to send the CRNCC Performance Management team (via crncc.performance@nihr.ac.uk) ideas for how the LCRN Partner Survey might be improved	Elizabeth Moss
EM33	EM to a) review permissions on the LCRN's Patient Research Experience Survey (PRES) dashboard to ensure that CRN colleagues are able to access, and b) to share the dashboard with other LCRNs	Elizabeth Moss

EM34	Representation to be made at the next ISG for the recording of date of birth wherever possible (in relation to Specialty Objective 5)	Elizabeth Moss
EM35	BM to review the register with the Host and update as required	Elizabeth Moss
EM36	CRNCC Performance Management team to a) update the Central Contacts list with details of the CRN East Midlands' new Partnership Group Chair (Richard Mitchell from Sherwood Forest Hospitals NHS Foundation Trust), and b) provide support with buddying with another LCRN Partnership Group Chair	CRNCC Performance Management team - complete
EM38	EM and DR to speak to Richard Mitchell (the new Partnership Group Chair) about the retendering for Hosting of the LCRNs	Elizabeth Moss and David Rowbotham

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.

NIHR CLINICAL RESEARCH NETWORK EAST MIDLANDS

Governance Framework

CONTENTS

1. INTRODUCTION

1.1 The National Institute for Health Research Clinical Research Network (NIHR CRN) is the clinical research delivery arm of the NHS in England. Its purpose is to ensure patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research; integrate health research and patient care; improve the quality, speed and co-ordination of clinical research; increase collaboration with industry partners and ensure that the NHS can meet the health research needs of industry. 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 now 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 Before April 2014, there were over 100 clinical research networks in England hosted by NHS Trusts in adjacent localities. From April 2014, there will be only one research "branch" of the NIHR CRN in each NHS region; these are termed Local Clinical Research Networks (LCRNs). 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) successfully applied to host this 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 Chief Executive Officer, John Adler.

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 commercial research within the LCRN.

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

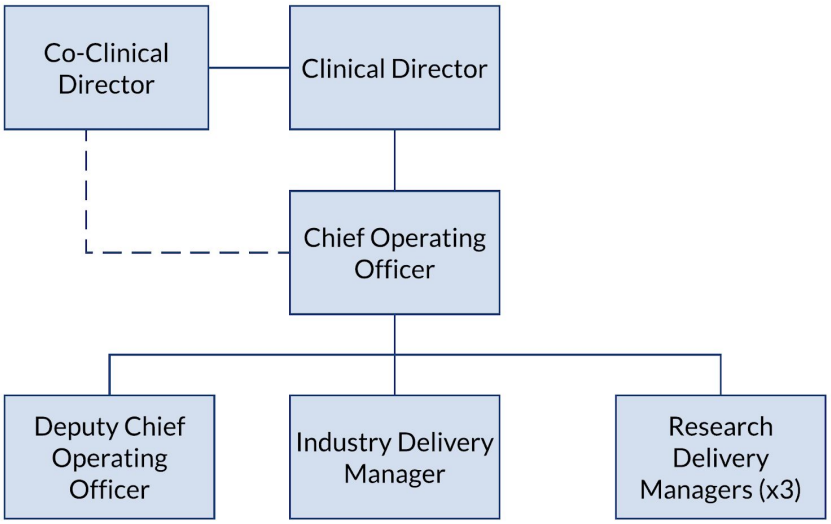
- Deliver the management and operational (i.e. non-clinical) activities of the LCRNs, in line with any agreed governance requirements;

- 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.

