CRN: East Midlands Quarterly Host Board Report

Author: Prof. David Rowbotham Sponsor: Mr Andrew Furlong **Trust Board paper N**

Executive Summary

Context

University Hospitals of Leicester (UHL) NHS Trust is the Host organisation for the National Institute for the National Institute of Health Research (NIHR) Clinical Research Network East Midlands, (CRN). UHL is contracted by the Department of Health to take overall responsibility for the monitoring of governance and performance of the network. The purpose of this regular update paper is to summarise our performance, major achievements, challenges and actions. This is the third formal report of 2016-17 which has been taken to the CRN East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive Lead for the CRN) in March 2017. It was then considered by the UHL Executive Performance Board on 28 March 2017 and is submitted for UHL Board review on 6 April 2017.

Questions

1. In order to provide assurance to the Host, what are the major achievements and challenges of the Network, performance from 15 November 2016 – 13 February 2017 and what actions are being taken to improve performance moving in to 2017-18?

Conclusion

1. Our commercial performance has improved and we are fairly confident that we will achieve our target by year end. Overall study recruitment continues to cause concern and we have previously highlighted this issue to the Board. This has also been fed back to the NIHR CRN Co-ordinating Centre, who are more focused on the attainment of efficiency measures for the studies we are delivering. The report also outlines our early priorities and plans for 2017-18. Appended is a dashboard detailing key performance measures for 2016-17, Risk Register, Governance Framework and 'Shaping the Future of NIHR' letter.

Input Sought

Trust Board is asked to review the update on the performance of the EM CRN and approve the annual updates to CRN EM Governance Framework 2017-18 (Appendix 3).

For Reference

Edit as appropriate:

1. The following **objectives** were considered when preparing this report:

Safe, high quality, patient centred healthcare	[Not applicable]
Effective, integrated emergency care	[Not applicable]
Consistently meeting national access standards	[Not applicable]
Integrated care in partnership with others	[Yes]
Enhanced delivery in research, innovation & ed'	[Yes]
A caring, professional, engaged workforce	[Not applicable]
Clinically sustainable services with excellent facilities	[Not applicable]
Financially sustainable NHS organisation	[Yes]
Enabled by excellent IM&T	[Not applicable]

2. This matter relates to the following **governance** initiatives:

Organisational Risk Register	[Yes]
Board Assurance Framework	[Yes]

3. Related **Patient and Public Involvement** actions taken, or to be taken: [Insert here]

4. Results of any **Equality Impact Assessment**, relating to this matter: [Insert here]

5. Scheduled date for the **next paper** on this topic: 25/04/17 (CRNEM Annual Plan 2017-18 submission)

6. Executive Summaries should not exceed **1 page**. [My paper does comply]

7. Papers should not exceed **7 pages.** [My paper does comply: Total of 7 pages excluding appendices]

Clinical Research Network
East Midlands

NHS
National Institute for Health Research

CRN East Midlands Quarterly Board Report

Progress, challenges and performance update

Date: 22 March 2017

Authors: Elizabeth Moss - Chief Operating Officer
Carl Sheppard - Project Manager

Executive Editor: Professor David Rowbotham - Clinical Director

Executive Summary

This report provides a summary of 2016-17 year to date performance for the Clinical Research Network East Midlands and highlights risks and issues. In response to a previous request from the UHL Chairman, Karamjit Singh CBE, there will be a short presentation at the UHL Trust Board in relation to a key development within the wider research environment. At the April Trust Board meeting, this will feature a recent open letter from Prof Chris Whitty: Shaping the future of the NIHR: some reflections of NIHR one year in as Chief Scientific Advisor.

1. Background

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

1.2 This is the third formal report of 2016-17 which will be taken to the CRN East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive Lead for the CRN) in March 2017. It will then be considered by the UHL Executive Performance Board and submitted for UHL Board review in April 2017. Appended to this written report is a dashboard detailing current performance measures for 2016-17 (Appendix 1).

1.3 In line with the CRN East Midlands Executive meeting schedule and the UHL Trust Board meeting schedule, the previous report covered the period 1 August 2016 – 14 November 2016. This report covers the period from 15 November 2016 – 13 February 2017. It should be noted that the performance figures presented in this report do not give an end of year position as all annual data is not yet required to have been uploaded to the national database. Our next Board report, due in July 2017, will include finalised year end performance figures for 2016-17.

2. 2016-17: Current Performance & Progress

2.1 Appendix 1 presents data extracted on 13 February 2017 reflecting performance to date. This shows the various NIHR High Level Objectives (HLOs) the CRN is managed against. We wish to highlight the following issues for the Board's specific attention:

i. We previously highlighted concerns in relation to our recruitment rate, High Level Objective (HLO) 1 and presented some key mitigating actions. Since November, our performance has remained relatively unchanged; we are currently at 70% of our year to date target (previously 69%). We remain 8th in the national table for total recruitment but have dropped one place to 6th based on weighted activity. Within this overall stable position, we have seen fluctuations, with NUH improving their relative activity and UHL falling slightly. This is of some concern as this data is used in part to calculate our annual budget for future years. However, in recent discussions with the NIHR Co-ordinating centre it has become evident that this is

not the sole performance or financial driver, with other aspects of regional performance also valued. Activities undertaken by the network to reverse this decline are highlighted within the risk register in Appendix 2 and referenced in Section 3, below.

ii. The proportion of commercial studies recruiting to time and target (HLO2a) is a key national priority for the CRN and we have continued to improve with respect to this objective over recent months. Our performance has increased to 86% (previously 78% in November) thus we are currently exceeding the target of 80% for the first time this year. Furthermore, we have also moved up two places in the national table and are now ranked in 2nd position of the 15 regional networks. We are continuing to focus resource in this area and are fairly confident that we will maintain our position above 80% to achieve our target at year end; however, this can still flex and is not stable until year end has been reached.

