

Trust Board Paper BB

To:	Trust Board										
From:	David Rowbotham (Clinical Director) & Cathryn Love-Rouse (Interim Chief Operating Officer) NIHR Clinical Research Network: East Midlands										
Date:	24 April 2014										
CQC regulation:	N/A										
Title:	National Institute for Health Research (NIHR) Clinical Research Network: East Midlands Annual Plan 2014/15, Financial Planning Principles 2014/15 and Governance Framework										
Responsible Director:	Kevin Harris, Board Executive Lead										
Purpose of the Report:	To further inform the Board and facilitate discussion on the activities of the NIHR Clinical Research Network: East Midlands and to ask for approval of the three papers as above as mandated by the NIHR.										
The Report is provided to the Board for:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Decision</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">Discussion</td> <td style="width: 25%; text-align: center;">X</td> </tr> <tr> <td style="text-align: center;">Assurance</td> <td></td> <td style="text-align: center;">Endorsement</td> <td style="text-align: center;">X</td> </tr> </table>			Decision		Discussion	X	Assurance		Endorsement	X
Decision		Discussion	X								
Assurance		Endorsement	X								
Summary / Key Points:	On behalf of the Department of Health and NIHR, UHL is the host of the NIHR Clinical Research Network: East Midlands which became operational on April 1, 2014. The annual plan gives details of progress so far in the establishment of this new organisation, and strategic and operational plans for this year. The financial plan describes the strategy underlying the budget in response to a 4.8% reduction in expected allocation. The governance framework includes scheme of delegation, assurance framework, escalation process and risk management system. A more detailed summary of these papers is provided in the introduction.										
Recommendations:	Trust Board are requested to approve these papers.										
Previously considered at another corporate UHL Committee?	Executive Strategy Board, April 1, 2014 Host Executive Group, NIHR Clinical Research Network: East Midlands, April 10, 2014										
Board Assurance Framework:	Performance KPIs year to date:										
Resource Implications (eg Financial, HR):											
Assurance Implications:											

Patient and Public Involvement (PPI) Implications:

Stakeholder Engagement Implications:

Equality Impact:

Information exempt from Disclosure:

Requirement for further review?

NIHR Clinical Research Network: East Midlands Annual Plan 2014/15

Host Organisation	University Hospitals Of Leicester NHS Trust
Partner Organisations – Members of the Partnership Group	<ol style="list-style-type: none"> 1. Chesterfield Royal Hospital NHS Foundation Trust 2. Derby Hospitals NHS Foundation Trust 3. Derbyshire Community Health Services NHS Trust 4. Derbyshire Healthcare NHS Foundation Trust 5. East Midlands Ambulance Service NHS Trust 6. Kettering General Hospital NHS Foundation Trust 7. Leicestershire Partnership NHS Trust 8. Lincolnshire Community Health Services NHS Trust 9. Lincolnshire Partnership NHS Foundation Trust 10. Northampton General Hospital NHS Trust 11. Northamptonshire Healthcare NHS Foundation Trust 12. Nottingham University Hospitals NHS Trust 13. Nottinghamshire Healthcare NHS Trust 14. Sherwood Forest Hospitals NHS Foundation Trust 15. United Lincolnshire Hospitals NHS Trust 16. University Hospitals Leicester NHS Trust
Other Affiliated Organisations identified (e.g. CCGs/Social enterprises)	<p>19 CCGs, 3 LATs, 1 Social Enterprise</p> <p>NHS Nene CCG NHS Corby CCG NHS Leicester City CCG NHS West Leicestershire CCG NHS East Leicestershire & Rutland CCG NHS Lincolnshire East CCG NHS Lincolnshire West CCG NHS South Lincolnshire CCG NHS South West Lincolnshire CCG NHS Erewash CCG NHS Hardwick CCG NHS North Derbyshire CCG NHS Southern Derbyshire CCG NHS Nottingham City CCG NHS Nottingham North and East CCG NHS Nottingham West CCG NHS Rushcliffe CCG NHS Mansfield and Ashfield CCG NHS Newark and Sherwood CCG</p> <p>NHS England Derbyshire & Nottinghamshire Area Team NHS England Leicestershire & Lincolnshire Area Team NHS England Hertfordshire & the South Midlands Area Team</p> <p>Nottingham CityCare Partnership NIHR CLAHRC East Midlands</p>

	<p>East Midlands Academic Health Science Network Leicester Experimental Cancer Research Unit Leicester Cardiovascular Biomedical Research Unit Nottingham Hearing Biomedical Research Unit Nottingham Digestive Diseases Biomedical Research Unit Leicester Respiratory Biomedical Research Unit Leicester-Loughborough Diet, Lifestyle and Physical Activity BRU Leicester Clinical Trials Unit Nottingham Clinical Trials Unit</p>
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Historic LRNs	<p>Derby/Burton (NCRN) East (MCRN) East Midlands (MHRN)* East Midlands & South Yorkshire (PCRN) Leicestershire, Northamptonshire & Rutland (CCRN) South East Midlands (DRN) Leicestershire, Northamptonshire & Rutland (NCRN) Mid Trent (NCRN) Trent (CCRN) Trent (SRN) Thames Valley DeNDRoN covered Leicestershire Partnership NHS Trust and Northamptonshire Healthcare NHS Foundation Trust</p> <p>*Heart of England Hub of the Mental Health Research Network included Leicestershire Partnership as a founder member, and later included Northamptonshire.</p>
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Host Organisation Accountable Officer for the LCRN (Chief Executive Officer)		
Name	Mr John Adler	Email: john.adler@uhl-tr.nhs.uk Tel: 0116 258 8940
Nominated Executive Director for the LCRN		
Name	Dr Kevin Harris Medical Director	Email: kevin.harris@uhl-tr.nhs.uk Tel: 0116 258 8016
LCRN Clinical Director		
Name	Professor David Rowbotham	Email: DRowbotham@uhl-tr.nhs.uk Tel: 0116 258 5291

LCRN Chief Operating Officer**Name**

Elizabeth Moss
 (start date to be confirmed)
 Cathryn Love-Rouse
 Interim COO

Email:
Cathryn.love-rouse@uhl-tr.nhs.uk
 Tel: 07921 545537

Transition Facilitation Lead for the LCRN**Transition Facilitation Lead**

Janet Boothroyd
 Senior Manager, Trent CLRN
 and Local Transition Facilitation
 Lead (East Midlands)

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Please briefly outline the process of engagement/consultation with LCRN Partners, existing local CRN Network Leadership and other stakeholders regarding the submitted LCRN Annual Plan 2014-15:

The approach to the development, preparation and collation of the annual plan and financial plan has been a collaborative one, led largely by the interim Operational Management Group (OMG) working with Divisional and Specialty Group Leads and supported by a Project Adviser and Project Manager.

Initial approaches to preparation of the plan were presented to the Interim Partnership Group in February 2014. The draft plan will be emailed to the Interim Partnership Group and OMG for comment prior to final submission. Subsequent meetings and teleconferences with OMG have considered the strategic approach to recruitment target setting supported by data from network information management teams. 2014-15 recruitment goals are ambitious in a bid to attract additional activity based funding and to reverse the trend of budget reductions. Goals are indicative and will be revised in May 2014. Network Managers have facilitated completion of specialty actions, further local development of these will continue at divisional level.