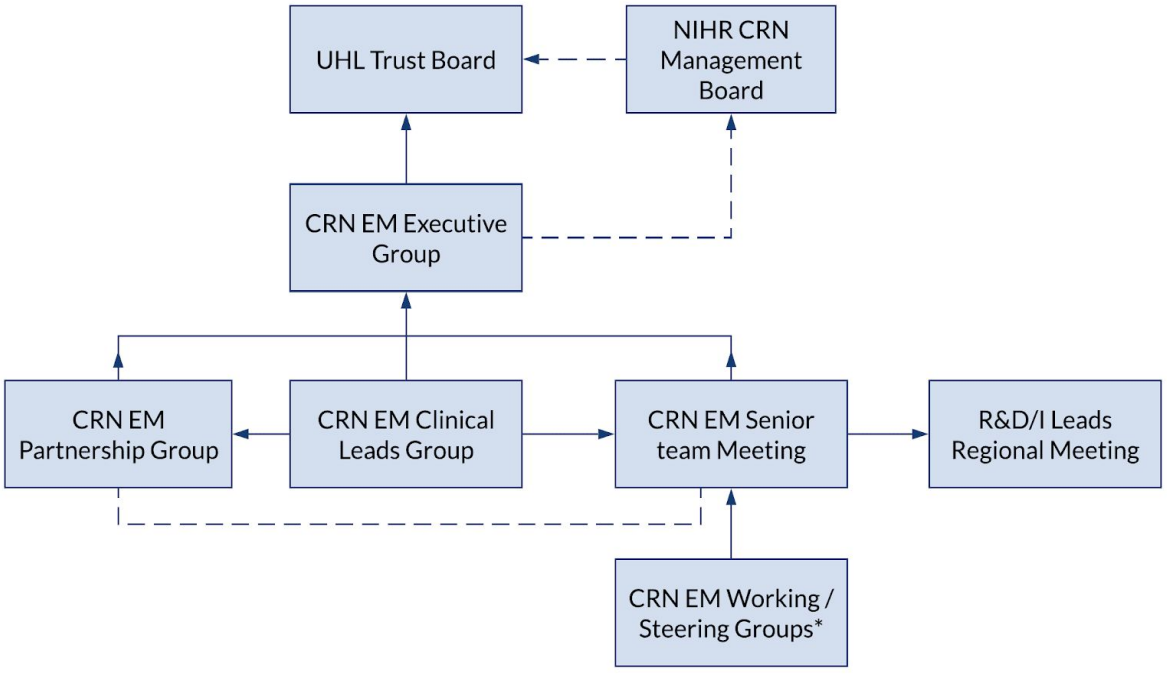
5.8 The LCRN has appointed local Clinical Research Specialty Leads for all 30 specialties. The LCRN Clinical Research Specialty Leads report to the LCRN Divisional Clinical Research Lead responsible for that Specialty. Local Clinical Research Specialty Leads will be responsible for the clinical leadership 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

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 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 report will be submitted to 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 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. 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 the financial accountability of the network on behalf of the Trust. Martin produces LCRN financial reports for review by the LCRN Executive Group and LCRN Partnership Group.

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

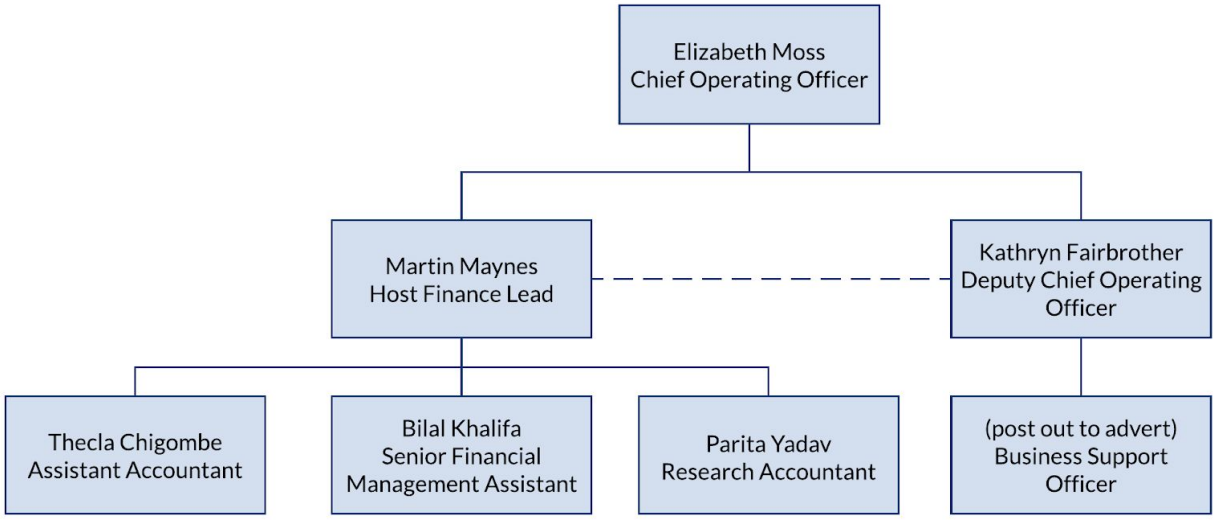
8.10 The Trust, as Host Organisation, has appointed Kathryn Fairbrother as **LCRN Deputy Chief Operating Officer** who is responsible for operational management for the infrastructure and central budgets with accountability shared with the LCRN Host Finance Lead. Kathryn provides oversight of the Service Support Costs budget.