iii. For the proportion of non-commercial studies recruiting to time and target where the Lead site is in the East Midlands (HLO2b), we have also seen an improvement over recent months. Our current performance is 77% (previously 72%) against a target of 80%. However, current predictions indicate we are unlikely to meet this target in 2016-17, and indeed due to a number of closing studies may well dip slightly here; we unable to alter this within the CRN as this closure data is driven by the Chief Investigator. More work will be undertaken in 2017-18 to move towards the 80% target, with earlier focus in-year and closer dialogue with local Chief Investigators.

iv. Outside of hospital sites, our Mental Health, Community and Ambulance Trusts are recruiting well, on average, over 30% more activity than at this point last year.

v. We are currently working on the budget planning exercise for 2017-18 and have recently received formal notification of the budget from the NIHR CRN Co-ordinating Centre. Our confirmed budget for next year will be an overall reduction of 3.4%; the maximum reduction we could have received was 5%. This budget is broadly in line with our forecasting prediction, which we advised to partner NHS Trust in December 2016. The reduction in budget is linked partly to reduced regional activity, and partly to a national budget reduction in the total CRN budget. At present, all partner organisations have submitted plans against their forecast budget envelopes, these are currently being fully reviewed and will be confirmed in due course, prior to the submission of our full Annual Financial Plan (AFP) by 7 April 2017.

vi. Our mid-year performance review meeting with the NIHR CRN Co-ordinating Centre took place on 18th January 2017. A number of achievements were acknowledged including a). in-year progress towards commercial performance; b). our work to engage stakeholders and partners across the region through a large NIHR @ 10 celebratory event in October; c). recent work to engage with potential researchers and participants/patients in palliative research settings and d). collaborative work with Health Education East Midlands (HEEM) in relation to medical trainees.

3. 2016-17: Challenges and Actions

3.1 Risks and issues are formally discussed through the Executive Group for the CRN, which is chaired by Andrew Furlong. A risk register (Appendix 2) is maintained for the CRN with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Co-ordinating Centre.

3.2 Our primary concerns relates to HLO1, (risk #23) which is overall recruitment, as detailed above. At this stage in the year, much work has been done to both mitigate this risk and progress this objective (see Appendix 2). We are not likely to meet this target in 2016-17; our HLO1 outturn data will inform our HLO1 target for 2017-18. The primary reasons for not meeting our HLO1 objective in 2016-17 are: a). a fall in the study pipeline of NIHR portfolio research which is available to us to contribute to in the East Midlands; b). a reduction in the sample size/change in the type of studies on the national portfolio and c). the closure of a number of larger sample size studies during the year, which have not been replaced with similar studies; this is particularly seen in the primary care setting.

3.3 In previous reports, we have also highlighted concerns around objective HLO2b, (#25). The level of risk has increased for this objective and we are also unlikely to meet this at year end. A number of mitigating actions have been employed, with a heavy management focus on this in Q3/4. We believe that the data is now more accurate, which has been a significant issue in understanding this objective. For 2017-18, we have identified a range of measures to be implemented to meet this objective next year, outlined in section 4, below.

3.4 Earlier this year, we had a specific concern in relation to one of our larger, research active partners; over the past 6-8 months we have implemented a range of strategies detailed in risk #22 which have begun to stabilise their recruitment position and thus reduce this risk.

3.5 Other risks where the profile has reduced are #20 and #24. Risk #20 refers to delays in the national process (HRA) for approving studies and whilst this has had an effect on overall recruitment levels, the impact of this risk has now reduced. This risk is expected to be resolved by end of year as the changes become business as usual and we are more able to manage them. Risk #24 relates to commercial efficiency (HLO2a), this risk has reduced as the planned actions have resulted in improved performance and the likelihood of meeting this objective has increased.

4. Emerging Priorities for 2017-18

4.1 In line with the LCRN Planning, Reporting and Review Cycle, we are currently in the process of producing our Annual Delivery Plan 2017-18. This will set out our regional priorities and plans for 2017-18; we will look to build on achievements made and consider challenges experienced in this current year. This will be submitted to the UHL Trust Board for approval in May 2017.

4.2 In advance of our Annual Delivery Plan submission, we would like to bring to the attention of the Board, some of the emerging challenges and priorities facing the CRN as we move into 2017-18:

i. The NIHR CRN High Level Objectives remain a clear priority for 2017-18. The key focus will be on achieving HLO2a and HLO2b, demonstrating that the East Midlands delivers efficiency and meets the expectations of Chief Investigators, Funders and Sponsors. Commercial performance remains important and we intend to build upon HLO2a and HLO6b attainment from 2016-17.

ii. To achieve these national priorities, we will have a range of local action plans and work-streams. Specifically, we will look to improve patient access to studies through developing and maintaining a balanced portfolio, increasing our delivery efficiency and looking for all opportunities to maximise future income.

iii. In particular, we wish to highlight our plans around HLO1 and HLO2b where it is important that we make improvements in 2017-18. The table below sets out our goals for next year and summaries key plans to achieve these objectives.

HLO 1 - Number of participants recruited in a reporting year into NIHR CRN Portfolio studies	**Goal: 42,500**
<u>Planned Activities for 2017-18</u> • Continue working with key partners: Specialty leads, research teams and R&D colleagues to increase portfolio activity • Planned work on improving data quality and accuracy in Local Portfolio Management System (LPMS) as the systems shift nationally • Comms-led campaign to promote the importance of research across all settings • To shift focus on HLO2a/b further ensuring the studies we have are operating to maximum efficiency • Aim to work with NIHR CRN Co-ordinating Centre on pilot work to shift delivery to appropriate populations, as per Prof Chris Whitty direction of travel • Through the Early Contact support we provide to Chief Investigators to seek more sites within the East Midlands where practical • Strengthen links with partners through county-wide & regional initiatives, always promoting research input & role e.g. Sustainability and Transformation Plans (STPs), South East Midlands Oncology Centre (SEMOC), Alliance Board, East Midlands Partnership Organisations (EMPO) • Ensure work with Independent Sector Healthcare Providers is maximised to increase activity	

HLO 2b - Proportion of non-commercial studies achieving or surpassing their recruitment target during their planned recruitment period	Goal 80%

Planned Activities for 2017-18

- Improved monitoring of Lead Studies and active management as part of the fully established study support service with dedicated resource for performance management.
- Develop systems and processes which utilise the local LPMS systems and Central Portfolio Management System to performance monitor studies.
- Implement an escalation policy for failing studies utilising Specialty Leads, Research Delivery Managers and Clinical Leads.
- Develop and launch a promotional campaign to highlight the importance of studies to recruit to time and target. To target both internal CRN team and delivery teams and R&D staff within the partner organisations.
- Scope the potential to utilise financial incentives for studies that recruit to time and target locally.
- Establish named contacts for each study to support researchers, and to enable studies to recruit to time and target.
- Improved reporting to Partner Organisations to enable them to act quicker and support the delivery of studies.

