CRN East Midlands Quarterly Board Update

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Trust Board paper K

Purpose of report:

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

Previous consideration:

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

This report was reviewed by CRN East Midlands Executive Group on 10 June 2021.

Executive Summary

Context

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

For the information of the Board, we have prepared this quarterly update on the recent progress and current priorities of CRN East Midlands. This report includes content regarding our 2020/21 year-end position and some updates relating to progress this financial year (2021/22). Furthermore, we would like to request formal Trust Board approval for some of our key planning and reporting documents, as set out in the following section.

Questions

1. Since our last report, what have been the key areas of progress for CRN East Midlands (at year-end and in the current financial year) and do the Board require any further information or assurance in relation to this?

2. What are the main risks and issues currently affecting CRN East Midlands and does this paper provide sufficient assurance as to mitigating actions?

Conclusion

1. This report provides an update on regional Urgent Public Health (UPH) research and recovery of the CRN portfolio. The report also includes commentary pertaining to our year-end (2020/21) and current financial position, along with our year-end contribution to the CRN Performance Standards. The report is supplemented by the appendices in the table below, which describes specific actions required by the Trust Board.

Appendix	Paper	Action required by Trust Board
1	Finance Update: Year-end (2020/21) and current (10.6.21) position	For information only
2	LCRN Annual Report 2020/21	Requires Trust Board approval
3	LCRN Annual Plan 2021/22	Requires Trust Board approval
4	LCRN Governance Framework: annual update (updates are shown as tracked changes)	Requires Trust Board approval
5	Current risks and issues register	For information only

2. Our risk register is attached at Appendix 5 to the report. The risk relating to a potential underspend for our 2021/22 budget is being well managed and the overall risk score remains quite low. A new risk has been added in relation to uncertainty over our future budget as the LCRN finance methodology for 2022/23 LCRN budgets (often linked to performance) is not known. There is little ability for us to influence this and this is medium risk, with mitigating actions in place. Another new risk is that recovery of the CRN portfolio could be negatively impacted in the event of a further wave of COVID-19. This is medium risk and mitigating actions are set out on the risk register. Currently, there are no open issues on our issue register.

Input Sought

We would welcome the Trust Board's input to review our report and provide any comments or feedback you might have. Furthermore, the following documents require formal Trust Board approval:

- LCRN Annual Report 2020/21 (Appendix 2)
- LCRN Annual Plan 2021/22 (Appendix 3)
- Annual update to LCRN Governance Framework (Appendix 4)

For Reference

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

1. Quality priorities

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

2. Supporting priorities:

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

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

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

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

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

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

4. Risk and Assurance

Risk Reference:

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

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

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

NIHR | Clinical Research Network East Midlands

CRN East Midlands - Quarterly Board Update, 23 June 2021

1. Introduction

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. This report includes the following items:

- an update on regional Urgent Public Health (UPH) research, and recovery of the CRN portfolio;
- our year-end (2020/21) and current (10.6.21) financial position (Appendix 1);
- our year-end (2020/21) position with respect to the CRN Performance Standards;
- LCRN Annual Report 2020/21 (Appendix 2) - **requires Trust Board approval**;
- LCRN Annual Plan 2021/22 (Appendix 3) - **requires Trust Board approval**;
- our updated LCRN Governance Framework (Appendix 4) - **requires Trust Board approval**;
- an update on our current risks and issues register (Appendix 5).

This report is reviewed by the CRN East Midlands Executive Group in June 2021 and is submitted to UHL Trust Board for review in July 2021.

2. Update on Urgent Public Health (COVID-19) research and recovery of the CRN Portfolio

As the caseload of COVID-19 patients has fallen over recent months, we have continued with our work to support the recovery of the wider CRN portfolio of research studies. Notably, the national process for designating studies as Urgent Public Health (UPH) research has now been stood down. Existing UPH studies remain an area of focus, however, these COVID-19 studies are now treated as a speciality alongside other specialities as part of managing a diverse portfolio. New COVID-19 portfolio studies will be supported in line with local priorities and capacity, alongside studies into other disease areas.

On 1 April 2021 we entered the second phase of the DHSC Recovery, Resilience and Growth (RRG) programme, which has three key challenges:

1. Reduce emphasis on our UPH portfolio
2. Enable an orderly recovery of the non-Covid portfolio
3. A strong focus on UK Life Sciences

We are focussing on the most urgent non-Covid studies in a phased way, at a time and pace appropriate to the recovery of NHS services and NIHR infrastructure. This approach is time limited to the context of managing the rapid and ordered recovery of research studies and is founded upon the principles of partnership, improved patient outcomes and economic benefit.

The NIHR has been working with both commercial and non-commercial research funders and partners across the UK's research system to develop a plan to manage the recovery of those studies that require support over the next 6-12 months. As of 26 May, 118 studies have been identified to receive support via this process. Locally we are working with our partner organisations to ensure that as studies are identified as part of the formal managed recovery process, they can be restarted.

3. Financial Position

In line with both UHL and CRNCC expectations, the 2020/21 financial year has been closed and fully reported through both routes. It has been a very challenging year, managing the fluctuating priorities as the pandemic unfolded. It has also been difficult to manage a number of additional funding streams in-year with further unplanned funding provided to LCRNs.

At year end, the CRN (and thus Host) reported a small underspend of £58,985, which had arisen in one of our Partner Organisations. Unfortunately full assurance of qualifying expenditure could not be provided at year end. Towards the end of last year the CRN supported the Partner Organisation through the undertaking of a financial health check and a number of supportive actions have been offered to improve reporting and ensure this situation is not repeated.

With respect to the current financial year, as previously reported, the East Midlands will be in receipt of c.£2M additional CRN funding. Budget plans have been submitted and approved for this additional income, with good progress being made against these plans. A summary finance report can be found at Appendix 1.

4. LCRN Annual Report 2020/21

CRN East Midlands Annual Report 2020/21 is attached at Appendix 2 of this report. We have developed this report in line with guidance set by the NIHR CRN Coordinating Centre in respect of structure and content. This short document reports on our activities across six areas and the content is framed in the context of how we contributed to/achieved success in difficult circumstances due to COVID-19. The report has been considered and agreed by CRN East Midlands Partnership Group and was submitted to the CRN Coordinating Centre on 23rd June 2021. It is now submitted to the Trust Board for formal approval. We would like to thank UHL for hosting the CRN East Midlands and providing support to the Network over the last year.

5. CRN Performance Standards 2020/21

As we have reported to the Board previously, our performance priorities for this year have been incorporated into a set of slimmed down Performance Management Standards. These are ambitions rather than targets. Our final year-end performance is presented in the following table.

Objective	Ambition	Year-end East Midlands Performance
New Commercial Studies recruiting to time and target	70%	100%
Provider Participation in Research	(A) NHS Trusts - 100%	100%
	(B) Commercial Activity in NHS Trusts -70%	56%
	(C) Research Activity at GP Practices - 45%	56%
	(D) Non-NHS Organisation Active Research Sites - National Target 2250	42
Research Participant Experience	12,000 (National) 400 (East Midlands)	1,177
Urgent Public Health Study Set Up	9 Days	2 days
Restart of studies paused due to the pandemic	80%	72%

As referenced in the table above, there are two areas where regional performance was slightly lower than the performance standard. However, due to the pandemic this was not a contractually managed element last year, and the outturn data represents the competing priorities during the year. There is no impact to the Host for this.

6. LCRN Annual Plan 2021/22

CRN East Midlands Annual Plan 2021/22 is attached at Appendix 3 of this report. The document has been completed in the format of a mandatory template issued by the CRN Coordinating Centre. The content requirements have been slimmed down this year, meaning it functions largely as an assurance document rather than a detailed plan. The plan has been considered and agreed by CRN East Midlands Partnership Group and was submitted to the CRN Coordinating Centre on 28th May 2021. It is now submitted to the Trust Board for formal approval.

The plan includes information in relation to our compliance against the CRN Performance and Operating Framework (POF) and our contribution to the CRN High Level Objectives. Additionally, it outlines our planned activities to contribute to the CRN National Priorities, key local initiatives and our financial management approach for 2021/22. This assurance based approach is underpinned by a number of supporting plans, such as Comms & PPIE, NHS/Partner Engagement, Workforce Development, Business Development & Marketing regional profile, along with project specific plans. If any colleagues are interested in further discussing these, please feel welcome to get in touch (see page 5 for contact details).