A Financial Sub Group of OMG supported by the host finance officer, facilitated the principles behind the draft budget which were presented to the Partner Organisations in March for discussion and review. A regional Finance Forum has also been established.

A summary of engagement activities are included in appendix 11 to demonstrate engagement and collaboration in the thinking behind the plan and developmental actions going forward. This plan has been shared with OMG, Divisional Clinical Leads and Speciality Leads and the Partnership Group. The original plan for Trust Board approval was submission to the March meeting. However, it was suggested at the March meeting of the

LCRN Executive Group that the plan could be discussed comprehensively at the Trust Executive Strategy Board on 1st April 2014 which meets monthly. It was thought that this was an excellent opportunity to do this but it would mean delaying full Board approval until 24th April 2014. This was discussed by the LCRN CD at the recent CD COO Development meeting with John Sitzia who agreed to this arrangement. The plan was indeed extensively discussed and approved by the Executive Strategy Board on 1st April and will receive full Trust Board approval as above.

Confirmation of approval by the Host Organisation Board: as above, expected 24th April 2014

Name	Dr Kevin Harris	Email: kevin.harris@uhl-tr.nhs.uk Tel: 0116 258 8016	
Role	Medical Director		
Signature		Date	
Contact for any communication regarding the LCRN Annual Plan			
Name	Cathryn Love-Rouse	Email: Cathryn.love-rouse@uhl-tr.nhs.uk Tel 07921 545537	
Role	Interim COO		
Date	March 2014		

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Executive Summary

Mission

Enhance the health and wealth of the East Midlands population through participation in high quality research

Vision

Secure a top 3 position in the performance ratings of the NIHR Clinical Research Networks by 2015, recognised for activity and quality, engagement and delivery and a network that offers added value

Challenges

- Sustain strong performance against the national high level objectives through the transition period and maintain the skilled workforce to support this
- Achieve growth necessary to maximise funding whilst delivering a balanced budget (goal = 50,000 patients)
- Attract industry partners to the region and secure repeat business and protected income generation for investment and re-investment locally
- Promote and achieve effective partner and public engagement as the foundation for successful delivery
- Promote equity of access to research at participant, investigator and delivery team level
- Deliver a balanced portfolio of NIHR activity maximising opportunities to participate and lead research
- Participate in a competitive environment that demands consistently high performance but where opportunities for growth and innovation exist

Immediate Priorities

- Ensure effective partner, clinical, public and industry engagement
- Provide the environment for research to flourish (infrastructure, resources, facilities, people, funding, support, training, IT)
- Maintain clinical and managerial strategic and operational leadership across the region
- Deliver with industry partners
- Ensure governance structures add value and promote transparency in all aspects of delivery
- Market the East Midlands as a region to do and deliver research
- Facilitate all partners to be actively involved with growth in all clinical specialties

Mid - Long Term Priorities

- Contribute and influence the research pipeline supporting and enabling Chief Investigators
- Secure investment and increase levels of income
- Demonstrate value for money
- Provide a flexible, skilled professional research responsive workforce
- Ensure PCPIE is evident across key workstreams
- Reward and recognise contribution
- Enable integration that removes silo working “family status”
- Develop mutually beneficial collaborative relationships
- Facilitate innovation and improvement

Section A: Review of 2013-14 performance and local intelligence gathering

All local research networks within the region completed a standard proforma in January 2014 to capture 2013-14 performance; identify good practice and successes; highlight challenges and mitigating actions and explore priorities and opportunities. Network returns can be found in [APPENDIX 1](#). Consistent responses across the majority of networks included:

- the challenge of maintaining performance during the transition period and embedding new structures
- the risk of financial instability and the need to attract network and industry investment
- ensuring transparent funding models reflect complexity, performance, activity and delivery
- the need to ensure we maintain current strategic and operational clinical, management and delivery expertise and experience across the workforce
- the danger that opportunities for growth may be hampered by limited portfolio availability in some areas
- to enable equity of access to studies for participants and to encourage keen research teams to join and lead studies
- the danger of silo working and under representation in some clinical and service areas
- establishing the infrastructure to support delivery as an immediate priority
- effective communication and engagement and establishing/embedding partnership working with partner organisations and stakeholders
- opportunities to work collaboratively and share practice across a larger geographical region with enhanced coverage
- enthusiasm for creating an attractive supportive environment for research to flourish

Section B: 1. Progress and Plans against the LCRN Development and Improvement Objective

POF Area	POF requirement	POF Ref	Information Required	RAG** status	Commentary
LCRN Governance	Host Organisation sign-off of LCRN Governance Arrangements	3.4	Provide RAG status and commentary if applicable	Green	These are set out in the LCRN Assurance and Governance Framework signed off by the Host Trust Executive Strategy Group on 1 st April 2014 with recommendation for Trust Board approval on 24 th April 2014 (see APPENDIX 14). Reporting structure can be found in APPENDIX 3 with the Senior Management structure.
	Nominated Executive Director identified	3.6, 3.7	Provide RAG status and commentary if applicable	Green	Appointed: Dr Kevin Harris, UHL Medical Officer
	Scheme of delegation and Host Board controls and assurances established	3.8	Provide RAG status and commentary if applicable	Green	An Assurance and Governance Framework, which includes the scheme of delegation and Host Board controls, has been created for the LCRN. This was signed off by the Trust Executive Strategy Group on 1 st April 2014 with recommendation for Trust Board approval on 24 th April 2014. The final version is included in APPENDIX 14 .

	Assurance Framework & Risk Management System developed	3.12	Provide RAG status and commentary if applicable	Green	The LCRN Assurance and Escalation Framework is due to be signed off by the UHL Board on 27 March 2014. LCRN Risk Management Strategy: A detailed Action Plan has been created by the CRN East Midlands Host Organisation to help ensure the requirements as specified in the Contract and POF are carried out. Anything that may impact UHL's ability to deliver on time is highlighted as a risk. A risk register has been created to capture these, and this is reviewed monthly by the Executive Group.
	Business continuity arrangements are in place for the LCRN in the event of a pandemic or other emergency	3.14	Provide RAG status and commentary if applicable	Amber	The CRN: East Midlands will follow the business continuity arrangements currently in place for the Comprehensive and Topic Research Networks within the region. CRN: East Midlands will establish business continuity arrangements once the CRN is more established and key appointments are in place.
	Plans in place for inclusion of LCRN activity in the local internal audit programme of work	3.16	Provide RAG status and commentary if applicable	Green	The Clinical Director and Finance Lead have arranged for LCRN activity to be included in the internal audit programme. These arrangements have been finalised with UHL's Interim Finance Director and the auditor, PWC.
	Implement and maintain a documented LCRN escalation process	3.17	Provide RAG status and commentary if applicable	Green	This is included in the LCRN Assurance Framework approved by the Host Trust Executive Strategy Group on 1 st April 2014.
	LCRN Partnership Group	3.19 - 3.29	Provide a copy of Terms of Reference for the Group	Green	Interim Partnership Group met for the second time on 7 th February 2014 to agree proposed membership of the full group. Proposed membership can be found in APPENDIX 2 . NHS Trust Chief Executives have been requested to nominate a representative, and work is currently underway to fulfil membership from all partners.
Leadership Team	Appointment of LCRN Leadership Team, including as a minimum; the nominated executive director; the LCRN Clinical Director; and LCRN Chief	4.1	Provide RAG status and commentary if applicable	Green	Executive Director: Dr Kevin Harris Clinical Director: Professor David Rowbotham Chief Operating Officer: Elizabeth Moss