4.3 We have also identified challenges, some of which bring risk in the attainment of goals. The most significant challenge in the East Midlands remains a reducing pipeline of available studies. With the development of the larger CRN regions it is an increasing challenge to identify studies, where we are not the lead, which are potentially able to open within our region. We will therefore need to use a range of measures to support portfolio growth and development within the region, working with partners to enable this shift.

5. CRN East Midlands Governance Framework 2017-18

5.1 CRN East Midlands Governance Framework (Appendix 3) describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system and escalation process for the management of the LCRN. This framework is updated on an annual basis in order to reflect any changes in governance, assurance and escalation processes. In this annual update, there are no fundamental changes to the governance framework, however, it has been updated with some governance and administrative changes linked primarily to various groups and meetings. This document requires annual review by the UHL Trust Board and is provided to this Board for approval.

6. Research Highlights

6.1 As part of this report, we would like to highlight a recent letter from Prof Chris Whitty who took over responsibility for the National Institute for Health Research (NIHR) from Prof Dame Sally Davies approximately 1 year ago (Appendix 4). This gives a good indication of the future strategic direction of the NIHR.

6.2 The Clinical Research Network (CRN) accounts for approximately 30% of the total NIHR budget (allocated by the network centre to the regions); UHL hosts CRN East Midlands and also receives significant NIHR funding for research including infrastructure and grants.

6.3 The most significant conclusions are written in bold - several are of interest to UHL. In summary: (i) the general purpose and achievements of the NIHR are supported strongly; (ii) the mechanism for allocation of NIHR funding for basic medical research (e.g. Biomedical Research Centres) is likely to remain unchanged; (iii) there is a desire to place clinical applied and public health research in populations where there is the greatest need (not necessarily in the Chief Investigator's region); (iv) the NIHR funding application processes will be streamlined; (v) the NIHR is seen to be complex, especially by external stakeholders - this needs attention; (vi) it is recognised that excess treatment costs remain a barrier to research delivery but there is no clear solution currently apparent; (vii) the present NIHR policy on equality of gender opportunities will continue; (viii) there is emphasis on research involving nurses and allied health professionals; (ix) public health, primary care and social care research in the UK should be best in the world; (x) the importance of the life sciences industry is again emphasised.

6.4 This strategic direction could give more opportunities for patients in the East Midlands to participate in research and, as far as the CRN East Midlands is concerned, we need to ensure that our network is performing as efficiently as possible in order to attract this new source of clinical trials.

7. Summary

7.1 Our commercial performance has continued to improve and we are fairly confident that this will be maintained to achieve our target by year end. Overall study recruitment continues to cause concern and we have previously highlighted this issue to the Board with mitigating actions seeking to address performance. However, this has been fed back on several occasions to the NIHR CRN Co-ordinating Centre, who are more focused on the attainment of efficiency measures for the studies we are delivering, where our performance is improved from 2015-16.

7.2 We are currently planning NHS partner organisations' budgets for 2017-18, and are seeing some changes in the planned spend. We have increased confidence that work undertaken over the past years is now paying dividends with clearer investment in growth areas, for future portfolio expansion. This is not the case, however, with all partners, and there will continue to be a need to use both incentivisation and corrective action in order to improve performance into 2017-18.

7.3 Early plans and concerns are also highlighted here, with 2017-18 bringing increased opportunities if we can achieve increased efficiency measures. The full Annual Plan, when presented at the following Board meeting, should provide the confidence that all required actions will be established to achieve these plans, alongside the necessary host assurance requirements.

8. Recommendations

8.1 UHL Trust Board is asked to review and comment upon our current performance figures for 2016-17 alongside our reported challenges and actions.

8.2 In particular, we wish the Board to review and approve the annual updates to CRN East Midlands Governance Framework 2017-18.

Appendix 1 – Dashboard 2016-17

Clinical Research Network: East Midlands **Refreshed: 08/03/2017** **Network Progress Overview**

	HLO Description	Study Type	Target		Progress/Summary				Actions	Status	Owner	Year End RAG Assurance
			England	East Midlands	Curr. YTD	Previous	Trend					
1	Number of patients recruited into NIHR studies	All	650,000	48,000	28,013	19,391	↑ 1%	70% of Year to Date goal (40,000) CRN: East Midlands in 8th position out of 15 LCRNs n.b. in 6th position based on weighted recruitment	- Ongoing review of UKCRN database for potential studies and open new sites - Shift focus to recruitment to time and target - Added to risk register (risk #23) with mitigating action plan	Ongoing	Chief Operating Officer	Red
2	Proportion of NIHR studies delivering to recruitment target and time	Commercial	80%	80%	86%	78%	↑ 8%	115 studies recorded as closed and reported recruitment across all Network supported sites. CRN: East Midlands in 2nd position out of 15 LCRNs	- Divisional performance review meetings - Added to risk register (risk #24) with mitigating action plan	Ongoing	Industry Operations Manager	Green
		Non-commercial	80%	80%	77%	72%	↑ 5%	77% (33) for 43 closed HLO studies	- Flag up studies that are underperforming - Appoint Lead Performance Facilitator - Added to risk register (risk #25) with mitigating action plan	Ongoing	Chief Operating Officer	Amber
4	Proportion of eligible studies achieving NHS set up within 40 calendar days	All	80%	80%	21%	20%	↑ 1%	20% (21) for 99 closed HLO studies	- Focus on Early Contact service and engagement - Continued communication with sponsors locally	Ongoing	Business Intelligence Lead	Red
6	Proportion of NHS Trusts recruiting into NIHR studies	All	99%	99%	100%	100%	↔	16 out of 16 Trusts reported recruitment	Target achieved	Complete	Chief Operating Officer	Green
		Commercial	70%	70%	81%	81%	↔	13 out of 16 Trusts reported commercial recruitment.	Target achieved	Complete	Industry Operations Manager	Green
	Proportion of General Medical Practices recruiting into NIHR studies	All	35%	35%	65%	59%	↑ 6%	393 out of 601 GPs, Surgeries & Health care sites reported recruitment	Target achieved	Complete	Division 5 Research Delivery Manager	Green
7	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) NIHR studies	All	20,000	1,250	622	404	↑ 6%	57% of Year to Date goal (1082) Requires 24 recruits per week	- Increase number of studies by actively searching NIHR portfolio	Ongoing	Division 4 Research Delivery Manager	Red