7. LCRN Governance Framework

CRN East Midlands Governance Framework (Appendix 4) 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 have been a number of minor governance and administrative changes. In addition to annual updates, the Framework has also been updated in line with recent audit findings, where there was a requirement to ensure CRN authorisation limits were in line with those within the Host. As such, this section has been updated in line with the Host Trust scheme delegation. All other audit findings are in hand and due to be completed on time. The updates are shown as tracked changes in red text to make them visible. This document has been reviewed by CRN East Midlands Executive Group and is provided to this Trust Board for formal approval.

8. Risks & Issues

Risks and issues are formally reviewed through the CRN Executive Group chaired by Andrew Furlong. A risks & issues register (Appendix 5) is maintained with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Coordinating Centre (CRN CC).

Risks and issues are recorded on the register as follows:

- Risk #59 - risk of a potential underspend for CRN East Midlands budget for 2021/22 due to a significant uplift in funding. The risk probability remains scored as unlikely as a number of actions have been taken to plan and manage the additional funding. The risk impact is scored as moderate meaning the overall risk score is still relatively low.
- Risk #60 (new risk) - As at 02.06.21, the LCRN finance methodology for 2022/23 LCRN budgets (often linked to performance) is not known, which presents a potential risk to our future regional budget and an inability to influence this. The risk probability is currently scored as possible and the risk impact is scored as moderate meaning the overall risk score is medium. It was discussed at the CRN Executive Group that there is little ability to

influence this, although it still remains as a risk, with mitigating plans being made against this.

- Risk #61 (new risk) - The recovery of the CRN portfolio could be negatively impacted in the event of a further wave of COVID-19. The risk probability is currently scored as possible and the risk impact is scored as moderate meaning the overall risk score is medium.
- There are no open issues on our issue register.

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

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

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: CRN EM EXECUTIVE COMMITTEE

DATE: 10th JUNE 2021

REPORT FROM: MARTIN MAYNES – HOST FINANCE LEAD

SUBJECT: CRN EM FINANCE UPDATE

1. Purpose

This report provides an update on the following issues:

- 20/21 financial out turn
- 21/22 financial plan

2 2020/21 Finance Out Turn

The table below summarises the 20/21 outturn position and key variances to the opening plan.

	2020/21 Annual Plan	Actuals	Variance
	£'000	£'000	£'000
Income			
NIHR Allocation	21,008	21,934	926
Expenditure			
Network Wider Team	540	478	-62
Host Services	350	350	0
Management Team	753	712	-41
Study Support Service (SSS) Team	537	513	-24
Research Study Team (RST)	548	487	-61
Clinical & SG Leads	97	110	13
Research Site Initiative	798	784	-14
Primary Care Service Support Costs	200	69	-131
Vaccine Delivery Funding	0	396	396
Partner Organisation Infrastructure	16,580	17,412	832
ETC	0	93	93
CRN EM Non Pay Non Staff	188	162	-26
Innovation Fund	418	313	-105
Total	**21,009**	**21,878**	**869**
Underspend		**56**	

The main points to note are as follows.

Income
Additional non recurrent income of £926k was received for ETC, UPH and to deliver vaccine delivery research, broken down as follows:

- Urgent Public Heath - £429k
- Vaccine Delivery - £349k (net of £150k to be returned as not required)
- Excess Treatment Costs - £148k

Primary Care Support Costs
This budget has been discussed at the FWG and the underspend has been released due to decline in recruitment as a result of the pandemic.

Vaccine Delivery
As part of the COVID 19 pandemic the CRN initially received £497,984 to set up 10 studies. However, as the project progressed, only four studies were set up due to various reasons. As a result £150,000 will be returned to the centre.

Partner Organisation Infrastructure
The overspend against the original plan is due to reallocating the funding to support UPH.

Innovation Fund
The Innovation fund was unable to be fully utilised as planned due to the pandemic and as a result underspend was released and recycled to other areas such as COVID 19 overtime and other priorities.

Non Pay
Many of the other budgets have spent less than planned because of a reduction in non pay. This is as a result of CRN staff working from home, and much less travel and physical meetings and conferences than the previous year.

£56k Underspend
This was caused by the fact that some PO's did not have their ETC expenditure/invoices recognised in time for the 20/21 accounts closedown process. It has been agreed that UHL will pick this cost up in 21/22 so POs will still receive the expected funding. Lessons have been learned to avoid this issue in future.

Post Accounts Note re Partner Organisation
After the year end closedown one Partner Organisation issued a credit note for £58k relating to delivery funding. This will be returned to NIHR in the current financial year.

3. 2021/22 Finance Position

The latest financial position and forecast as at April 2021 updated financial plan for the CRN for 21/22 is set out in the table below.

		Apr-21		
	Annual Plan	YTD Actual	Forecast Expenditure	Variance
	£'000	£'000	£'000	£'000
Income				
NIHR Allocation	22,303	1,940	23,276	974
Expenditure				
Network Wider Team	682	56	679	-3
Host Services	350	27	350	0
Management Team	797	58	807	10
Study Support Service (SSS) Team	493	44	525	32
Research Study Team (RST)	538	37	771	232
Clinical & SG Leads	126	12	126	0
Research Site Initiative	795	0	790	-5
Primary Care Service Support Costs	100	8	100	0
O11 - CRN EM ADDITIONAL FUNDING	740	2	1,358	617
Partner Organisation Infrastructure	17,040	1,384	16,907	-133
ETC	0	0	0	0
CRN EM Non Pay Non Staff	191	17	184	-7
Innovation Fund	450	0	501	51
To be allocated			180	180
Total	**22,303**	**1,645**	**23,276**	**974**

Key issues are summarised below.

Income
The initial indicative funding allocation communicated by the coordinating centre in March 2021 was £22,302,510. However, subsequently the allocation was updated in April 2021 as £23,276,499. The favourable movement is made up of additional funding for the transformation programme (£909k) and PH prevention research funding (£65k).

Research Study Team
There is a favourable variance in RST team is £11k due to a Senior Research Nurse being on half pay and two new posts slipping in recruitment by a month. However there is also significant additional funding to support the transformation team to deliver new roles and responsibilities.

Additional Funding
This contains two funding streams -Recovery, Resilience and Growth (RRG) - £740k for which bids are being reviewed, decisions made and POs are informed on an ongoing basis. The second funding stream is the balance of transformation funds - £617k, of which £194k has been committed and plans are being drawn up to utilise the remainder of the funding.

Partner Organisation Infrastructure
The current forecast underspend reflects the fact that most of the cost pressure funding within the network has not yet utilised as the pay award for NHS staff for 21/22 has yet to be announced. There are also multiple staff changes with the Partner Organisations. It may well be that expenditure against this budget will revert to plan as the financial year progresses.

To Be Allocated
There remains £180k of the new funding which remains to be allocated. This is not unexpected given that the funding has only recently been confirmed.

4. Recommendations

The CRN Executive Committee is asked to:

- Note the 20/21Out Turn
- Note the 20/21 Financial Forecast

Appendix 2

CRN East Midlands 2020/21 LCRN Annual Report

Section 1. The LCRN's contribution to three Category 1A or Category 1B Urgent Public Health (UPH) Research Priority studies of our choice

The East Midlands has demonstrated a significant contribution to the Category 1A RECOVERY study (ID 45388), with over 4,000 participants enrolled across the region. All of our trusts have been fantastically responsive and flexible to the initial, and then additional, request to commit resources and support to this very important study, with often a consistent average of at least 16% of positive cases enrolled, at some sites over 25%. In addition to the exceptional performance of our Host trust, the University Hospitals of Leicester NHS Trust (UHL) as the exemplar site for this, with many other trusts seeking their advice, we consistently had three of our trusts in the top ten national contributors. We would wish to acknowledge Nottingham University Hospitals NHS Trust and Northamptonshire General Hospitals NHS Trust, along with Chesterfield Royal Hospitals NHS Trust who for the size of trust made a phenomenal contribution to the national effort.

The delivery of a range of COVID-19 vaccine studies (Category 1A) should also be noted as a highlight. There has been excellent collaborative working between primary care, secondary care, and mental health research colleagues, along with the Leicester NIHR Patient Recruitment Centre (PRC). Key to the success of these studies has been the appointment of four dedicated Vaccine Project Managers who supported the sites and coordinated regional efforts. Notable success was demonstrated in ENSEMBLE 2 (ID 46804) at the Leicester PRC; Valneva (ID 48118) at Nottingham University Hospitals; Medicago (ID 47462) (halted early by Sponsor) at the University Hospitals of Derby and Burton; Novavax (ID 46787) and Valneva (ID 48118) at Lakeside (GP site), along with COV002 (ID 45551), COM-COV (ID 48289) and COM-COV 2 (ID 48968) at Cripps (GP site). Although these site names are listed, the effort has been truly regional, involving staff from a much larger pool of organisations, along with the CRN Research Support Team (RST) and Primary Care team, whose response to the need for flexibility and responsiveness has been first rate.