	Operating Officer				
Management arrangements	Research Delivery Cross-Cutting Team	5.25-5.29	Provide RAG status and commentary if applicable	Amber	Organisational senior management structure has been developed and agreed at OMG (see APPENDIX 3). These posts will contribute to the planning and continued development of the LCRN research delivery cross cutting team when appointed. Draft actions associated with cross-cutting areas have been identified and will be finalised by the COO on return from maternity leave in May.
	LCRN Support Team	5.30, 5.31	Provide RAG status and commentary if applicable	Amber	Organisational senior management structure has been developed and agreed at OMG. These posts will contribute to the planning and continued development of the LCRN support team following management of change process, anticipated completion mid May.
	Operational Management Group	5.38-5.40	Provide confirmation the Group has been established in accordance with the provided Terms of Reference	Green	Interim OMG have been meeting monthly since October 2013. Membership can be found in APPENDIX 6 . From 1 st April membership will include Trusts representation. ToR to be amended at April OMG meeting.
Research Delivery	All LCRN organisations adhere to specified national systems, Standard Operating Procedures and operating manuals in respect of research delivery. The Host Organisation ensures that the LCRN management team provides excellent study performance management in order that all NIHR CRN Portfolio studies recruit to agreed timelines and targets	6.1-6.19	Provide confirmation the LCRN has an engagement and communication strategy in place for stakeholders involved in the research delivery and governance pathway	Green	Communications strategy has been agreed by the Executive Group (see APPENDIX 12). Communications Working Group was convened in January and meets monthly. Agreed Terms of Reference and Objectives can be found in the Working Group summary paper APPENDIX 7 .
			Provide a brief outline of local plans for implementation, delivery and oversight of research management and governance services by the LCRN	Amber	A detailed action plan for RM&G delivery has been developed (see APPENDIX 8). This plan will be reviewed during 2014/15 in response to HRA developments in order to assess impact upon LCRN RM&G functions and delivery. The RM&G Working Group has been established, Terms of Reference and Objectives can be found in the Working Group summary paper APPENDIX 7 . Trent and LNR CLRN's have both included examples of strong RM&G performance and good practice in their local intelligence reports in APPENDIX 1 . The Life Sciences Industry Working Group is led by Karen Pearson. The group have agreed their membership and ToR (Working Group summary paper APPENDIX 7).

Patient, Carer and Public Involvement and Engagement (PCPIE)	Promotion of research opportunities in line with the NHS Constitution for England, including informing patients about research conducted within the LCRN and actively involving and engaging patients, carers and the public in research	8.1-8.6	Provide confirmation that a PCPIE workplan is in place	Green	PCPIE Working Group has been convened (met Jan and Feb 2014) and agreed Terms of Reference and Objectives (see Working Group summary paper APPENDIX 7). PCPIE draft strategy and workplan is can be found in APPENDIX 9 . As part of the governance structure, the first priority is to establish Patient, Carer and Public Advocate posts in the various working groups. The advert for Patient, Carer and Public Advocates to join the Partnership Group has been circulated.
Workforce Development	Workforce development plan developed in partnership with relevant stakeholders and other local learning providers	10.1-10.9	Provide confirmation that a workforce development plan is in place	Amber	Colleagues from the region met once in 2013 as a regional group. A formal WD working group has been established following change of leadership and have agreed the Terms of Reference and Objectives which can be found in the Working Group summary paper APPENDIX 7 . LTFL was asked to talk at Horizon Planning Event at LETB on 14 February.
Corporate Support Services	Provision of management processes or support services identified as necessary within the Host Organisation to enable effective running of the LCRN	11.1, 11.2	Provide confirmation all specified Corporate Support Services are in place	Green	<ul style="list-style-type: none"> • Governance, risk and assurance arrangements, information governance – these have been documented in the LCRN Assurance and Escalation Framework which were signed off by the Host Trust Executive Strategy Group on 1st April with recommendation for approval at the Host Trust Board on 24th April 2014. • Information Governance – support identified within Host Organisation – Robin Smith, Head of Privacy. • Finance management and reporting – regular meetings with Interim Finance Director. Host organisation has appointed a Finance Lead, Martin Maynes. Martin has regular contact with Assistant Finance Director who has corporate responsibility for R&D. Martin Maynes has convened an East Midlands Finance Forum, with representatives across the region. • Human Resources – Host organisation has appointed a HR Lead, Smita Ganatra to ensure HR processes are streamlined across the East Midlands. Smita and

					<p>Clinical Director have regular meetings with UHL HR Director. A regional HR group was established in December 2013.</p> <ul style="list-style-type: none"> Information Technology – Clinical Director has discussed the CRN and local IT requirements with the IT Director. IT support is provided to all staff and jobs will be escalated if authorised by the Clinical Director. The provision of IT support by CRN East Midlands Partner Organisations will be written into the subcontracts. Office space and facilities for LCRN staff –The Host Organisation is working with POs to ensure that current facilities across the region are retained. New accommodation is currently being sourced for staff based at UHL as more capacity is required. The Clinical Director has assigned two LCRN senior managers to work closely with the UHL Project Manager, Louise Naylor, to ensure suitable accommodation is found. Legal and contracting support – Clinical Director has confirmed support arrangements with Stephen Ward (Director of Corporate and Legal Affairs, UHL) and Steve Murray (Head of Legal, UHL)
Information Systems	Appropriate, reliable and well maintained information systems and services are in place and fully operational	13.1 - 13.18	Confirm LPMS systems are in place as required	Amber	Working Group was convened in January and meets monthly. Terms of Reference and Objectives have been agreed and ratified; see Working Group summary paper APPENDIX 7 . Completed tasks include development and dissemination of a local LPMS leaflet, survey/mapping of current systems across the region and 3x supplier introductory demo's. Priority actions include the development of the local minimum (must have) spec for LPMS. A Host procurement contact has been identified to join the Working Group and a project brief has been submitted to the Host IT team. There is a collaborative approach to this workstream with CRN: West Midlands (information sharing and co-attendance at meetings in development).
			Confirm arrangements are in place for provision of an	Amber	Not started – likely to form part of working group objectives after 1 April 2014.