Sources: Commercial Reporting on ODP 17/02/2017, Portfolio ODP Last update: 13/02/2017, Portfolio ODP 1516 Annual Cut Last update: 31/05/2016, Portfolio ODP Reporting Last update: 13/02/2017
Network Summary Report 13/02/2017, Commercial Team update: 17/02/2017 Provided by: CRN: East Midlands Business Intelligence Team

N.B: HLO 3 & HLO 5 are not included as these relate to national objectives

Appendix 2 – NIHR Clinical Research Network East Midlands - Risk Register

Scoring legend	**1**	**2**	**3**	**4**	**5**
Likelihood	Rare	Unlikely	Possible	Likely	Almost Certain
Impact	Very low	Low	Medium	High	Very high

#	Risk Description	RISK SCORE				Consequence of failure to manage	Status	Mitigating Action Plan	Due Date	Action Owner	Action RAG status	Risk Owner	Progress Update / Required Date
		Likeli-hood (1-5)	Impact (1-5)	Overall Risk Score	Risk Trend								
20	Delays in HRA AAC process	5	3	15	↓	• Delays to study start-up • Delays to implementation of amendments • Problems with information flow as study details will not be known to CRN • Ultimate consequence will be lower than expected recruitment – this is being realised	OPEN	Continued communication with sponsors locally	Ongoing	SSSWG	4	COO, Business Intelligence Lead	SSS Working Group reports
								Focus on Early Contact Service and engagement with teams	Ongoing	SSS Team	4		
								Item on agenda for discussion at next SSS meeting	20.03.17	SSSOM	4		
								New SSS posts - Primary Care and Mental Health Facilitators out to advert to increase capacity	Actioned	SSSOM	5		
22	Lack of improvement in recruitment at NUH during 2016/17	3	4	12	↓	• HLO1 not met by end of year 2016/17 • Reduction in Activity Based Funding (ABF) for 2017/18 • Budget reduction targeted at NUH	OPEN	Division 1 plan prepared and to be implemented to aid risk mitigation	31.03.17	D1 RDM + CL	4	COO & D1 RDM	COO & CD updates
								Working closely to improve financial planning therefore making sensible investments to turn around this situation	Ongoing	CD, COO	4		
								2017/18 Budget likely to prompt a response for planning next year	31.03.17	COO	4		
								CRN RDMs to meet with NUH RPMs and Director to identify practical ways for NUH staff to support/manage recruitment issues	Actioned	RDMs	5		
								2017/18 Indicative Budget Plan received and feedback given. Better spread of allocation of budget across all divisions	Actioned	STL / COO	5		
								Weekly meetings with NUH R&I Team and CRN Staff continue and support around performance monitoring/management, resource allocation, target setting etc.	Ongoing	CRN	4		
23	HLO1 will not be met (currently 70% of YTD target) by end of year 2016/17	5	4	20	↔	• Impact on future budget i.e. reduction • Reputational impact for EM slipping down national league tables • Could be beginning of further decline and impact on morale	OPEN	Review CPMS database for potential studies and open new sites	Ongoing	RDMs & PST	4	COO & RDMs	CD reporting to Host Trust Board. Next Board report due 06.04.17.
								Work with Partner Organisations to target resource	Ongoing	CD + COO	4		
								Shift focus from HLO1 to RTT measures	Ongoing	COO + RDMs	4		
								Communication campaign to explain goals and importance of RTT	Q1 17/18	COO / Comms Lead	4		
								Liaise with BRUs and CLAHRC to ensure studies are portfolio badged wherever possible	Ongoing	RDMs	4		
								Work with EMAS as there is scope to undertake more studies - ensure these are portfolio badged	Ongoing	D6 RDM	4		
								Target resource to expedite set-up of key studies, such as FAST & CODEX (both UHL)	Actioned	COO/ BIL/RDM Div5/2	5		
								Escalate adoption issues for Lunchbox study and PEACH study	31.03.17	COO / BIL/ Div 2&5RDM	4		

24	HLO2a will not be met (target 80%, currently 86%) by end of year 2016/17	2	3	6	↓	• Damage to East Midlands reputation • Potential loss of future commercial contract research to region • Reduction in funding from the CRN CC for time & target performance • May impact on any future RCF	OPEN	Monthly Divisional performance meetings	Ongoing	IOM	4	Industry Operations Manager	Monthly updates to COO & Executive Group
								Attendance at site selection visits in areas of poor performance	Ongoing	IOM	4		
								Request updates from sponsors for all studies expecting to close to recruitment this year	Actioned	IOM	5		
								Communications campaign - general PR on importance of RTT	Q1 17/18	Sr Team	4		
								Regular teleconferences with sponsors running studies at multiple primary care sites	Ongoing	IOM & IIM	4		
25	HLO2b will not be met (target 80%, currently 77%) by end of year 2016/17	5	3	15	↑	• Damage to East Midlands reputation • Reduction in funding from the CRN CC for time & target performance due to potential implementation of non-commercial performance premium	OPEN	Flag up studies that are underperforming	Ongoing	Sr Team	4	Business Intelligence Lead	Monthly updates to COO & Executive Group
								Understand reasons for underperforming studies and develop plan	Actioned	BI Lead	5		
								Analysis to predict year end RTT performance	Actioned	BI Lead	5		
								Communications campaign - general PR on importance of RTT	Q1 17/18	Sr Team	4		
								Meeting with Communications Lead to plan communication campaign	Actioned	BI Lead	5		
								Appoint Lead Performance Facilitator	March 17	BI Lead	3		