The network enabled the rapid set up and delivery of 2 UPH badged studies where we were the Lead CRN - PHOSP Covid (ID 46443) the first long covid study and UK REACH (ID 47157) across the 15 LCRNs and Devolved Administration (DA) sites. Regular meetings were held between the study team and relevant LCRNs/DAs to aid smooth delivery of studies, address any issues quickly and monitor recruitment levels. Good support was also established with our CRN Comms manager who provided a seamless service with a robust communication plan between the CI/study team, the NIHR CRN Coordinating Centre (CRNCC) and the other LCRN/DA colleagues across the nation. Both studies continue to deliver well.

Section 2. Challenges recruiting to Urgent Public Health (UPH) Prioritised studies

Overcoming barriers: a range of different barriers were identified, the network worked with partners to seek solutions

- Communication was addressed and improved through regular dialogue and consistent messaging, including: establishing weekly meeting with R&D Leaders in the region; developed a weekly bulletin with all NIHR updates; tailored bulletins for Specialty Leads; set-up an on-call rota to ensure partners always had a point of contact for escalations
- A cluttered portfolio: initially it was very difficult to prioritise studies and for CRN to be clear on expectations, with a feeling of overwhelm for many Partner Organisations. Competing studies were also unhelpful, however a streamlining of studies, and the emergence of platform studies helped; the opportunity to co-enrol patients into more than one UPH study was also very welcome.

Portfolio balance

- With a portfolio very focussed on acute, treatment-based studies, and later vaccines, there was a significant gap on mental health UPH studies; this still remains the case, with some of these aspects of the pandemic not well explored. For research delivery teams in these settings there was a sense of frustration, however offering opportunities such as the ISARIC study (ID 14152) to these trusts was welcomed.
- Many of these organisations played a key role in relation to embracing true partnership working. CRN funded research staff in many of the non-acute sites stepped up to support UPH delivery in other areas, of note would be staff in Lincolnshire Partnership NHSFT (LPFT) supporting United Lincolnshire Hospitals, especially with the ISARIC study (ID 14152); Nottinghamshire Healthcare NHSFT supporting vaccine work at the Cripps Medical Centre & the SIREN study (CPMS 45906) at Sherwood Forest NHSFT (SFH); in Northamptonshire, staff from Northampton General Hospital provided resource at Lakeside for the delivery of Novavax (CPMS 46787) and in Leicestershire support for the ENSEMBLE 2 study (CPMS 46804) provided through the Patient Recruitment Centre (PRC), UHL (as host) and from Leicestershire Partnership NHS Trust.

Section 3. Workforce

Workforce was the most challenging element of our response to the pandemic, with a range of responses required for different aspects, this seeks to summarise some of these.

Central delivery resource: RST and Primary care

- Our most flexible resource was used exactly as intended, our Research Support Team (RST) and primary care staff members have been incredibly responsive and open to working in many different ways as was required. This included working in red/hot covid areas of trusts, working on many different wards and settings, and constantly changing placement to meet changing demands and movements across other areas of the workforce.
- The successful county-based model for these teams has been invaluable to this approach, and will be further built upon for the Direct Delivery Team in 2021/22.
- As soon as the call for vaccines work came, the network ensured all RST members were trained in vaccine studies, in readiness for these essential trials.
- Within RST we also supported a number of shielded staff who were assigned work that could be done from home. Primarily this was study related (e.g. data management) where this could be done remotely. The return to work at the end of shielding was also managed carefully, as these staff members did play a key role in our regional response.

Partner organisation initiatives

- In acute trusts, the primary pull on workforce was into covid front line care, and naturally research staff, especially nurses and medics, were asked to contribute to this on a number of occasions. Additionally, in some of the non-acute trusts, staff were asked to work in second line roles to support the front line such as co-ordinating PPE and as part of county-wide responses to testing provision.
- All partner organisations took the view that the research workforce should be focused on research, especially UPH studies, wherever possible. However, during the first wave, and then again in the second, there were times when ICUs were significantly over-stretched and where qualified staff wanted to give their time and skills to the wider effort, which as a CRN we supported.
- Partner organisations worked in many diverse ways, which have included the use of junior medics and academics to support delivery; accessed the GP returner list (although not actively used); some organisations also made use of retirees and returners in the region.

- Specific examples include that UHL pooled all research staff (all NIHR and wider), and deployed them as a collective workforce to support UPH studies; SFH implemented 7 day working to ensure recruitment to RECOVERY (CPMS 45388) and REMAP-CAP (CPMS 38197), and for studies such as SIREN (CPMS 45906) both SFH and LPFT trained staff new to research, such as phlebotomists, to get involved in straightforward tasks (such as blood taking), which then developed into these staff getting more involved in the delivery of these studies, thus expanding their workforce.
- Partner Trusts also had programmes to support shielding staff and as a CRN, we made sure staff were aware and could access this additional support.

Central CRN functions & central staff

- Within the core team a number of staff undertook tasks which were not part of their primary role, the priority of our existing work was balanced against the relative priority of the additional task and the stage of the pandemic. Work undertaken included: ITU work in a nursing capacity (Deputy Chief Operating Officer and Business Delivery Ops Manager); rapid study set up at an acute hospital (Project Manager); support with phlebotomy and CRF completion for the SIREN study (SSS Facilitator).
- In the CRN workforce development function, activity was diverted to support the regional and national efforts on UPH/vaccines, specifically this included: supporting the creation of the national vaccine training matrix and promotion to partners; work locally to lead on the genetically modified organism (GMO) content for this on NIHR Learn; specific workforce plans were also created for each vaccine trial running in the region.
- Team Wellbeing was another aspect which we prioritised during the pandemic, to develop a sense of community and shared purpose for the core team. A comprehensive programme of wellbeing was put together which included regular meetings with the whole team and sub-teams; listening events in relation to returning to the office; exercise and breaks from screen-time being advised; regular birthday singing (groan!) and fun events such as a murder mystery night, quizzes and bingo at the virtual pub, “The Treatment Arms”. We were mindful of very different working patterns with some staff working from home, some shielding and others working in clinical settings, it was important to try to keep the team connected.

Section 4. Restart and Partner organisation engagement

Within weeks of the UK lockdown and declaration of a pandemic, the CRN East Midlands Urgent Public Health Plan and Business Continuity Plans had been triggered. Two specific groups had formed, one focussed on internal working and the other managing wider impacts, these groups would later come together as one. By early April 2020 we had developed and enacted our response plan to support with team re-organisation and aid our working approach. This plan was formally stepped down on 1 December 2020. These documents which clearly outline the rationale and priorities for the internal Red and Blue Teams were essential in ensuring both a co-ordinated response to UPH, and allowing sufficient focus on what became a new BAU and then Restart. It also supported us through the second wave of Covid-19, when there was no need to make this specific provision, as we had moved into a new business continuity phase. The team cannot be praised enough for their responsiveness and adaptability to a different way of working throughout this time.

To ensure there remained space in the conversations with partners for restarting and non-covid work, we continued and strengthened the role of the Senior Team Link to support two-way partner dialogue. Through this we were keen that BAU and Restart were on the agenda and to understand potential blocks and identify enablers to support the restarting non-UPH research. Together with partners, the network also developed specific forums and meetings, such as the UHL/CRN roundtable meetings as a vehicle for open discussion across our respective Leadership teams.

To aid with Restart, it was also important to maintain and grow our workforce development/ learning provision. We adapted a lot of our existing training offers and were able to offer these through virtual, online platforms. Additionally, the team continued to deliver engagement events such as those for specialty leads, R&D finance teams and a range of other training and development opportunities, adapting to new ways of delivering virtually.

Once commercial, non-covid, work had begun to restart, the CRN EM Industry Operations Manager (IOM) took on the role of chairing of the national CRN IOM meeting along with Business Development, initially weekly. This ensured a consistency of messaging to Industry and sharing of on the ground intelligence to support accurate feedback to Industry.