			LCRN Service Desk function and provide contact details		
Communications	Dedicated communications function and delivery plans in place, and budget line identified	14.1	Confirm a dedicated communications function is in place	Green	Interim Host Comms lead identified: Tiffany Jones. During the transition we have confirmed a dedicated communications resource in the form of the Head of Communications & Engagement at the University Hospitals of Leicester NHS Trust (the host organisation) supported by two network administrators who will each provide two days support per week. A working group has been convened and met (Jan and Feb 2014). Lead: Sarah Nicholson NCRN LNR Network Manager. Terms of Reference and Objectives have been agreed and are included in the Working Group summary paper APPENDIX 7 . We are in the process of confirming a job description to recruit a dedicated communications lead for the new CRN: East Midlands.
		14.2	Confirm a communications work programme is in place	Green	Working Group was convened in January and meets monthly. Lead: Sarah Nicholson NCRN LNR Network Manager. Terms of Reference and Objectives have been agreed, see Working Group summary paper APPENDIX 7 . A communications strategy has been created and approved by the Host Exec Group, see APPENDIX 12 to get the network through the transition to inception and implementation of the CRN: East Midlands. The action plan within that strategy outlines a number of activities that will be carried out during transition and in the early days of the new network. Once the dedicated communications lead has been recruited it will be their role to create a new action plan that supports the agreed Annual Plan and promotes the activities of the CRN: East Midlands.
		14.3	Confirm the LCRN is operating in compliance with brand guidelines	Green	We can confirm that we are operating within the LCRN guidelines and that responsibility for assuring compliance will sit with the communications lead.
Information Governance	Promote and enable good Information Governance (IG) relating to all areas of LCRN activity	15.1-15.8	Provide baseline (2013) IG toolkit score for the LCRN Host Organisation and confirmation of attainment of Level 2 or above on all	Green	Table included as APPENDIX 13 .

			requirements or any exceptions that arise from or impact on LCRN-funded activities		
			Confirm a process is in place for timely reporting to the CRN Coordinating Centre of all information governance incidents arising from LCRN-funded activities	Amber	This process is not yet in place – with reference to the IG Lead role outline and responsibilities and interim lead has been identified. This will be discussed at the April OMG meeting and the RM&G working group.

**** RAG status – guidance for LCRN self-assessment**

	Arrangements in place
	Arrangements not yet in place but plans developed and on schedule
	Plans not agreed/implementation significantly delayed/behind schedule

Section B: 2. Details of key groups and lead individuals

POF Area	Information Required	POF Ref	Name	Job title	Organisation	Clinical Profession
LCRN Governance	Provide the name, job title and organisation of the LCRN Partnership Group Chair	3.25	Dr Peter Miller	Chief Executive Officer	Leicestershire Partnership NHS Trust	
	Provide a list of members (name, job title and organisation) of the LCRN	3.29	Dr Sean Scanlon/Dr Alex O'Neill-Kerr	Associate Medical Director/Medical Director	Northamptonshire Healthcare NHS Foundation Trust	
			TBC – awaiting response from CEO	TBC	Northampton General Hospital NHS Trust	

	Partnership Group		Dr Gwyn McCreanor	AMD Clinical Services & Clinical Lead for Research	Kettering General Hospital NHS Foundation Trust	
			Dr Kevin Harris	Medical Director	University Hospitals of Leicester NHS Trust	
			TBC – awaiting response from CEO	TBC	Leicestershire Partnership NHS Trust	
			Dr Gail Collins	Medical Director	Chesterfield Royal Hospital NHS Foundation Trust	
			Prof Richard Donnelly	Director of Research & Development	Derby Hospitals NHS Foundation Trust	
			TBC – awaiting response from CEO	TBC	Derbyshire Healthcare NHS Foundation Trust	
			TBC – awaiting response from CEO	TBC	Derbyshire Community Health Services NHS Foundation Trust	
			Dr Trevor Mills	Medical Director	East Midlands Ambulance Service NHS Trust	
			TBC – awaiting response from CEO	TBC	Lincolnshire Community Health Services NHS Trust	
			TBC – awaiting response from CEO	TBC	Lincolnshire Partnership NHS Foundation Trust	
			TBC – awaiting response from CEO	TBC	Nottingham University Hospitals NHS Trust	
			Dr Nick Manning		Nottinghamshire Healthcare NHS Trust	

			TBC – awaiting response from CEO	TBC	Sherwood Forest Hospitals NHS Foundation Trust	
			Dr Suneil Kapadia	Medical Director	United Lincolnshire Hospitals NHS Trust	
			TBC – to be advertised	PCPIE Representative x 3		
			TBC – written to Research Lead		Nottinghamshire CCGs	
			TBC – written to Research Lead		Derbyshire CCGs	
			TBC – written to Research Lead		Northamptonshire CCGs	
			TBC – written to Research Lead		Lincolnshire CCGs	
			TBC – written to Research Lead		Leicestershire CCGs	
			TBC – written to Medical Director		NHS England LAT – Derbyshire & Nottinghamshire	
			TBC – written to Medical Director		NHS England LAT – Leicestershire & Lincolnshire	
			TBC – written to Medical Director		NHS England LAT – Herefordshire & South Midlands	
			TBC	Primary Care contractors x 3		
			TBC		Academic Health Science Network	
			TBC		CLAHRC East Midlands	
			Prof David Rowbotham	Clinical Director	CRN East Midlands	
			Elizabeth Moss	Chief Operating Officer	CRN East Midlands	
Management arrangements	Provide a list of names of local Clinical Research Specialty Leads and their clinical profession	5.7-5.16	Dr Ann Thomas			Cancer
			Dr Vaughn Keeley			Cancer
			Prof David Walker			Cancer
			Prof Melanie Davies			Diabetes
			Prof Kamlesh Khunti			Diabetes
			Dr Peter Mansell			Metabolic &

<p><i>Note: existing CLRN Specialty Group and Topic Network Clinical Leads are rolling over until appointment process is finalised</i></p>				Endocrine
	Dr Jonathan Barratt			Renal
	Dr Chris McIntyre			Renal
	Dr Nikola Sprigg			Stroke
	Prof Nilesh Samani			Cardiovascular
	Dr Gerry McCann			Cardiovascular
	Dr Justin Cooke			Cardiovascular
	Dr Elaine Boyle			Children
	Dr Munib Haroon			Children
	Dr Jon Dorling			Children
	Prof Alan Smyth			Children
	Dr Julian Barwell			Genetics
	Dr Rachel Harrison			Genetics
	Prof Doug Tincello			Reproductive Health & Childbirth
	Dr George Bugg			Reproductive Health & Childbirth
	Prof Jim Thornton			Reproductive Health & Childbirth
	Prof Tom Dening			DeNDRoN
	Prof Cris Constantinescu			Neurology
	Prof Richard Morriss			Mental Health
	Dr Azhar Zafar			Primary Care
	Prof Azhar Farooqi			Primary Care
	Dr Simon Conroy			Ageing
	Dr Tahir Masud			Ageing
	Dr Waji Hassan			Musculoskeletal
	Dr Chris Deighton			Musculoskeletal
	Dr Anton Alexandroff			Dermatology
	Dr Adam Ferguson			Dermatology
	Prof Hywel Williams			Dermatology
	Dr Daniel Harvey			Critical Care
	Dr Jonathan Thompson			Critical Care
	Prof Tim Coats			Injuries & Emergencies
Prof Frank Coffey			Injuries & Emergencies	