8.11 Catherine Ashman-Lee, Kiran Mistry, Chris Siewierksi, Marie Thompson, Bryony Berridge (**Study Support Service Managers**) & Roz Sorrie-Rae (**Study Support Service Operations Manager**) are responsible for the attribution step in relation to unmet Service Support Costs budget. 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.

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	Administrator (NUH)
Cost Code	Description	Up to £600,000	Up to £100,000	Up to £5,000	Up to £5,000	Up to £5,000
O11	CRN EM Non-Primary Care Service Support Costs	Y	Y	N	N	N
S18	CRN EM RSI	Y	Y	N	N	N
S19	CRN EM Clinical and Specialty Leads	Y	Y	N	N	N
S89	CRN EM Primary Care Service Support Costs	Y	Y	N	N	N
S90	CRN EM General Infrastructure	Y	Y	N	N	N
S97	CRN EM UHL Infrastructure	Y	Y	N	N	N
S98	CRN EM LPMS	Y	Y	N	N	N
U08	CRN EM RST	Y	Y	Y	Y	N
U14	CRN EM SSS	Y	Y	N	N	N
U89	CRN EM Management Team	Y	Y	N	N	N
U96	CRN EM Host Services	Y	Y	Y	N	N
U97	CRN EM Network Wider Team	Y	Y	N	N	N
COR014	Central Network Funding (NUH)	Y	Y	N	N	Y

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 identify 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 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

9.10 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

9.11 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.

9.12 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

9.13 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 Chief Executive Officer – John Adler

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 is 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 2019/20 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