Section 5. Patient and Public Involvement and Engagement (PPIE)

As a result of the pandemic, the network adopted a different approach to the Participant in Research Experience Survey (PRES) for 2020/21. This involved identifying studies being delivered as part of the research response to COVID-19, and integrating PRES within those specific studies. For the sake of easing the burden on research delivery teams and respecting concerns around infection control, this primarily included two types of study: COVID-19 vaccine research studies and UPH studies with a strong digital focus, which enabled participants to complete a digital version of the PRES.

A full report has been produced, however headline data demonstrates broad satisfaction and enthusiasm for research from the respondents, with key findings that:

- 95% of respondents strongly agreed/agreed that they felt researchers valued their taking part in the research
- 99% of respondents strongly agreed/agreed that researchers always treated them with courtesy and respect
- 97% of respondents strongly agreed/agreed that they would consider taking part in research again

Participants also provided a range of insights and suggestions based on their experience, some of which have been captured and changes made to research delivery practice, others which will be used to inform the development of research practices in due course to ensure research is as enjoyable, effective and efficient as possible for all taking part.

In addition to the adaptations to PRES for 2020/21, other changes were made to our approach to participation, including the moving of Research Champions (RCs) support and involvement to online meetings, supporting RCs to become part of a national digital community, and involving RCs in analysing results from PRES (particularly improvement suggestions).

Other engagement activities are detailed below, in relation to work undertaken with the Leicester Centre for BME Health to raise awareness and involvement in research across wider communities.

Section 6. Selected non-COVID-19 LCRN achievement

In the East Midlands, we remain committed to seeking digital solutions and improvements to research delivery. Last year we produced a short report which outlined some of the progress made against our Digital Maturity Proposition. The work done with this will support us well in our Transformation work as we will have a specific program which will support us in seeking digitally enabled solutions to further support research delivery, as detailed in our 2021/22 Annual Plan.

Also in relation to digital work, a dashboard has been developed for TYA. Over the past few years, we have struggled to see growth in Teenage and Young Adult (TYA) access and participation in cancer research. We have a very keen specialty lead and several TYA specialist nurses, however it has been very difficult to know what impact was being made. We held a meeting with a number of key stakeholders in the region, and the overwhelming theme was that there was limited knowledge of what trials were available that were suitable for TYA. In conjunction with local teams, a simple dashboard was developed which was web based and could be used on any device. The idea was to use this in multidisciplinary team (MDT) meetings and be able to quickly identify suitable trials. It has been extremely successful and several participants have been included in trials because of the dashboard. Several other LCRNs have also engaged with our team to identify how it is working and there are others who have similar tools, a national group of interested parties has also been developed. As part of that group, the CRN have engaged with the NIHR Experimental Cancer Medicine Centre team who have also developed a similar tool for all early phase trials, this has led to national discussion with the NIHR CRNCC Head of BI and we are taking forward a proposal to NHS Digital as part of the NIHR wide strategy, as it is quite clear that there is a national need for tools such as this, and needs to be wider than one type of trial or specialty.

In addition to regional work, the East Midlands CRN is always keen to collaborate on areas of national work, making a network-wide contribution. During 2020/21 this included the Clinical Director and Chief Operating Officer, working with the NIHR CRNCC and Leicester Centre for Ethnic Health, to deliver a comprehensive package of support, as described in this collaboration project summary. Outputs from this work included:

- Established a UK-wide network of clinicians, Chaired by CRN EM Clinical Director
- Developed information resources video library which were released on NIHR.tv on youtube
- Developed and released NIHR Learn training modules

Additionally, members of our team were involved in the capacity as Co-Business Lead (CRN East Midlands Chief Operating Officer) and Project Manager in leading and supporting the UK COVID-19 Vaccine Research Delivery Programme (June 2020-Jan 2021), which has had a significant impact on the global research response to the pandemic.

Appendix 3

NIHR | Clinical Research Network East Midlands

Clinical Research Network East Midlands

Annual Plan 2021/22

Document date: 28 May 2021

Contents

Section 1. Contract Compliance

This section provides CRN East Midlands' RAG compliance status against the mandatory requirements of the NIHR CRN Performance and Operating Framework.

RAG Status	
Green	Fully compliant with all mandatory requirements within 2021/22
Amber	Compliant with some but not all mandatory requirements within 2021/22
Red	Not compliant with any of the mandatory requirements within 2021/22

Plan Ref	POF Section		RAG	Comments
1.1	C.2.	General Management	Amber	POF section C.2.1.5 - we are not compliant with the expected minimum meeting frequency of the Executive Group (as set out in CSD088). In accordance with our LCRN Governance Framework (signed off annually by the Host Trust Board) our Executive meets formally every 3 months, although with correspondence in between, as needed. This aligns with our agreed reporting arrangement, as the CRN submits a report to the Host Trust Board on a quarterly basis, with the Clinical Director and Chief Operating Officer attending the Board each quarter. Currently, we feel that the expectation for the Executive Group to meet every month is disproportionate to the current needs of the LCRN & Host and would not add sufficient value to be justified. Also, we have strong support from our Host, as such we intend to continue with existing arrangements, although are happy to further discuss. POF section C.2.1.6 - the Partnership Group approves the planned approach for the Annual Financial Plan (AFP) each year, it is discussed, agreed and minuted as such. This includes allocations to partners. However, due to the very detailed nature of the planning tool, and the membership of the Partnership Group full access to the finance tool, or a detailed breakdown of the AFP is not discussed and formally agreed. Additionally, all partners are required to submit their own AFP, which is formally agreed and approved.
1.2	C.3.	Financial Management	Green	N/A
1.3	C.4.	CRN Specialties	Amber	POF section C.4.1.4 (Undertake analyses to identify disparities between local health and care needs and the local research portfolio in all CRN Specialties) - this will require further work in-year to be considered fully compliant, although this work is planned, please see Section 4 (LCRN Initiatives) for further detail.
1.4	C.5.	Research Delivery	Green	N/A
1.5	C.6.	Information and Knowledge	Green	N/A
1.6	C.7.	Communications	Green	N/A
1.7	C.8.	Patient and Public Involvement and Engagement (PPIE)	Green	N/A

1.8	C.9.	Health and Care Services Engagement	Green	N/A
1.9	C.10.	Workforce Learning and Organisational Development	Green	N/A
1.10	C.11.	Business Development and Marketing	Green	N/A

Section 2: High Level Objectives

Plan Ref	Objective		Measure	Ambition	LCRN Target	How target has been determined and supporting rationale	Contribution
2.1	Efficient Study Delivery	Deliver NIHR CRN Portfolio studies to recruitment target within the planned recruitment period	(1) Proportion of new commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed CRN sites	80%	N/A	N/A	Over the past 3 years, in collaboration with partners, CRN East Midlands have routinely delivered c. 80% of studies to time and target for both commercial and non-commercial studies. We aim to continue in our approach, both in relation to new studies and those within managed recovery.
			(2) Proportion of commercial contract studies in the managed recovery process achieving their refreshed and agreed recruitment target within the newly set time period	80%	N/A	N/A	See above
			(3) Proportion of non-commercial studies in the managed recovery process achieving their refreshed recruitment target within the newly set time period	70%	N/A	N/A	See above, despite the target at 70% for this, we will aim for 80% in the East Midlands
2.2	Provider Participation	Widen participation in research by enabling the involvement of a range of health and social care providers	(1) Proportion of NHS Trusts recruiting into NIHR CRN Portfolio studies	99%	N/A	N/A	We have routinely achieved this, working in partnership with NHS Trusts, and will continue to do so.
			(2) Proportion of NHS Trusts recruiting into NIHR CRN Portfolio commercial contract studies	66%	N/A	N/A	Community trust, commercial growth plan - specific project plan in place with partners, currently in the process of confirming CRN resource requirements for this

			(3) Proportion of General Medical Practices recruiting into NIHR CRN Portfolio studies	45%	N/A	N/A	Through CRN leadership in primary care, use of primary care delivery team and the Research Site Initiative (RSI) scheme. Also will bring in the pilot PCN work currently in train. Further details can be provided as are required.
2.3	Participant Experience	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 Participant Research Experience Survey, each year	12,000	TBC	TBC	Within PPIE and Engagement plans for the year, targets currently under discussions nationally

Section 3: CRN National Priorities

This section details CRN East Midlands' planned contributions to the CRN National Priorities for 2021/22