			Mr Matt Bown			Surgery
			Prof Dileep Lobo			Surgery
			Prof John Scholefield			Surgery
			Prof Deb Hall			Ear, Nose & Throat
			Dr Adrian Palfreeman			Infectious Diseases
			Prof Irene Gottlob			Ophthalmology
			Prof Chris Brightling			Respiratory
			Prof Alan Knox			Respiratory
			Dr John DeCaestecker			Gastroenterology
			Prof Krish Ragunath			Gastroenterology
			Dr Toby Delahooke			Hepatology
			Dr Stephen Ryder			Hepatology
			Dr Andrew Wilcock			Palliative Care
	Provide the name and email address of the individual appointed as LCRN Research Delivery Manager ¹ for Division 1	5.17-5.24	To be appointed by mid May			
	Provide the name and email address of the individual appointed as LCRN Research Delivery Manager for Division 2		To be appointed by mid May			
	Provide the name and email address of the individual appointed as LCRN Research Delivery Manager for Division 3		To be appointed by mid May			
	Provide the name and email address		To be appointed by mid May			

¹ Note: LCRNs are not required to appoint six separate individuals to the 6 Divisional Research Delivery Manager posts

	of the individual appointed as LCRN Research Delivery Manager for Division 4					
	Provide the name and email address of the individual appointed as LCRN Research Delivery Manager for Division 5		To be appointed by mid May			
	Provide the name and email address of the individual appointed as LCRN Research Delivery Manager for Division 6		To be appointed by mid May			
	Provide details of the membership of the LCRN Executive Group	5.36	Prof David Rowbotham	Clinical Director	CRN East Midlands	
			Elizabeth Moss (from appointment). Cathryn Love-Rouse (interim COO)	Chief Operating Officer	CRN East Midlands	
			Dr Kevin Harris	Medical Director & Executive Lead (CRN: EAST MIDLANDS)	University Hospitals of Leicester NHS Trust	
			Martin Maynes	Finance Lead	University Hospitals of Leicester NHS Trust	
			Smita Ganatra	Senior HR Advisor	University Hospitals of Leicester NHS Trust	
	Provide details of the membership of the Clinical Research	5.37	Prof David Rowbotham	Clinical Director	CRN East Midlands	Professor of Anaesthesia and Pain Management
			Prof Poulam Patel	Clinical Research	Nottingham	Professor of Clinical

	Leadership Group			Lead Division 1	University Hospitals NHS Trust/University of Nottingham	Oncology
			Prof Melanie Davies	Clinical Research Lead Division 2	University Hospitals of Leicester NHS Trust/University of Leicester	Professor of Diabetes Medicine
			Prof Alan Smyth	Clinical Research Lead Division 3	Nottingham University Hospitals NHS Trust/University of Nottingham	Professor of Child Health
			Prof Richard Morriss	Clinical Research Lead Division 4	Nottinghamshire Partnership NHS Trust/University of Nottingham	Professor of Psychiatry
			Prof Azhar Farooqi	Clinical Research Lead Division 5	GP, East Leicester Medical Practice, Co-Chair Leicester City CCG	General Practitioner
			Dr Stephen Ryder	Clinical Research Lead Division 6	Nottingham University Hospitals NHS Trust/University of Nottingham	Consultant Hepatologist
Research Delivery	Provide the name and email address of the appointed Industry Operations Manager	5.25	To be appointed by mid May Key contacts for RM&G, CSP and Industry have been provided previously.			
PCPIE	Provide the name of the senior leader with identified responsibility for PCPIE within the LCRN	8.6	Mark Howells: Working Group Lead. Mark.howells@nuh.nhs.uk			
Continuous Improvement (CI)	Provide the name and email address	9.5	Ann Priddey Ann.priddey@nottingham.ac.uk			

	of the senior leader with identified responsibility for continuous improvement within the LCRN					
Workforce Development	Provide the name and email address of the senior leader with identified responsibility for LCRN workforce development	10.4	Julie Berridge: Working Group Lead. julie.berridge@nuh.nhs.uk			
Information Systems	Provide the name and email address of the identified lead for the Business Intelligence function	13.2	Cathryn Love-Rouse: Working Group Lead. Cathryn.love-rouse@uhl-tr.nhs.uk Colin Bray: Host Procurement contact. Colin.bray@uhl-tr.nhs.uk Both CLRN Information Managers sit on the nation ISM Transition Working Group and will be able to advise on the Business Intelligence Function.			
Information Governance (IG)	Provide the name and email address of the individual with specialist IG knowledge identified to respond to IG queries relating to LCRN-funded activities	15.7	Robin Smith Head of Privacy Robin.smith@uhl-tr.nhs.uk			

Section C: 3. LCRN plans and goals in support of NIHR CRN High Level Objectives

Objective	Measure	CRN Target	LCRN Goal/Target	LCRN actions/activities for 2014-15	Timescale
1	Increase the number of participants recruited into NIHR CRN Portfolio studies	650,000	Enter the overall LCRN goal for 2014-15 recruitment 50,000 (indicative, to be reviewed with final 13/14 data)	Please enter as appropriate; the number of lines shown is an example not an expectation and more lines may be added as necessary <u>Strategic:</u> <ul style="list-style-type: none"> • In all activities ensure the CRN: East Midlands works to and maintains clear intent and value added purpose (see Executive summary mission and vision). • Engage with CRN: East Midlands partners, stakeholders and affiliated organisations, industry and business partners to support research activity planning (short, mid, long term) that offers a balanced portfolio and opportunities for growth, informed by Divisional Clinical Leads and Clinical Specialty Groups. • Local actions to support national specialty objectives can be found in section c of this plan. • Build upon and establish new mutually beneficial connections that bring added value to each party and support the strategic objectives of the CRN: East Midlands allowing for innovation and improvement. This will include taking forward East Midlands wide initiatives with existing and new partners. • Enable growth, strategic development and equity of access to clinical research without restriction (geography, skills, people, facilities, resources). • Maximise opportunities to secure external financial investment and reinvestment locally • Maintain regional expertise in both strategic and operational leadership, clinical, managerial and delivery aspects. • Ensure effective engagement with specialty leads and partners in the development of realistic but ambitious recruitment targets. • Engage with experts in the marketing field to positively promote the 	Please outline timescale for actions Indicative Q2-Q3