			Impact				
			1	2	3	4	5
			Very Low	Low	Medium	High	Very High
Likelihood	1	Rare	1	2	3	4	5
	2	Unlikely	2	4	6	8	10
	3	Possible	3	6	9	12	15
	4	Likely	4	8	12	16	20
	5	Almost certain	5	10	15	20	25

RISK RATING (SCORE)

Low (1-6)	Acceptable risk requiring no immediate action. Review annually.
Moderate (8-12)	Risk may be worth accepting with monitoring. Continue to monitor with action planned within six months. Place on risk registe
High (15-20)	Must manage and monitor risks. Action planned within three month. Review at monthly intervals. Place on risk register.
Extreme (25)	Extensive management essential. Action planned and implemented ASAP. Review weekly. Place on risk register.

RISK TREND

Static: ↔

Increasing: ↑

Decreasing: ↓

Action RAG Status Key:	5	**Complete**	4	**On Track**	3	**Some Delay – expected to be completed as planned**	2	**Significant Delay – unlikely to be completed as planned**	1	**Not yet commenced**

National Institute for Health Research

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 in 2017/18(section 9).

NIHR CLINICAL RESEARCH NETWORK: EAST MIDLANDS

Governance Framework

C O N T E N T S

NIHR CLINICAL RESEARCH NETWORK EAST MIDLANDS

Governance Framework

1. INTRODUCTION

1.1 The National Institute for Health Research Clinical Research Network (NIHR CRN) is the clinical research delivery arm of the NHS in England. Its purpose is to ensure patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research; integrate health research and patient care; improve the quality, speed and co-ordination of clinical research; increase collaboration with industry partners and ensure that the NHS can meet the health research needs of industry.

1.2 Before April 2014, there were over 100 clinical research networks in England hosted by NHS Trusts in adjacent localities. From April 2014, there will be only one research "branch" of the NIHR CRN in each NHS region; these are termed Local Clinical Research Networks (LCRNs). The formal name of the LCRN in the East Midlands is NIHR CRN East Midlands (the LCRN). University Hospitals of Leicester NHS Trust (the Trust) successfully applied to host this network on behalf of the NIHR and partner organisations in the East Midlands (Derbyshire, Nottinghamshire, Lincolnshire, Leicestershire, Rutland and Northamptonshire).

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

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

2. PURPOSE

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

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

3. GENERAL PRINCIPLES

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

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

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

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

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

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

4. EXECUTIVE LEADERSHIP TEAM

4.1 The **LCRN Accountable Officer** is the Trust's Chief Executive Officer, John Adler.

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

4.3 The Trust has appointed Professor David Rowbotham as the **LCRN Clinical Director**. The Clinical Director has local overall responsibility for the LCRN reporting to the Nominated Executive Director and the national CRN Coordinating Centre. The Clinical Director also leads 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 **LCRN Chief Operating Officer** who is responsible for the operational delivery of the contract and overall operational management of the network. The Chief Operating Officer reports to the LCRN Clinical Director and the national CRN Coordinating Centre. The Board understands that it is a contractual obligation to ensure that the Chief Operating Officer is a Trust employee.

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

- Deliver the core activities of the LCRN, in line with the agreed governance requirements within the Host Contract and Performance and Operating Framework;
- Ensure any activities are carried out as may be necessary for the proper governance of the LCRN;
- Ensure that a proper and auditable process is developed and executed for the fair and effective distribution of LCRN funding;
- Be available for regular meetings as a core Leadership Team;
- Support scrutiny and transparency, for example by providing any information as required for the internal auditors, and attending the audit committee of the Trust as requested;
- Ensure the timely delivery of performance and other reports;
- Support the Trust by adhering to any local governance requirements, such as the local standing financial instructions and all relevant national NHS requirements;
- Convene regular Partnership Group meetings;
- Make freely available to the Trust and all Partner organisations, as requested, any information that is not commercial and/or in confidence and in line with national NHS policies;
- Manage the LCRN so as not to compromise either the Host organisation or Partner organisations through reasons of conflicting issues such as competition law or data protection.

5. LCRN LEADERSHIP TEAM

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

- **LCRN Clinical Director** who 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 Divisional Research Delivery Managers** who provide day-to-day operational management of research activity in each of the six operational divisions;
- **Industry Delivery Manager** who is responsible for commercial research within the LCRN;
- **Business Intelligence Lead** who is responsible for monitoring budget expenditure and LCRN overall performance

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:

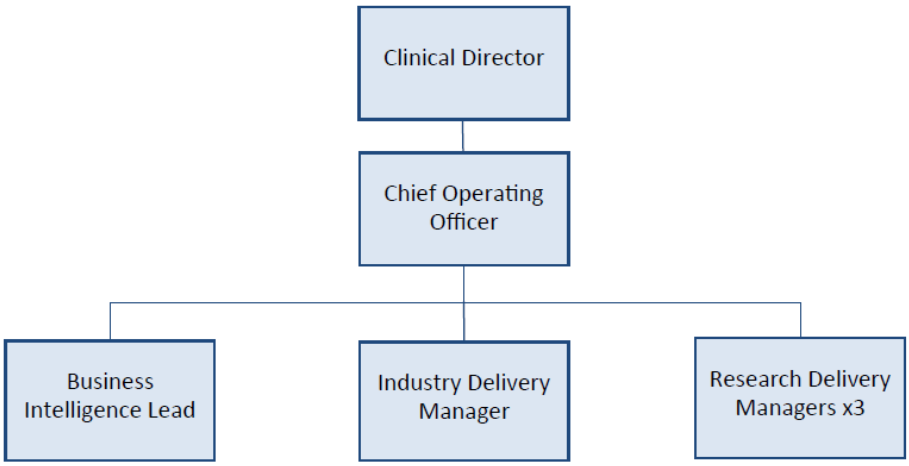

Figure 1 - CRN East Midlands Leadership Structure

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 and 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.