Plan Ref	Priority Activity	Description of planned contributions
COVID-19 Research		
3.1	Deliver new and existing activities relevant to the research response to the COVID-19 pandemic a) COVID-19 Vaccine studies b) COVID-19 Non-Vaccine studies	This remains a key priority for the East Midlands CRN. As a region we were able to enrol significant numbers of participants into Urgent Public Health (UPH) studies, including platform studies, vaccines research and other studies. It is essential we provide the right support to continue the delivery of this work, ensuring all required data is collected to complete these vital studies. Also to ensure we are prepared should further waves of the disease follow. From the commencement of the financial year, due to a proactive and tailored approach, we had confirmed funding of c. £700k to a wide range of partners specifically to ensure this vital work can continue. Some partners have established targeted teams, which we are helping to resource, others are strengthening support departments such as pathology, or channelling resource to affected areas, e.g. respiratory or infection research teams. We also have this targeted fund which we are in the process of allocating, to date c.30% of this has been allocated.
Recovery, Resilience and Growth of Clinical Research		
3.2	Deliver the CRN activities in the DHSC Recovery, Resilience and Growth Programme	We are also very engaged with this work, and are working closely with partners to share regular updates and systematically work through our regional portfolio together to help to recover and grow NIHR research. Our targeted funding (described and referenced above), also supports this work.
NIHR CRN Strategic Improvement Priorities		
3.3	Primary Care Research Engagement	In the East Midlands there is a strong track record of research delivery in primary care, which we intend to further build upon, informed by the recently published National Primary Care Research Strategy. In 2020/21 we commenced a Primary Care Network (PCN) Pilot which will run to September 2021, reporting by the end of the calendar year. The purpose of this pilot is to identify the needs and support requirements for PCNs to become research active, and we look forward to the findings which will further inform the approach for PCNs. We have a dedicated team for primary care, supporting General Practices with the RSI scheme, along with a focussed research delivery workforce through nurses and other practitioners. We intend to strengthen this support in 2021/22, as the wider Direct Delivery Team (DDT) is formed, encompassing a range of settings outside of

		hospitals, and reflecting that primary care is very broad. Another aspect of this is through our support arrangements for Community Pharmacy, which we will continue and exploring new areas such as Community Dentistry where we are currently scoping further opportunities for community dental practices keen to be involved in research.
3.4	Review and Refresh Research Delivery (including Direct Delivery Team)	With respect to the Direct Delivery Team, as per our recent submission, we are planning to appoint a dedicated Lead post (fixed term) who will lead work to transform our current delivery support infrastructure, and with the addition of new roles to form the Direct Delivery Team. Currently we have delivery support in place for NHS Trusts and for primary care, although not as one workforce; these roles can, and do, also support other settings outside of the NHS.

Section 4: LCRN Initiatives

This section details local initiatives and projects to be delivered in 2021/22, that the LCRN would like the CRN Coordinating Centre and other LCRNs to be aware of.

Plan Ref	Supra-network (collaborating with other LCRNs)	POF section(s)	Title of Project	Expected outcome(s)
4.1	No	C.4. CRN Specialties	Work to identify and understand any disparities between local health and care needs and the local research portfolio in the East Midlands (POF 4.1.4)	- To better understand our regional landscape with respect to disease burden - To target any gaps that emerge through encouraging and supporting researchers in those areas - To ensure research in areas of greatest need, based on disease/health profiles, is sufficiently resourced through the Direct Delivery Team (DDT) - To feed this into our work outside of NHS providers also
4.2	No	Cross cutting	Targeted digital solutions fund, through Transforming work	Alongside the development of the DDT, through the Transformation of Research work, we are keen to have a targeted digital work-stream which will allow us to: - Identify key concerns which impact research delivery - Do this through working with frontline research delivery teams - Seek innovative digital solutions to these issues - Work with a range of experienced digital innovators to develop or identify these approaches - To recommend and implement existing technologies if they exist, rather than need to develop new ones
4.3	Yes	C.10. Workforce Learning and Organisational Development (WLOD)	Direct Delivery Team (DDT) as part of Transforming work	As a supra-region, we have begun discussions regarding an "Educator" role, focusing on the competencies and needs for the 'non-NHS' workforce and DDT. The plan is for the post to be hosted by CRN Eastern but will work across the supranetwork. The Educator for Non-NHS Settings will work within the Workforce Development team in Eastern/East Midlands and West Midlands and be responsible for the development and delivery of the Learning and Development Plan for Non-NHS Settings across the 3 geographies.

4.4	Yes	C.10. Workforce Learning and Organisational Development (WLOD)	Supranetwork improvement and innovation collaboration	Following the successful implementation of our Supranetwork Ideas Cloud and project support process in 2020/21, the next steps for our Supranetwork collaboration are: - Promotion of our Supranetwork approach to continuous improvement by delivering a communications and engagement campaign throughout 2021/22. This will likely include a quarterly newsletter, case stories, videos, and potentially an event towards the end of the year to showcase collaborative projects and create further opportunities for joint working. - Support further continuous improvement training and development opportunities, including Supranetwork workshops to embed knowledge gained from e-learning, and to develop new collaborative ideas & projects. - We will work as a Supranetwork to support each other with respect to continuous improvement culture within our partner organisations to identify target areas to further embed continuous improvement
4.5	No	C.5. Research Delivery	A review of CRN East Midlands Study Support Service (SSS) provision: activities, outputs and roles	Ultimately to clarify key components of SSS, how and by whom they are best undertaken to support researchers across the region, this will include specifics such as: - Identify areas of SSS provision where there may be potential duplication between Partner Organisations and Central SSS Team and make recommendations about how these areas could be better streamlined. - Define the boundaries of SSS provision to provide clarity on what should be delivered by the Central SSS Team and what should be delivered by Partner Organisations. - Provide clear expectations for provision of each of the SSS components.

Section 5: CRN East Midlands Financial Management		
n1	In respect of the LCRN 2021/22 local funding model, please confirm if the principles have changed from the 2020/21	Overall yes. In previous years we have employed various funding models which have been activity driven, looking at aspects of performance alongside historic allocations with the application of a cap and collar to prevent significant fluctuations. Due to the unusual year we have had in 2020/21, we opted to establish a working group and undertake a short partner survey to consider the best options for 2021/22 funding. A summary paper was produced, which was discussed with the Partnership Group. It was agreed to allocate partner budgets (Primary care is treated as a single partner organisation) using a flat budget pass-through model in line with 2020/21. This may be well described as a roll-over approach. In the model at the start of the year, we also agreed to also establish a High Priority Fund of £450,000 to focus on supporting the delivery of the highest priority studies, which included those defined as Urgent Public Health (UPH) and the restarting of the NIHR portfolio. In order to maximise the impact of this funding our intention was to allocate as much as possible of this at the start of the year. On submission of this planning document (23/04/21) this has been allocated in full to partner organisations. This puts us in a strong position to then allocate the additional funding, since received. As we have not followed an allocation methodology, but rolled-over allocations based on previous methodology, we have not completed the % information below, with the exception of the Host/management costs and the strategic funding, as the other categories do not really apply to our approach this year.
n2	In respect of the LCRN 2021/22 **l**oca**l** funding model, please complete the following table* by entering the proportion of LCRN funding (%) within the funding elements detailed. If there are any other elements to the model please describe what this is for and the proportion of funding allocated to this. **Please note above, we did not use a methodology which allows us to do this across all categories, as we rolled over the previous year's budget allocation approach. We could adjust the %, based on our increased allocation, but it would not present a representative picture**	
*Notes	1. It is assumed that the local funding model is net of any national top-sliced funding as this is pass through cost	
	2. If the funding element category is not applicable to your local funding model, please enter 0%	
	3. The percentages (%) entered in the table should equate to 100%	

Funding Element	Examples	Description of model	% of Total CRN Funding Budget 2021/22 Budget (Please note that these should total 100%)
Host Top-sliced element	Core Leadership team, Host Support costs, LCRN Centralised Research Delivery team	This includes the cost of our Local Portfolio Management System (Edge), Costs for Speciality & Divisional Clinical Leads, our Workforce Development team, costs for the delivery of SSS (incl some payments for staff embedded in Partner Organisations), Leadership & Management, Host supporting costs, Comms/Engagement and PPIE, Information Management/Business Intelligence. It also includes our current Research Support Team (flexible workforce of delivery staff), however as outlined in our recently submitted plans for the Direct Delivery Team, we are planning a significant transformation of this team, and in future would anticipate the % of costs here increasing to accommodate this, or indeed move to another category, as advised.	19%
Block Allocations	Primary care, Clinical support services (i.e. pharmacy), R&D contributions	N/A as above re. this year's approach	N/A
Activity-based	Recruitment HLO 1, number of studies, activity weighting	N/A as above re. this year's approach	N/A
Historic Allocations	PO funding previously agreed	N/A as above re. this year's approach	N/A