Appendix 6 - Risk Register

NIHR Clinical Research Network East Midlands - Risk Register

University Hospitals of Leicester NHS Trust

Owner of Risk Register: Executive Group

Last updated: 18.09.19

PRE-RESPONSE (INHERENT)										POST-RESPONSE (RESIDUAL)							
Risk ID	**Primary category**	**Date raised**	**Risk owner**	**Risk Description (event)**	**Risk Cause and Effect**	**Probability**	**Impact**	**Value (PxI)**	**Proximity**	**Response Actions**	**Action owner(s)**	**Action status**	**Probability**	**Impact**	**Value (PxI)**	**Risk status (open or closed date)**	**Trend** (since last reviewed)
R045	Performance	Jan-19	COO	Ongoing issues with NUH employed members of the core team resulting in disproportionate amounts of time spent on staff management/support for the these team members and concerns around how well both staff and managers are supported. This also impacts on our overall ability to focus on other aspects of CRN delivery under the Host contract	**Cause:** Inconsistency in local policies/procedures (NUH/UHL); lack of and poor HR support (NUH); ongoing, badly managed HR cases; very few NUH employed managers in core team; lack of understanding/clarity at NUH of network and staffing arrangements **Effect:** Focus diverted from CRN core business; real concerns that staff are not being given appropriate advice and support; managers not well supported, quite vulnerable	5	3	15	Jan-19	To discuss with Host HR (Tina/Smita) for advice and support	COO	4	5	3	15	Open	Static
										Begin discussions with NUH HR/Corporate Governance	COO & Host HR	4					
										Following meeting with NUH, write paper with possible options	COO	5					
										To raise options with staff as and when appropriate	COO	1					
R046	Reputational	Mar-19	COO	Ongoing delays to payment of all CRN invoices from suppliers and partners, breaching the contractual obligation, to negatively impact reputation of CRN & UHL and effect some elements of study and business delivery	**Cause:** CRN invoices not being paid on time by UHL Accounts Payable. **Effect:** Negative effect on future engagement with our Partners with potential to impact on ability to deliver research. For suppliers, where invoices are late, the risk is for services to cease, e.g. Google and Edge which which are underpinning systems to allow our business to proceed, and ultimately deliver the contract. Non compliance with the Host contract. This could also have an adverse effect on reputation of UHL for future re-bids related to NIHR infrastructure.	5	3	15	Mar-19	Meeting scheduled with UHL Chief Finance Officer seeking to resolve this	COO / CD	5	4	2	8	Open	Decreased
										Set up real time monitoring system to enable us to understand the problem and report to the Host Board	DCOO/ COO	5					
										Include report on Accounts Payable performance in July Board Report	PM	5					
										Continue to monitor performance and provide updates to key groups as appropriate	DCOO/ COO	4					
										Highlight to Accounts Payable the need to make BACS payments promptly by end of Q2	DCOO	4					
R047	Performance	Jun-19	Div 4 RDM	CRN EM will not deliver against HLO7 target for 2019-20 (number of participants recruited into Dementias and Neurodegeneration NIHR studies) Currently 127% of YTD Target	**Cause:** Challenging target, due to previous strong performance, however there is a reduction in the national pipeline for new portfolio dementia studies, especially those with large sample sizes. **Effect:** Unable to meet this HLO, which we are contractually expected to do. Potential reputational risk. At present there is no financial impact. This area is something which will be considered nationally, as this is a concern from all CRNs.	3	2	6	Mar-20	Scope pipeline for potential studies open to new sites	Div 4 RDM & OM	4	3	2	6	Open	Static
										As this is a national issue, SL to raise concerns to national group	Dementia SL	4					
										Raise and review issue at Division 4 Steering Group	Div 4 RDM	4					
										To work with SL and IMH to look for ECR and grow our own PIs/CIs to generate our own studies	Div 4 RDM	4					
R048	Information	Jun-19	DCOO	Lack of visibility of performance data for all studies/sites, due to changes in data upload methods, making it difficult to manage key metrics (esp. HLO 1A&B, 2A&B, HLO7 and 9)	**Cause:** Change in systems from central to local upload has resulted in lack of local visibility, not helped by ODP not displaying full data in an accurate way. **Effect:** We don't have an accurate reflection of our current performance, which makes it difficult to plan and understand our local landscape.	4	3	12	Jun-19	Lobby the CRNCC nationally to address this issue of how data is shared with LCRNs	DCOO/ COO	4	3	3	9	Open	Decreased
										Communicate this to our Partners, and seek to explain how and when this will improve	Comms Lead/STL /DCOO	4					
										Continue to work locally with our LPMS systems, including implementation of our data quality strategy, key link through TLAs	BDM/ DCOO	4					
										Ensure we are ready for Phase 2 of the integration work in relation to comms and training for CIs in region	BDM/ DCOO	5					
										Work with partners to consider whether we can easily obtain RA data from local systems in the interim	BDM/ DCOO	5					
										Now that RA confirmation is live, to continue our relationships with regional CIs	BDM/ DCOO	4					
										Continue checking verified data closely over Q2	BDM/ DCOO	4					
R049	Performance	Sep-19	IOM	CRN EM will not deliver against HLO1B target for 2019-20 (Number of participants recruited to commercial contract NIHR CRN Portfolio studies) Currently 66% of YTD Target	**Cause:** Multiple: Lack of high recruiting commercial studies; large number of studies with lower targets and annual target set is significantly higher than EM baseline. **Effect:** Potential reputational impact for the region, if viewed that we do not deliver for commercial, companies will; be reluctant to place studies with us. Additionally, we will have to report non-compliance for this new HLO.	4	3	12	Mar-20	Conduct analysis of top 20 recruiting studies nationally	IOM	5	4	3	12	New	New
										Explore options with Sr Nurse to target additional resource at high sample size studies within the region	IOM/SN	4					
										Work needed to verify/check data as due to recent system changes, some anxiety around this	IOM/ DCOO	3					
										Work needed to understand if we have sufficient studies/targets to achieve this, or not, to give realistic plan	IOM	3					