6. LCRN GOVERNANCE STRUCTURE

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

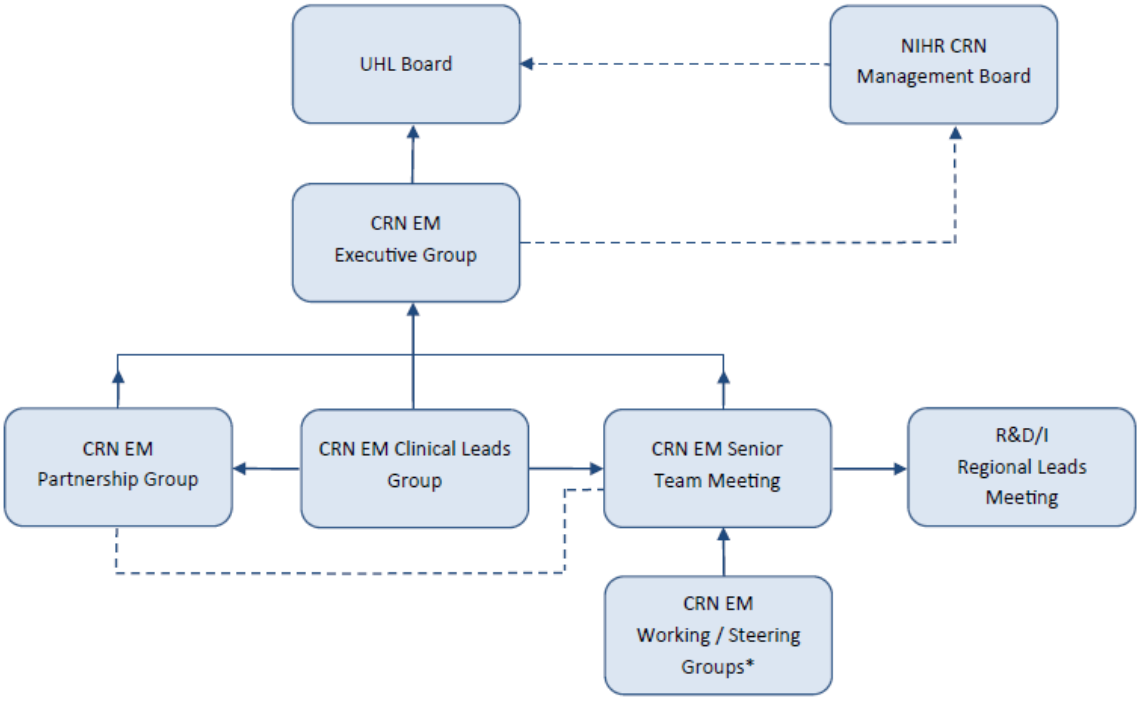

Figure 2 – CRN East Midlands Governance Structure

*Workforce Development Steering Group, Life Sciences Working Group, Business Intelligence Working Group, Communications Working Group, Finance Working Group, Patient and Public Involvement and Engagement Working Group, Study Support Service Working Group, Continuous Improvement Working Group, Combined Dementia Challenge Steering Group & EnRICH Advisory Group

6.2 The Trust has established the **LCRN Partnership Group**. The Group is a formal forum of LCRN partners (those receiving significant funding from the LCRN). 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 (Peter Miller, Chief Operating Officer, Leicestershire Partnership NHS Trust) and the group will be attended by the Trusts' Nominated Executive Director, LCRN Clinical Director and LCRN Chief Operating Officer. The Group meets four 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 Business Intelligence Lead, LCRN Project Manager, LCRN Host Financial Lead, and LCRN Communications Lead. Its purpose is to oversee and deliver good governance of the LCRN as defined by the Host contract and LCRN Operating Framework. The Group will meet every 3 months.

6.4 The Trust has established a **Senior Team Meeting** chaired by the Chief Operating Officer and reporting to the LCRN Executive Group. This group fulfils the expectations

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

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

6.6 The Trust has appointed a Clinical Leads Group consisting of the Clinical Director, Chief Operating Officer and LCRN Divisional Leads. The Clinical Leadership Group will work closely with the Senior Leadership Team; it's 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 the 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 the 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 (DH)-approved standard template sub-contracts, or other forms of agreement with DH-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 DH and the Trust. Measures will be developed to provide assurance that LCRN funding provided to partner organisations is used solely for these purposes.

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

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

8.5 The Trust, as Host Organisation, is required to submit an end-of-year financial return to the National CRN Coordinating Centre in respect of LCRN funding received. The financial return reports on all LCRN funding and expenditure, for all organisations in receipt of that funding and agrees the year-end figures for respective Partner Organisations.

Financial Scheme of Delegation

8.6 The Trust, as Host Organisation, has appointed Martin Maynes as **LCRN Host Finance Lead** who is responsible for the financial accountability of the network on behalf of the Trust. Martin produces LCRN financial reports for review by the LCRN Executive Group and LCRN Partnership Group.

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

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

8.9 Catherine Ashman-Lee, Kiran Mistry and Chris Siewierksi (**Study Support Service Managers**) & Kathryn Fairbrother (**Business Intelligence Lead**) are responsible for the operational management of the Service Support Costs budget.