Performance-based	HLO performance, value for money metric	N/A as above re. this year's approach	N/A
Population-based	Adjustments for NHS population needs	N/A as above re. this year's approach	N/A
Project-based	Study start up	N/A as above re. this year's approach	N/A
Contingency / Strategic Funds	Funds to meet emerging priorities during the year, including targeting local health needs	We have established a High Priority fund of £450,000.	1.90%
Other Funding Allocations		We have also received additional funding, since the planning was undertaken. Three elements: - Cost pressure funding (£551k), this has been provided out to partners (& centrally) based on a % of budget allocation method, this is not included here. - "Staff retention" funding (£740k) is included in this category; we have opened a targeted funding call for this, to support with RRG (and if necessary UPH), to date c.£200k has been provided to Partner Organisations. - Transforming Research (£909k), a plan was recently submitted to CC for this, and we are planning against this, we have included this funding here	7%
Total			N/A

Cap and Collar	Please provide your upper and lower limits if applicable	We did not use a cap and collar this year, due to a pass-through approach	N/A
		We did not use a cap and collar this year, due to a pass-through approach	N/A
Comments			
n.3	Please provide the pros and cons of the 2021/22 LCRN local funding model, and include constraints you face whilst determining the model	Pros - Simple, straightforward and easy to understand - Fair, in that all organisations were treated the same, during a year where activity was significantly impacted by patient flows and study availability linked to sites seeing more/less covid patients, and sites with different capacity to continue to involve patients in studies - Approach reached by consensus discussion with partners - Allowed us to focus on core CRN business, delivery of UPH studies and managing and supporting our teams and our research in a time of national crisis, rather than spending time we did not have working through numerous modelling exercises Cons: - May be perceived as unfair, if sites had been VERY busy and delivered high levels of activity - however they were supported through additional UPH funding in-year and other CRN resources/support - Was a change, which by nature of any change, causes some instability - At time of setting, no growth opportunity offered (since off-set by new funding) This was discussed in a paper presented at the Partnership Group on 11/11/2020.	
n.4	In which financial year did your previous internal audit take place? Have all of the auditor's recommendations been implemented and, if not,	An internal audit was undertaken in December 2020, final report issued in February 2021 (shared with CRN Coordinating Centre on 23/04/21) and recommendations to be implemented by end of Q1 2021/22.	

	when will they be implemented?	
n.5	If the next internal audit is due in 2021/22, please give the estimated date of the audit	not due until 2023/24 financial year

Appendix 4

NIHR | Clinical Research Network East Midlands

NIHR Clinical Research Network East Midlands

GOVERNANCE FRAMEWORK

Host Organisation:

University Hospitals of Leicester NHS Trust

Change Control

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

7.0	22.09.20	Annual review (2020/21) - updated introduction (1.1 & 1.2), updated Trust's Acting Chief Executive Officer (4.1), updated description of Industry Delivery Manager role (5.1), updated list of Working/Steering groups (6.1), clarified title of Communications and Engagement Lead (section 6.3), updated reporting format (section 6.5), updated funding description (8.2), updated LCRN Host Finance Lead role description, (8.8), updated costing and financial management arrangements (8.11 and 8.12), updated CRNEM Finance Support Structure (8.13), updated financial cost codes table (8.15), added reference to issue log (9.9), updated Trust's Acting Chief Executive Officer (12.2).
8.0	02.06.21	Annual review (2021/22) - added DCOO to Exec Leadership team (4.5), added Transformation Lead (5.1 & 5.3), updated governance structure (6.1) updated financial management section (8), added roles for budget authorisation purposes (8.17), updated delegated authorisation table (8.18), added latest audit findings (9.13), removed Contract Compliance Assurance Framework (9.14), added Risk Identification and Escalation process (11.4)

NIHR CLINICAL RESEARCH NETWORK EAST MIDLANDS

Governance Framework

CONTENTS

1. INTRODUCTION

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

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

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

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

2. PURPOSE

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

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

3. GENERAL PRINCIPLES

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

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

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

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

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

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

4. EXECUTIVE LEADERSHIP TEAM

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

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

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

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

4.5 It is a requirement of the NIHR CRN Performance and Operating Framework that the LCRN Chief Operating Officer has a nominated deputy. This may be by means of either (a) a substantive post of 'Deputy Chief Operating Officer' or (b) another LCRN senior manager who is the nominated deputy. The Trust has appointed Kathryn Fairbrother as the **LCRN Deputy Chief Operating Officer** (DCOO). The DCOO reports to the Chief Operating Officer, with the capacity to deputise for the COO, as required.

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

- Deliver the core activities of the LCRN, in line with the agreed governance requirements within the Host Contract and Performance and Operating Framework;
- Ensure any activities are carried out as may be necessary for the proper governance of the LCRN;
- Ensure that a proper and auditable process is developed and executed for the fair and effective distribution of LCRN funding;
- Be available for regular meetings as a core Leadership Team;
- Support scrutiny and transparency, for example by providing any information as required for the internal auditors, and attending the audit committee of the Trust as requested;
- Ensure the timely delivery of performance and other reports;

- Support the Trust by adhering to any local governance requirements, such as the local standing financial instructions and all relevant national NHS requirements;

- Convene regular Partnership Group meetings;

- Make freely available to the Trust and all Partner organisations, as requested, any information that is not commercial and/or in confidence and in line with national NHS policies;

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

5. LCRN LEADERSHIP TEAM

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

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

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

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

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

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

- The Leadership team will incorporate an additional post of Transformation Lead for the period of 12 months, from Aug 2021, due to a programme of change where senior leadership is required.

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

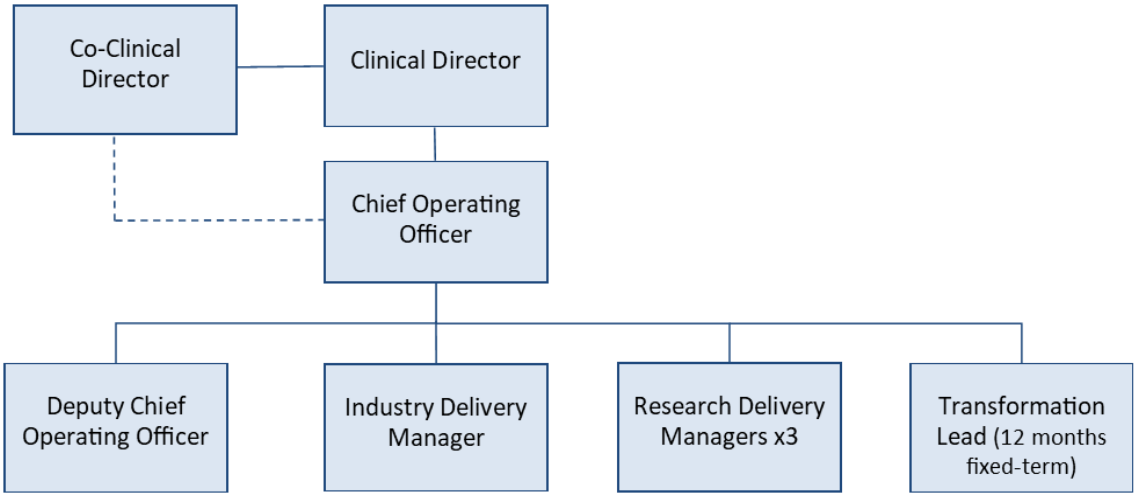
- Deliver the management and operational (i.e. non-clinical) activities of the LCRNs, in line with any agreed governance requirements;

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

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

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

Figure 1 - CRN East Midlands Leadership Structure



LCRN Divisional Clinical Research Leads

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

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

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

LCRN Clinical Research Specialties

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

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

- Division 1: Cancer
- Division 2: Cardiovascular disease; Diabetes; Metabolic and endocrine disorders; Renal disorders; Stroke;
- Division 3: Children; Genetics; Haematology; Reproductive health & childbirth;
- Division 4: Dementias and neurodegeneration; Mental health; Neurological disorders;
- Division 5: Ageing; Dermatology; Health services and delivery research; Oral and dental health; Musculoskeletal disorders; Primary care; Public health;
- Division 6: Anaesthesia, perioperative medicine and pain management; Critical care; Ear, nose and throat; Gastroenterology; Hepatology; Infectious diseases and microbiology; Injuries and emergencies; Ophthalmology; Respiratory disorders; Surgery.