Objective	Measure	CRN Target	LCRN Goal/Target	LCRN actions/activities for 2014-15	Timescale
				<p>EM region as a place to do research, sell ourselves and our successes.</p> <ul style="list-style-type: none"> • Continue to use the Partnership Group, Clinical Leadership Group, OMG and Working Groups for strategic and operational planning incorporating mapping of opportunities, expertise, resources, facilities and good practice. Ensure that the Clinical Division Leads work closely with the Division Mangers and OMG to ensure effective operational and strategic decision making . • Develop and implement Divisional annual budget and action plans with Divisional Clinical Leads, Specialty Leads and Divisional Managers with continuity of local leadership and a strong managerial and clinical focus on operational strategies. • Develop and implement annual action plans in each of the workstreams that support both strategic and operational goals. • Establish robust and transparent finance and activity reporting and performance management mechanisms to support openness and encourage partnership working. • Prioritise engagement opportunities to enable partners to be involved in strategic planning and delivery (particularly in the early stages of divisional planning with Clinical Leads). • Contribute to national initiatives/working groups • Build confidence and understanding amongst all network staff that they are part of the NIHR family and an integrated team supporting a common goal. • Ensure a stable infrastructure exists to support delivery through planning with partners and a flexible research ready workforce. • Work closely with other partners on common goals, e.g. AHSN, BRU's, CLAHRC, RDS to establish opportunities to grow our own Cl's with effective training, funding and support, exploring new Cl's from other clinical professions. • Develop areas with low coverage and establish expertise in under-developed areas through effective workforce development, supervision and training for research teams. • Engage with supporting services across the region to maximise opportunities for clinical research participation and delivery (e.g. 	

Objective	Measure	CRN Target	LCRN Goal/Target	LCRN actions/activities for 2014-15	Timescale
				<p>exploring service leads, community resources, community sites, community Champions).</p> <ul style="list-style-type: none"> • Explore incentive schemes with partners to maximise engagement and participation (reward and recognition/job planning/awards/protected time). • Review infrastructure and resources at midyear point. <p>Operational:</p> <ul style="list-style-type: none"> • Local actions to support national specialty objectives can be found in section 5 of this plan. • Ensure sustainable strong performance and delivery across the CRN: East Midlands during the continuing transitional period informed by robust action planning and review. • Maintain a highly skilled, professional workforce, research taskforce, delivery staff and support staff across the region, supported by a robust T&E strategy and programme that offers personal development and opportunities. • Utilise mapping and existing good practices to support this HLO. • Develop and implement consistent approaches to scanning the portfolio, sharing study opportunities and pipeline knowledge. • Ensure effective and regular communication with partners (comms strategy/review of distribution lists). • Embed new organisational delivery structures swiftly. • Establish effective performance management mechanisms. • Provide active collaborative study and data management, supported by an effective LPMS. 	Indicative Q2
2	A: Proportion of commercial contract studies achieving or surpassing their recruitment target during	80%	80%	<p>Strategic: actions cover both 2a and 2b</p> <ul style="list-style-type: none"> • Continue to use the Partnership Group, Clinical Leadership Group, OMG and Working Groups for strategic and operational planning incorporating mapping of opportunities, expertise, resources, facilities and good practice. • CD and Divisional Clinical Leads will play a key role in strategic initiatives to support this HLO with strong operational implementation led by Divisional Delivery Managers, Business Delivery Manager and industry Operations Manager. 	Indicative Q2-Q3

Objective	Measure	CRN Target	LCRN Goal/Target	LCRN actions/activities for 2014-15	Timescale
time	their planned recruitment period, at confirmed Network sites			<ul style="list-style-type: none"> • Work with Divisional and Clinical Specialty Leads, and senior management team (Delivery, Business, Industry managers) to support the strategic development of industry and non industry activity. • Develop and implement an Industry Action Plan (draft operational elements can be found in APPENDIX 15) with continuity of local leadership and a strong managerial focus on operational strategies that addresses T&T and performance management and active study management throughout the pathway. • Adopt industry good practices in non-industry performance and delivery where relevant. • Continue to build on the expert, professional workforce to provide maximum delivery and performance. • Strengthen relationships with industry partners to support effective working together. • Develop and agree reporting mechanisms and tools, ensuring delivery and performance reports reach Partner CEO's and are reported at trust Board level. • Review infrastructure and resources at midyear point. 	
	B: Proportion of non-commercial studies achieving or surpassing their recruitment target during their planned recruitment period	80%	80%	<p>Operational: actions cover both 2a and 2b</p> <ul style="list-style-type: none"> • Operational plan can be found in APPENDIX 15. Supplementary guidance papers are also available. • The Industry Delivery Manager will work closely with Divisional Delivery Managers and the Life Sciences Industry Working Group to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. • The Business Delivery Manager will work closely with Divisional Delivery Managers and the RM&G Working Group to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. • Ensure a single point of contact for industry is identified and communicated effectively. • Effective communication of T&T metrics: explore T&T champions – forward planning and readiness. 	Indicative Q1-2

Objective	Measure	CRN Target	LCRN Goal/Target	LCRN actions/activities for 2014-15	Timescale
				<ul style="list-style-type: none"> • Ensure delivery and support teams are “research ready” through effective communication, training and strategic planning. • Review and refine systems and process by analysing, amalgamating and coalescing processes adopting lean working principles. • Implement an LPMS that meets the needs of the CRN: East Midlands to support performance and data management and effective reporting. • Review and refine escalation processes that offer consistency across the region where relevant. • Standardise feasibility and Site Identification returns across the region. • Each division to identify a nominated person for liaising with the IOM and allowing clinicians/sponsors to have one person to liaise with. • Effective study management: ensure every study has a recruitment plan with regular review by a nominated lead and “contingency” plans to address study changes, recruitment blocks, red and amber performance: “recruitment toolkit”. • Monthly industry performance reviews and RAG data led by the Industry Delivery Manager in close collaboration with study teams and Divisional Research Delivery Managers. 	
3	A: Number of new commercial contract studies delivered through the NIHR CRN	600	n/a	<p>Strategic: actions cover both 3a and 3b</p> <ul style="list-style-type: none"> • Engage with experts in the marketing field to positively promote the EM region as a place to do research, sell ourselves and our successes. • Continue to develop the infrastructure across the region with outside investment to enhance visibility with external stakeholders, maximising the potential to provide an attractive environment to do research. • Continue to use the Life Sciences Industry Working Group for strategic and operational planning incorporating mapping of opportunities, expertise, resources, facilities and good practice. • Work with Divisional and Clinical Specialty Leads to support the 	Indicative Q2-Q3

Objective	Measure	CRN Target	LCRN Goal/Target	LCRN actions/activities for 2014-15	Timescale
				strategic development of industry activity and growth. <ul style="list-style-type: none"> Develop and implement an Industry Action Plan that addresses ensuring the percentage of commercial contract studies as per HLO 3 is 75% minimum. Build upon industry relationships to support study pipeline and access to industry studies that offer a balanced portfolio. 	
	B: Number of new commercial contract studies entering the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA approvals for Phase II–IV studies	75%	n/a	<p>Operational: actions cover both 3a and 3b</p> <ul style="list-style-type: none"> Operational plan can be found in APPENDIX 15. Supplementary guidance papers are also available. The Industry Delivery Manager will work closely with Divisional Delivery Managers and the Life Sciences Industry Working Group to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. Support the development of marketing and comms material. Review site identification processes to ensure consistency and speed. Seek and share feedback on site selection rejections and explore learning opportunities. Develop knowledge regarding site promotion, accurate feasibility and delivery to time and target across the region. 	Indicative Q1-Q2
4	Reduce the time taken for NIHR studies to achieve NHS Permission through CSP	Proportion of studies obtaining NHS Permission at all sites within 40 calendar days (from receipt of a valid complete application by NIHR CRN)	80%	n/a <ul style="list-style-type: none"> Continue to use the RM&G Working Group for strategic and operational planning incorporating mapping of opportunities expertise, resources, facilities and good practice. The Business Delivery Manager will work closely with the Partner Organisations, Divisional Delivery Managers and the Study Support Service teams to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. CRN: East Midlands RM&G overview and initial action plan can be found in APPENDIX 8. 	Indicative Q1-Q2