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

8.11 Figure 3, which presents the structure of the finance team, is set out below:

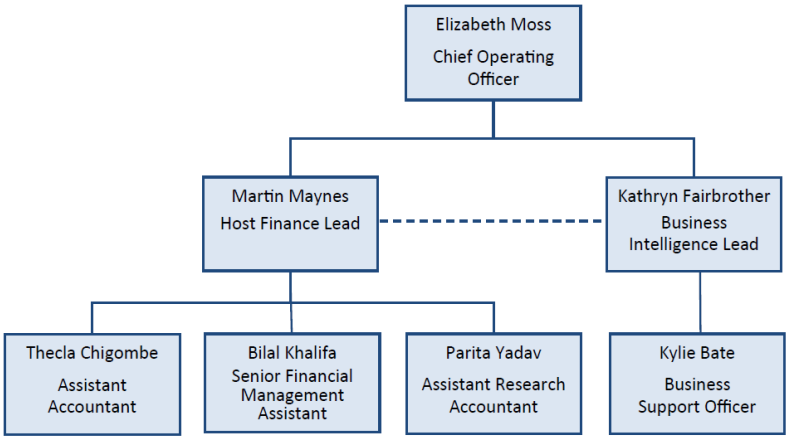

Figure 3 – CRN East Midlands Finance Support Structure

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

Table 1

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

9 ASSURANCE FRAMEWORK

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

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

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

Issue Management and Control

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

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

Table 2

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

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
Operational Management Group	
Staff surveys and exit interviews	
UHL Board feedback	
Executive Performance Board reporting	
LCRN Performance Dashboard	

LCRN Host Organisation Annual Review

9.9 The Trust may be requested, on an annual basis, to review its role in discharging the Department of Health 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

9.10 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.

9.11 The LCRN was audited in November/December 2014 and was provided a medium risk rating. There were six findings (5 minor, 1 medium) and the LCRN have prepared and enacted an action plan to ensure all findings were resolved by the end of Quarter 2, 2015/16.

9.12 The LCRN is due to undergo internal audit in 2017/18.

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 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				
			1	2	3	4	5
			Very Low	Low	Medium	High	Very High
Likelihood	1	Rare	1	2	3	4	5

	2	Unlikely	2	4	6	8	10
	3	Possible	3	6	9	12	15
	4	Likely	4	8	12	16	20
	5	Almost certain	5	10	15	20	25

RISK RATING (SCORE)	ACTION REQUIRED
Very Low and Low (1-6)	Acceptable risk requiring no immediate action. Review annually.
Moderate (8-12)	Risk may be worth accepting with monitoring. Continue to monitor with action planned within six months. Place on risk register.
High (15-20)	Must manage and monitor risks. Action planned within three month. Review at monthly intervals. Place on risk register.
Extreme (25)	Extensive management essential. Action planned and implemented ASAP. Review weekly. Place on 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 regards 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
2. Nominated Executive Director – Mr Andrew Furlong
3. The Trust Chief Executive Officer – John Adler
4. National CRN Coordinating Centre

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

13 MONITORING OF ACTION PLANS

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

13.2 The LCRN Executive Group will continue to monitor any new action plans created in 2017/18 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 subject to further development as the Trust hosting requirements and LCRN arrangements become embedded.

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

David Rowbotham
Clinical Director, CRN East Midlands

Appendix 4 – Shaping the future of NIHR Letter

Department of Health

NHS
National Institute for Health Research

From the Chief Scientific Adviser
Professor Chris Whitty CB FMedSci

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Our reference: 0005/17

6 February 2017

To:
Deans of Medical Schools, Council of Deans for Health,
AUKUH,
Directors of NIHR Schools,
NIHR Advisory Board,
NIHR Strategy Board

Dear Colleagues,

Shaping the future of NIHR - some reflections of NIHR one year in as Chief Scientific Adviser

It is now just over a year since I took over responsibility for NIHR from Dame Sally Davies, and about 9 months since Louise Wood took over from Russell Hamilton. We therefore thought it worth recording some reflections having had the chance to visit most (not yet all) of the medical schools, and speak to many of the wide range of people who have a direct or indirect interest in NIHR.

It has been a great privilege to see the fantastic science, of all sorts, being undertaken across the country. Like all of you we believe passionately in the demonstrable capacity of science in the broadest sense by multiple incremental steps to transform lives, improve public health and make the health service sustainable. None of the points we have captured from our discussions with you and many other colleagues below are new, but writing them down makes it easier to share them. Inevitably they are impressionistic and far from comprehensive.

The first, and by far the most important, impression is how much the NIHR does to underpin Health research, and therefore the future of health. The remarkable transformation that the creation of NIHR by Sally, Russell and many others was meant to achieve has happened, and the NIHR at 10 is a major part of the UK health research landscape, and currently the largest public funder.

In talking to colleagues, we have asked in every setting - what should NIHR keep, and what should it change? The answer has overwhelmingly been that current systems work well in the main. People identify improvements, but by-and-large they are upgrades of current systems rather than major changes. Whilst the points that follow inevitably concentrate more on the areas where it is sensible to explore changes, the main message from the community has

been one of **strong support for the current broad structures and direction of NIHR, as well as its commitment to public and patient involvement and engagement and partnership working within the life sciences ecosystem.** .

NIHR supports health and care research from early translational research through to clinical, public health and applied research. An issue which is raised frequently is the **balance of NIHR resource across the country**. Broadly, our view is that for experimental medicine/early translational research, such as science supported by the Biomedical Research Centres (BRCs) and Clinical Research Facilities, the single principle has to be to find the best internationally high-ranking science and fund it following open and competitive processes, as it is for basic research funded by the MRC and others. This does not logically work with a geographical preference. Research funded by NIHR must always be of high quality as weak science is of no use to anyone, but at **the more applied, clinical and public health end of the spectrum there is a strong scientific need for research to be conducted with and in the populations most affected**. Research activity should go to the populations who need it, and we would like to encourage the best researchers, wherever they are based, to undertake clinical and public health research in the areas of England with greatest health needs. There may be opportunities for the newer medical schools here.