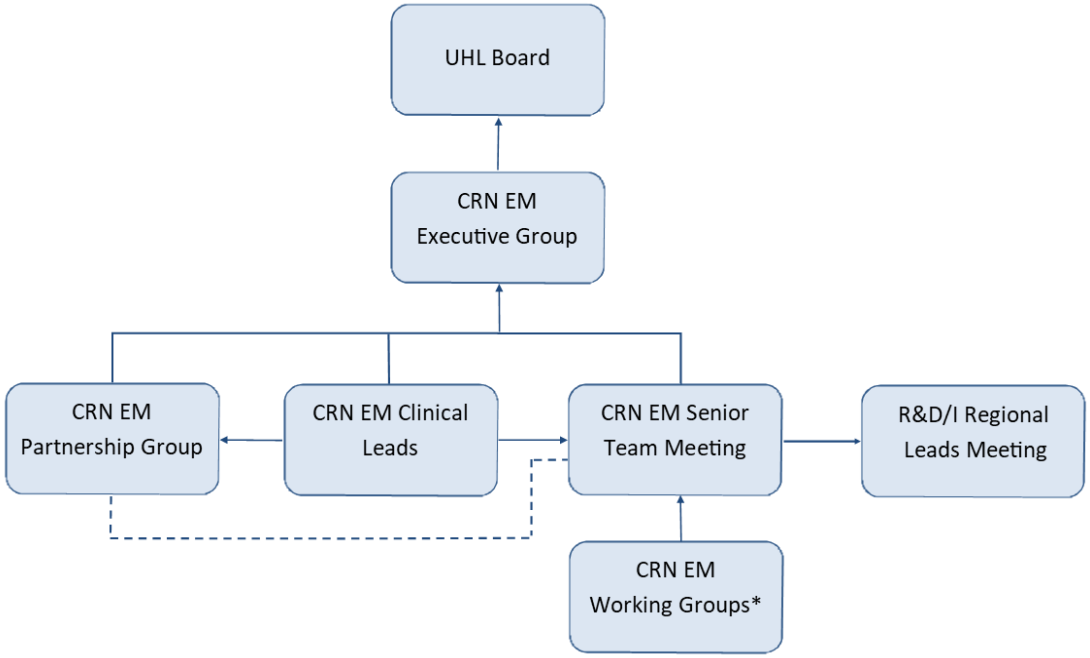
5.8 The LCRN has appointed local Clinical Research Specialty Leads for all 30 specialties. The LCRN Clinical Research Specialty Leads report to the LCRN Divisional Clinical Research Lead responsible for that Specialty. Local Clinical Research Specialty Leads will be responsible for the clinical leadership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

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

6. LCRN GOVERNANCE STRUCTURE

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

Figure 2 – CRN East Midlands Governance Structure



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

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

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

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

Team will convene a weekly teleconference to discuss ongoing operational matters.

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

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

7. HOST BOARD CONTROLS AND ASSURANCES

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

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

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

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

8. FINANCIAL MANAGEMENT

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

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

~~8.2~~8.3 Such assurance measures are in line with the Minimum Financial Controls, contained within LCRN Contract Support Document CSD007, which is annually updated by the NIHR CRN Coordinating Centre.

~~8.3~~8.4 The Trust (~~,~~as Host Organisation), is responsible for the financial reporting of the CRN activities. This responsibility is discharged to the LCRN Executive Leadership team, who ~~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 developed through the Finance Working group, in collaboration with partners. During its development it will be consulted through and shaped by the Partnership Group and LCRN Executive Group. ~~reviewed by the LCRN Partnership Group prior to submission.~~ The plan will also require review and approval through the ~~be approved by the~~ Trust Board. ~~and then submitted for approval to the national CRN Coordinating Centre.~~

~~8.4~~8.5 Through the LCRN Executive Leadership team, t~~T~~he 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~~8.6 Through the Executive Leadership Team, t~~T~~he 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~~8.7 The LCRN Executive Leadership team has ~~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 is in line with the Trust's own financial procedures and expectations. 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.

8.8 In order to meet the NIHR LCRN Minimum Financial Controls, the Executive

Leadership team are responsible for the preparation of relevant ~~the Trust, as Host Organisation, has produced a~~ Standard Operating Procedures for the m~~M~~onitoring 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.

~~8.7~~8.9 The Executive Leadership team is also responsible for the provision of guidance in relation to income generated from NIHR CRN portfolio commercial contract research with partner organisation, and will action this via ~~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~~8.10 The Trust, as Host Organisation, has appointed Martin Maynes as **LCRN Host Finance Lead** who is responsible for providing financial support and specialist technical accounting knowledge to the LCRN leadership team. Martin produces LCRN financial reports for review by the LCRN Executive Group, Host Board and LCRN Partnership Group.

~~8.9~~8.11 Elizabeth Moss, **LCRN Chief Operating Officer**, is responsible for overall LCRN budget oversight and strategic decision making.

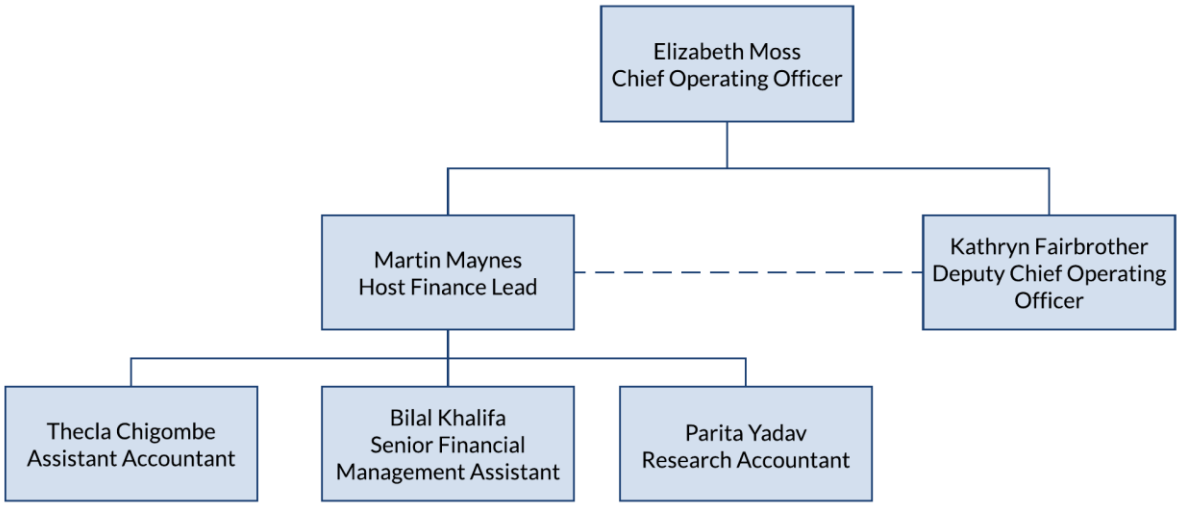
~~8.10~~8.12 The COO and CD ~~The Trust, as Host Organisation,~~ haves ~~s~~ appointed Kathryn Fairbrother as **LCRN Deputy Chief Operating Officer** who is responsible and accountable for operational management for the infrastructure and central budgets

~~8.11~~8.13 Each Lead LCRN study is assigned a study lead from within the Study Support Service team,who is ~~Kiran Mistry, Chris Siewierksi, Marie Thompson, Bryony Berridge (**Study Support Service Managers**) are~~ responsible for the cost attribution for all non-commercial NIHR portfolio studies led in the East Midlands via the Schedule of Events Cost Attribution Template (SoECAT) - these are authorised on behalf of the Network by Divisional Managers and the~~,~~ SSS Compliance and Assurance Manager~~, Deputy COO/COO~~. Unmet Service Support Costs provided to Primary Care and non-NHS organisations are managed by the Study Support Service team. Kathryn Fairbrother (**Deputy Chief Operating Officer**) is responsible for the operational management of the Service Support Costs budget.

~~8.12~~8.14 The CRN Executive Leadership Team have ~~Trust has~~ appointed a qualified and experienced finance team to monitor the budget on a day to day basis. The finance team work closely with research finance staff within partner organisations. All members of the finance team are line managed by the LCRN Host Finance Lead, with day to day operational management by the Deputy Chief Operating Officer.

~~8.13~~8.15 Figure 3, which presents the structure of the finance team, is set out below.

Figure 3 – CRN East Midlands Finance Support Structure



8.16 The scheme of delegation for financial authorisation limits has been set to reflect those of the Host organisation. The roles for CRN authorisation mirror the following roles within UHL for budget purposes only, and are summarised in 8.17, below.