										Ensure that all Senior Managers are aware of this issue as part of the regular monthly performance meetings with DCOO	IOM/ DCOO	4					
										Senior Team Links to work with partner organisations to promote the importance of this measure and link with IOM for action plans	STL/IOM	3					
R050	Performance	Sep-19	IOM	CRN EM will not deliver against HLO2A target for 2019-20 (proportion of commercial studies delivering to time & target) Currently 79% (target: 80%)	**Cause:** Multi-factoral - one of the biggest is historic studies within cancer, Div 1 with high targets which are not well performing; changes also in CC management **Effect:** Future budget impact - Budget: 5% of next year's funding is linked to this performance, also, may impact on any future RCF for trusts; Reputational: damage to East Midlands reputation and impact upon loss of future commercial contract research for the region; Compliance: will have to record underperformance against a HLO measure under NIHR CRN CC-Host contract.	4	3	12	Mar-20	Regular progress review meetings as part of HLO2A reporting schedule	IOM	4	4	3	12	New	New
										Increased involvement with partners in performance calls	IOM	4					
										Focus on early engagement specifically in Oncology at UHL and NUH	IOM/RDM Div 1	3					
										Develop a post for performance in commercial studies, based on the model for HLO2b.	IOM/ SSS OM	3					
										Ensure metric is discussed at monthly performance meetings and action plans to be developed with divisional managers and DCOO	IOM/DM/ DCOO	4					
										Update partner organisations regularly not only from an individual organisation perspective but as a network wide issue and potential effects on budget	DCOO/C OO/STL	3					
R051	Performance	Sep-19	DCOO	CRN EM will not deliver against HLO2B target for 2019-20 (proportion of non-commercial studies delivering to time & target) Currently 100% (target: 80%)	**Cause:** Some locally led studies which did not come through pipeline from the beginning, for feasibility support etc. or more independent CIs **Effect:** Budget: 5% of next year's funding is linked to this performance, also, may impact on any future RCF for trusts; Reputational: damage to East Midlands reputation for research delivery; Compliance: will have to record underperformance against a HLO measure under NIHR CRN CC-Host contract.	3	3	9	Mar-20	Monitor closely studies at high risk of not meeting time and target and implement action plan for recovery where possible	DCOO/ PM	4	3	3	9	New	New
										Ensure metric is discussed at monthly performance meetings and action plans to be developed with divisional managers and DCOO	DM/IOM/ DCOO	4					
										Update partner organisations regularly not only from an individual organisation perspective but as a network wide issue and potential effects on budget	DCOO/ COO/ STL	3					
										Ensure that performance is discussed at Early Contact meetings to ensure accurate targets and responsibilities are highlighted as soon as possible.	SSS Team	3					
R052	Performance	Sep-19	IOM	CRN EM will not deliver against HLO6B target for 2019-20 (proportion of NHS Trusts recruiting into commercial NIHR studies) Currently 56% (target: 70%)	**Cause:** Multi-factoral - Low number of suitable studies for Healthcare, Partnership & Community Trusts, challenging studies to set-up at some sites, reduced number of investigators, Trust restructuring. **Effect:** Recorded by the NIHR CRNCC as underperformance against a HLO measure. Potential reputational risk. At present there is no financial impact.	4	2	8	Mar-20	Review pipeline for potential studies in mental health, dementia and community setting	IOM/ RDMs	4	4	2	8	New	New
										Support set-up of existing studies at relevant Trusts	IOM	4					
										Conduct analysis of the non-commercial research at relevant Trusts to identify opportunities to undertake commercial studies	IOM	**4**					
										Conduct analysis of submitted EoIs to identify reasons for non-selection and areas for improvement	IOM	**3**					
										Senior Team Links to engage with Partners re developing plans for commercial research	IOM	4					
										Identify commercial partners and target for raising the profile for the East Midlands and encourage use of naive and less experienced sites	IOM	3					

SCORING:

	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*
6-11 YELLOW = MEDIUM
12-19 AMBER = HIGH
20-25 RED = EXTREME

Action RAG Status Key:

Complete	5
On Track	4
Some Delay – expected to be completed as planned	3
Significant Delay – unlikely to be completed as planned	2
Not yet commenced	1

***Only risks with an Inherent Risk of 6 or above are recorded on this Risk Register**
*** Risks with a scoring of 12 and above should be monitored and escalated**