Objective		Measure	CRN Target	LCRN Goal/Target	LCRN actions/activities for 2014-15	Timescale
5	Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies	A: Proportion of commercial contract studies achieving first participant recruited within 30 calendar days of NHS Permission being issued or First Network Site Initiation Visit, at confirmed Network sites	80%	80%	<ul style="list-style-type: none"> The Industry Delivery Manager will work closely with the Partner Organisations, Divisional Delivery Managers and the Life Sciences Industry Working Group to develop operational and performance management actions to support this HLO and will utilise the mapping and existing good practices to support delivery. The Business Delivery Manager will work closely with the Partner Organisations, Divisional Delivery Managers and the RM&G Working Group to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. Develop and implement Industry and RM&G action plans that address reducing the time taken to recruit the first participant into studies. Ensure delivery and support teams are “research ready and research responsive” through effective communication, training and strategic planning in close collaboration with R&D teams giving NHS permission for the study to start and study sponsor (e.g. agree SIV dates collaboratively). Review and refine systems and process by analysing, amalgamating and coalescing processes adopting lean working principles. Review and refine escalation processes to support a consistent approach. Ensure every study has a recruitment plan with regular review by a nominated lead and “contingency” plans to address study changes and recruitment blocks: “recruitment toolkit”. Monthly performance reviews led by the Industry Delivery Manager in close collaboration with study teams and Divisional Research Delivery Managers. 	Indicative Q1-Q2
		B: Proportion of non-commercial studies achieving first participant recruited within 30 calendar days of NHS Permission being issued	80%	80%		
6	Increase NHS participation in NIHR CRN Portfolio	A: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio	99%	99%	<ul style="list-style-type: none"> Utilise the mapping and existing good practices to support this HLO and to develop a specific action plan to support 6c. Partners to be represented on OMG and Working Groups, and to continue to be actively involved in the existing regional finance forum 	Indicative Q1-Q3

Objective		Measure	CRN Target	LCRN Goal/Target	LCRN actions/activities for 2014-15	Timescale
	Studies	studies			<ul style="list-style-type: none"> • Explore “champions” across the region to pioneer strategic initiatives, e.g. change champions for google apps etc • Develop and implement action plans in each of the workstreams that address effective engagement (close link to PPI and Comms in each one). • Prioritise relationship building and regular effective engagement. • To facilitate senior level strategic partner engagement, explore option for including CRN as a standing item on regional CEs meeting agendas. • Ensure CRN wide processes and systems provide transparency and promote collaboration. • Ensure equity of access to the regional workforce that support research delivery. • Act on feedback from CLRN service reviews. • Review Mystery shopper feedback and develop a plan to enhance engagement. • Facilitate the development of Partner KPIs. • Ensure all partner organisations have the necessary infrastructure to support engagement in the Portfolio. 	
		B: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio commercial contract studies	70%	70%		
		C: Proportion of General Medical Practices recruiting each year into NIHR CRN Portfolio studies	25%	25%		
7	Increase the number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio	13,500	As per LCRN goal for 2014-15 recruitment for Dementias and Neurodegeneration (DeNDRoN) Total 510	See table below 7.1	See below
					See table below 7.1	See below

Table 7.1: delivery of HLO 7

Deliverable	Planned LCRN actions in 2014-15	Milestones and outcomes once actions completed	Suggested timescale	Suggested Lead
1. Project manage and lead the local implementation in dementia services across the LCRN of business processes to enable the use of the RAFT system to recruit people to dementia studies	<ul style="list-style-type: none"> • Provide project management support to contribute to national programme and implement local delivery of RAFT • Suitably resource all RAFT related activities and identify an implementation lead 	<ul style="list-style-type: none"> • Resourced Project Manager/implementation lead identified/appointed • Local project plan in place to implement RAFT to recruit to studies 	<p>Q1* 14/15</p> <p>Q2-3* 14/15</p>	Division 4 Research Delivery Manager (D4 RDM) and Project Manager (PM)
2. Identify studies appropriate for inclusion in the RAFT system	<ul style="list-style-type: none"> • Using local intelligence identify current and projected studies that would benefit from a register approach • Gain researcher agreement to recruit from RAFT and support them with information 	<ul style="list-style-type: none"> • Local studies eligible for RAFT regularly identified and linked to RAFT website 	Q2-3 14/15	D4 RDM and PM
3. Engage local PIs and trusts in the implementation and use of the RAFT system	<ul style="list-style-type: none"> • Target RAFT information to key PIs and trust R&D depts. • Implement governance policies and recruitment processes defined by RAFT to support implementation • Communicate key study requirements to the researcher community • Oversee studies using RAFT at study launch 	<ul style="list-style-type: none"> • Governance arrangements in place in trusts • Training provided to trusts and PI's to demonstrate benefits of RAFT • 75% Trusts providing a dementia service in LCRN area agree to use RAFT 	<p>Q2 14/15</p> <p>Q2-3 14/15</p>	D4 RDM, PM and RM&G work stream lead
4. Identify local research support staff who will use the system to support recruitment to dementia studies, and support their training on the RAFT system	<ul style="list-style-type: none"> • Identify changes required for ways of working and use continuous improvement model to agree new processes with stakeholders • In conjunction with R&D departments and RDM, agree and implement local training plan for research support staff • Incorporate training in induction for new staff 	<ul style="list-style-type: none"> • Nominate a minimum of 2 staff per LCRN for RAFT training • RAFT accounts created for staff supporting DeNDRoN studies • Training delivered to staff supporting DeNDRoN studies • Staff are trained and equipped to use RAFT 	<p>Q2 14/15</p> <p>Q2 14/15</p>	D4 RDM, PM and workforce develpt. lead