Some of the issues people would like to see addressed are mechanistic, but mechanistic problems can act as a drag on the efficiency and time of researchers as well as influencing the attractiveness of research as a career. Four are worth a specific mention:

- **NIHR process is seen as heavy compared to other funders.** Having looked at the processes of NIHR we agree it is possible to make them simpler and faster, and in some cases significantly so. In all organisations process grows in complexity accidentally like barnacles on a ship. From time to time they need scraping off, and at 10 years old it is time for NIHR to do so, starting with the application processes for research projects, programmes and faculty. As an initial step the NIHR Co-ordinating Centres have been working with programme boards on a streamlined outline (stage 1) application form, which will be launched in May.
- **NIHR from the outside is seen as complex and difficult to navigate or explain**. Relatively few people actually know all the (many) bits of the system. We will aim to simplify the message, and where possible reduce the number of schemes which have tended to grow organically. Fewer, wider schemes would be a start.
- **Excess treatment costs** come up multiple times as a drag on productivity and cause of delay. There is no easy answer to this; if there was one it would have been found. It is clearly quite variable across the country, with some centres (Southampton is a standout) seeming to have largely fixed it locally. We will see what can be done centrally, but we do not underestimate the difficulties of a central fix, and we would urge people to share best practice and try and optimise local systems rather than wait for some central magic. We are however re-addressing this issue at the top of NHS England.
- The need for an **Athena Swan** silver award for many NIHR schemes, possibly surprisingly, has generated some of the most passionate views, both for and against. Few people can disagree both that women are under-represented at the higher levels of science, and that this is a **serious problem both of fairness and for the future of science in a country where the majority of those going into the health professions are women**. Those who argued most strongly for the benefits of Athena

Swan did so because it is totemic; those who expressed concerns thought that the bureaucratic burden was considerable. NIHR has a responsibility to play its part to help incentivise and facilitate improvements in getting rapidly towards parity. We do recognise there genuinely is a burden especially to smaller institutions in the process, but it is also clear that the need to get **silver status has catalysed important change in many institutions,** and that the change has not yet levelled off. Some institutions have a long way to go. We therefore intend to continue with the current NIHR policy on Athena Swan. It is not, however, a solution in itself, and we are looking at new incentives. For example, if an institution wishes to put two people forward for an NIHR Professor, now at least one must be a woman. **The really big fall-off is at post-doctoral stage** with women leaving and then not coming back into science, whilst they do go back into other high-level careers including medicine and allied professions. We would be **keen to improve the evidence base around what best to do about this**.

Training is a major part of NIHR's responsibility. If science funding has to be forward looking, research training has to be even more so. Many skills of researchers are timeless, but many are not. Dave Jones, the Dean of training for NIHR, is undertaking a review in which many of you will have been involved in. We are keen that NIHR's training schemes dovetail with those of other funders including the MRC and Wellcome Trust. Via its multiple routes NIHR is now the largest funder of health research training in the UK, so it is important we get this right.

The role of NIHR in early translational research, especially through the BRCs, and underpinning clinical research in the NHS is now well established and recognised widely. **Probably the areas for which there is the greatest opportunity to think things through are those at the more *applied* sciences, and in areas where other funders are not so active including nursing, therapies, nutrition, and other allied sciences and professions. Public health, primary care and social care are all areas we should be aiming for the UK to have the best research in the world**; no other country can undertake this for UK populations. There is much excellent research, including that funded by NIHR, but there may be (is in our opinion) a gap between the scale of the ambition and the scale of the need. The recent report by the Academy of Medical Sciences on the health of the public in 2040 identified some of the challenges, including the fact that the link between research and practice has been eroded. We look forward to discussing these with the NIHR Schools and others.

The inclusion of **Official Development Assistance (ODA**) funding in NIHR's budget for the first time from this year offers new opportunities to secure and build on the UK's leading contribution to health in developing countries. We are very encouraged by the response of the community to our initial funding calls for research to benefit health in low and middle income countries.

The importance of the **life sciences industry** has been thrown into sharp relief by Brexit. We currently have arguably the strongest industry in Europe and it is highly diversified and geographically dispersed. Having a vibrant life sciences industry has multiple wins: for patients, the NHS, public health and UK science as well as for the wider economy. Without a life sciences industry few of the fruits of translational research will progress. NIHR has established a positive reputation for supporting and collaborating with industry. Following the

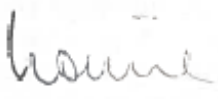
vote to leave the EU support for the industry has moved from being an important issue for NIHR to an urgent and central issue for government and has inevitably taken up more of our time the last six months than we had anticipated, pushing back some other less time-sensitive initiatives we had planned. **Brexit has also got implications for wider NIHR activity through its potential impact on UK science and the NHS**, but we do not think this letter is the right vehicle to address what are complex issues properly. We are very engaged on them within government, including contributing to the life sciences element of the industrial strategy, and appreciate the advice many of you have given us.

Research is by definition forward-looking. There are multiple steps, and delays, between research being conceptualised, funded, conducted, written up and getting into practice. The REF impact statement process demonstrated that for most fields (not just health) a median delay of 15 years to adoption was typical. **Those, like NIHR, funding clinical and applied research have a responsibility to look forward and identify the serious future problems which research could address**. Many of these sciences will be addressing already, but at any point in time there are gaps, where serious, predictable and solvable problems are not being addressed by anyone, or more commonly that the scale of the health problem and the scale of the research effort are badly misaligned. **NIHR should be identifying these scientific market failures and, where appropriate, incentivising leading researchers to take an interest in them.** We will be looking at ways to do this, and the starting point will be a 20 year *future look* to identify the predictable trends. We will shortly be inviting those who would like to help us through an informal process to do so; to be useful a future look should aim to be reasonably common ground among the community rather than the prejudices of a few people.

We would, finally, like to thank the very many people who over the last year have given up their time to provide advice, show us their science, and debate issues whether through formal structures and visits or informal interactions. We have learned a lot from it and will continue to do so. Getting unvarnished opinions and examples, good and bad, from all of you is essential if we are to continue to build on the successes (and shore up any cracks) in NIHR over the coming years.

Best wishes,

PROFESSOR CHRIS WHITTY
CHIEF SCIENTIFIC ADVISER



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