8.17 Table of corresponding CRN and Host roles for budget authorisation purposes, and to reflect approval limits.

UHL Role for budget control purposes	CRN corresponding role for budget control purposes
Other Executive Director	Chief Operating Officer
Deputy Head of Operations	Deputy Chief Operating Officer
Deputy Head of Nursing	Business Delivery Operations Manager, RDM (Div 2 & 5)
Service Manager	Budget Holder (Workforce Development Lead, RST Team Lead, Senior Nurse
Matron (requisition approval)	Project Support Officer

~~8.14~~8.18 The following table provides the LCRN financial cost codes and delegated authorisation allowances.

Table 1

		Authorisers							
		LCRN Chief Operating Officer	LCRN Deputy Chief Operating Officer	Workforce Development Lead	RST Team Leader	Senior Nurse (NUH)	Business Delivery Operations Manager	RDM (Div 2& 5)	Project Support Officer
Cost Code	Description	Up to £5~~6~~00,000	Up to £100,000	Up to £10~~5~~,000	Up to £10~~5~~,000	Up to £10~~5~~,000	Up to £50,000	Up to £50,000	Up to £5,000
O11	CRN EM Additional Funding~~accine Delivery~~ Fund	Y	Y	N	N	N	Y	N	N
S18	CRN EM RSI	Y	Y	N	N	N	N	Y	N
S19	CRN EM Clinical and Specialty Leads	Y	Y	N	N	N	Y~~N~~	N	N
S89	CRN EM Primary Care Service Support Costs	Y	Y	N	N	N	N	Y	N
S90	CRN EM General Infrastructure	Y	Y	N	N	N	Y~~N~~	Y	N
S97	CRN EM UHL Infrastructure	Y	Y	N	N	N	Y~~N~~	N	N
S98	CRN EM Non pay Non staff	Y	Y	Y~~N~~	N	N	Y~~N~~	N	Y
U08	CRN EM RST	Y	Y	Y	Y	N	N	N	N
U14	CRN EM SSS	Y	Y	N	N	N	N	N	N
U89	CRN EM Management Team	Y	Y	N	N	N	N	N	N
U96	CRN EM Host Services	Y	Y	N	N	N	Y~~N~~	N	Y
U97	CRN EM Network Wider Team	Y	Y	N	N	N	Y~~N~~	N	N
COR 014	Central Network Funding (NUH)	Y	Y	N	N	Y	~~N~~Y	N	N
O17	High Priority Funding	Y	Y	N	N	N	Y	N	N
O49	Income	Y	Y	N	N	N	N	N	N

9 ASSURANCE FRAMEWORK

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

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

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

Issue Management and Control

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

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

Table 2

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

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

- timely
- proportionate
- comprehensive
- inclusive
- effective.

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

Table 3

Procedure	Description	Delegation
1. Capture	Determine severity/ priority	

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

Internal and External Sources of Assurance

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

Table 4

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

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

9.10 The LCRN has produced an Issue Resolution Procedure so that stakeholders have a route to raise any matters of concern which may arise in relation to CRN East Midlands business.

LCRN Host Organisation Annual Review

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

LCRN Auditing Arrangements

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

9.13 The LCRN was audited in December 2020~~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 2023/24~~2020/21~~.

~~**LCRN Contract Compliance Assurance Framework**~~

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

10 BUSINESS CONTINUITY ARRANGEMENTS

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

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

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

11 RISK MANAGEMENT PROCESS

11.1 The Trust operates within a clear risk management framework which sets out how risk is identified, assimilated into the risk register, reported, monitored and escalated through the Trust's governance structures. The framework is set out in the Risk

Management Policy and is supported by relevant policies, including the Risk Assessment Policy and Policy for reporting and management of incidents including the investigation of Serious Untoward incidents.

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

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

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

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

11.4 Risk Identification and Escalation

If a member of CRN East Midlands Central team identifies a potential risk which they are concerned about, the following process should be applied:

1. Raise risk with line manager and line manager will decide if the risk should be escalated to the Executive Leadership team
2. The Executive Leadership team will review the risk and decide if a formal risk assessment is required. If this is the case, the Executive Leadership team will offer guidance to complete the required Trust risk form,
3. The Executive Leadership team will review risk and mitigations, and subsequently decide if the risk needs to be recorded on the LCRN risk register

12 ESCALATION PROCESS

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

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

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

2. Nominated Executive Director – Mr Andrew Furlong

3. The Trust Acting Chief Executive Officer – Rebecca Brown

4. National CRN Coordinating Centre

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

13 MONITORING OF ACTION PLANS

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

13.2 The LCRN Executive Group will continue to monitor any new action plans created in 2021/22~~2020/21~~ that develop from the Annual Plan or are required as routine or extraordinary plans throughout the year.

14 REVIEW

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

David Rowbotham
Clinical Director, CRN East Midlands

Appendix 5

NIHR Clinical Research Network East Midlands - Risk Register

University Hospitals of Leicester NHS Trust

Owner of Risk Register: Executive Group

Last updated: 23.06.2021

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)
R059	Financial	Mar-21	COO	There is a risk of an underspend for CRN East Midlands' budget for 2021/22 due to a significant uplift	**Cause:** Increased funding of c.£2.2 million (over 10%) to CRN EM annual budget for 2021/22. **Effect:** Budget surplus at end of year, which means funding intended for the region does not get sufficiently well invested to offer more research to our patients. Also this could impact on future funding if there is a perception we do not need the funding provided.	3	3	9	Mar-22	Robust financial monitoring and reporting on a monthly basis, with oversight from Finance Working Group	DCOO/ FWG	4	2	3	6	Open	Decreased
										Three separate funding streams, 1. Cost pressure funding (£550k), as at 26/04/21, all partner cost pressure is allocated and committed, thus reducing risk of u/spend	STLs	5					
										Three separate funding streams 2. Targeted funding for UPH/RRG (£740k), call opened to allocate funding promptly, as at 26/04/21 c.30% allocated, thus reducing risk	Leadership Team	4					
										Three separate funding streams 3. Transforming research (£909k) required plans submitted to NIHR CC, approved, beginning to action plans, funding not yet allocated	COO	4					
										Early identification of areas of underspend with timely targeting and redistribution of funding	COO/ Senior Team	4					
R060	Performance	May-21	COO	As at 02.06.21 the LCRN finance methodology for 2022/23 LCRN budgets (often linked to performance) is not known. This presents a potential risk to future regional budget and an inability to influence/maximise this through specific performance focussed work.	**Cause**: Uncertainty on how regional LCRN budgets will be set for 2022/23. **Effect:** Inability to maximise any increase for the East Midlands, with no ability to influence this. Further effect could be an impact on our regional approach to partner budgets setting, which is often informed by national model.	3	3	9	Q2-Q4 21/22	Seek further guidance and assurance from CRNCC	COO	4	3	3	9	Open	New
										Advise partners on the national view at next Finance event in June 2021	COO	5					
										Intention is for the East Midlands plan for budget distribution to be based upon how to incentivise and support partners to deliver the CRN contractual priorities, likely to no longer be linked to the national funding model to the regions. Budget planning to commence in Sept 2021	COO	1					
R061	Services	May-21	COO	Recovery of the CRN portfolio could be negatively impacted in the event of a further wave of COVID-19	**Cause**: Further wave of COVID-19 with increase in hospital admissions, and diversion of research delivery staff **Effect:** Resource has to be redeployed onto the frontline or to support an increase in UPH research activity, which would see activity on non-UPH studies reduce/significantly reduce. The impact for commercial studies is a lack of confidence in the UK research system, with reputational impact for the future. Also for commercial and non-commercial studies, the impact will be for patients not being offered the latest treatments/interventions.	3	4	12	Q2-Q4 21/22	When setting up studies, communicate to sponsors and study teams the risk of disruption in event of a further wave of COVID	SSS Team	4	3	3	9	Open	New
										Seek advice from CRNCC and other LCRNs if there is useful information that can be shared	COO / DCOO	4					
										Keep in close dialogue with partners regarding best placement of resource	STLs / COO	4					
										Ensure RST placements are maximised is further focus on UPH work, as needed	WFDL / COO	1					

SCORING:

	IMPACT				
PROBABILITY	**Insignificant (1)**	**Minor (2)**	**Moderate (3)**	**Major (4)**	**Catastrophic (5)**
Highly Likely (5)	5	10	15	20	25
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*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

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

CRN East Midlands Issues Register

There are no open issues on CRN East Midlands Issues Register.