5. Identify dementia services wanting to implement the RAFT system as a local consent-for-approach system and support them to implement it	<ul style="list-style-type: none"> Proactively engage with Memory Assessment Services (MAS) (including MSNAP** services) to agree ways to promote research participation and RAFT to their patients as standard practice Contact memory services, provide RAFT information and encourage its use Provide support where appropriate to NHS dementia services to access and make use of the implementation and communications toolkit 	<ul style="list-style-type: none"> MSNAP** services RAFT approach in place as standard practice Non MSNAP services have agreed to & have put RAFT approach in place as standard 	Q2-3 14/15 Q3-4 14/15	D4 RDM and PM
Additional LCRN deliverables				
6. Achieve target as outlined in dementia HLO	<ul style="list-style-type: none"> Identify senior leader in LCRN to take overall responsibility in delivering the dementia plan 	<ul style="list-style-type: none"> Senior dementia leader identified 	Q1 14/15	CD and COO
7. A minimum of 5% of Care Homes within the LCRN region participating in the Research Ready Care Home Network	<ul style="list-style-type: none"> Identify regional ENRICH leads to ensure local ENRICH development & to participate in national monthly ENRICH Delivery Team meetings Provide project management support to contribute to national programme and implement local delivery of ENRICH Develop and implement an engagement strategy to raise awareness Provide continued research support proactively to engage care home owners/managers and other fora, assisting growth of local and national research ready network 	<ul style="list-style-type: none"> ENRICH regional leads in place Research support/delivery team engaging in ENRICH promotion identified ENRICH rollout across LCRN area as per plan 5% of care homes signed up to ENRICH ENRICH is used to promote RAFT and existing disease registers 	Q1 14/15 Q1-4 14/15 Q4 14/15	D4 RDM & ENRICH lead
8. Maintain sub-specialty clinical leadership capacity and engagement in main disease areas of the DeNDRoN portfolio:	<ul style="list-style-type: none"> Identify and appoint clinical research lead in each of the 4 disease areas (Dementia, HD, MND, PD) Include time and costs for post holders to attend monthly 	<ul style="list-style-type: none"> Continuation of DeNDRoN clinical leadership posts as per 13/14 arrangements 	Q1 14/15	CD

Dementia, Huntington's Disease (HD), Motor Neurone Disease (MND) & Parkinson's Disease (PD)	teleconferences and national bi-annual meetings			
9. Increase rating skills and capacity of LCRN staff supporting DeNDRoN studies	<ul style="list-style-type: none"> Identify staff to attend CRN rater training programme Identify psychometric/global practice lead(s) Conduct skills audit and training needs analysis of staff supporting DeNDRoN portfolio Provide financial support (cost of training £450 plus travel and accommodation) for minimum of 7 DeNDRoN delivery staff to attend national psychometric and global rater training in 14/15 	<ul style="list-style-type: none"> 7 DeNDRoN delivery staff on national rater register LCRN to have at least 3 practice leads for both global and psychometric rating 	Q4 14/15	COO, D4 RDM and work force devt work stream lead
10. Promote innovation in the delivery of DeNDRoN research throughout the NHS	<ul style="list-style-type: none"> Support LCRN and trust staff to capture areas of best practice and upload case studies to patients in research website: www.patientsinresearch.org/ 	<ul style="list-style-type: none"> New case studies from LCRN entered onto patientsinresearch website: www.patientsinresearch.org/ 	Q4 14/15	D4 RDM and communications work stream lead
11. Professional research support staff leadership	<ul style="list-style-type: none"> Identify / appoint lead research nurse(s) (or other allied health professional(s) / clinical trials officer(s) to provide professional leadership Include time and budget to facilitate attendance at monthly teleconferences and bi-annual meetings 	<ul style="list-style-type: none"> Lead(s) identified Meetings attended 	Q1 14/15	D4 RDM
12. Increase number of new PI's delivering studies in the DeNDRoN portfolio	<ul style="list-style-type: none"> Develop strategies to increase number of new PI's Develop mentorship schemes to increase new PIs to support commercial research 	<ul style="list-style-type: none"> Number of new PI's working on DeNDRoN studies Mentorship scheme in place 	Q4 14/15 Q4 14/15	D4 Divisional Clinical lead/SG lead/ D4 RDM As above

Section C: 4. LCRN recruitment goals for CRN Specialties

Specialty	LCRN goal (indicative 50,000) (participants to be recruited in 2014-15)
Ageing	310
Anaesthesia, Perioperative Medicine and Pain Management	145
Cancer	3,917
Cardiovascular Disease	4499
Children	937
Critical Care	519
Dementias and Neurodegeneration (DeNDRoN)	510
Dermatology	665
Diabetes	2778
Ear, Nose and Throat (ENT)	1613
Gastroenterology	823
Genetics	464
Haematology	62
Hepatology	528
Infectious Diseases and Microbiology	278
Injuries and Emergencies	294
Mental Health	3801
Metabolic and Endocrine Disorders	156
Musculoskeletal	1175
Neurological Disorders	313
Ophthalmology	807
Oral and Dental	To be advised
Primary Care	12522
Renal Disorders	1645
Reproductive Health and Childbirth	4500
Respiratory Disorders	1,021
Stroke	756
Surgery	327
Unknown (includes other specialties)	4635

Section C: 5. LCRN plans against the NIHR CRN Specialty Objectives

Unless stated otherwise, the following are national targets for 2014-15.

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
Ageing	1	Increase the opportunities for patients to participate in NIHR CRN Portfolio studies	Establish mechanisms by which the age profile of NIHR CRN Portfolio study participants can be recorded	See note ²	This is a national level objective. Local support provided through contributing where required to relevant work group planning and activity. <ul style="list-style-type: none"> Work with SG lead locally to determine capacity and any local planning
Anaesthesia, Perioperative Medicine and Pain Management	1	Increase the number of Anaesthesia, Perioperative Medicine and Pain Management commercial contract studies on the NIHR CRN Portfolio	Number of new Anaesthesia, Perioperative Medicine and Pain Management commercial contract studies entered onto the NIHR CRN Portfolio	4	As currently low numbers of commercial contract studies available, aim to take part in 1-2 studies maximum across CRN: East Midlands.
	2	Establish links with the Royal College of Anaesthetists' Specialist Registrar networks to support recruitment into NIHR CRN Portfolio studies	Number of LCRNs where Specialist Registrar networks are recruiting into NIHR CRN Portfolio studies	4	Further exploration of RCoA SpR network required at a local level – as an interim aim, increase numbers of NHS Trusts engaged with the NIHR and recruiting to Portfolio studies
Cancer	1	Maintain a minimum level of participation in interventional Cancer studies on the NIHR CRN Portfolio	Recruitment to interventional Cancer studies as a proportion of LCRN cancer incidence	7.5%	In order to meet the cancer specific objectives, working with cancer research leaders in partner organisations, East Midlands Strategic Clinical Network (SCN) for Cancer Expert Advisory Groups (EAGs), research teams and individual principal investigators, CRN: East Midlands will: Objectives 1 & 2
	2	Increase recruitment into Cancer studies on the NIHR CRN Portfolio overall	Recruitment to Cancer studies as a proportion of LCRN cancer incidence	20%	CRN: East Midlands aims to maintain 2014/15 recruitment and will work towards achieving the recruitment targets set but this is ambitious given 2013/14 recruitment. In order to achieve this goal CRN: East Midlands will: <ul style="list-style-type: none"> Set targets for individual studies in partner organisation and flag any shortfalls in recruitment that prevent the Network meeting objectives 1&2 Support partner organisations to accurately monitor individual

² Qualitative objective to be assessed by a descriptive text from each LCRN.

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
					<p>study and organisation level recruitment and adjust portfolio to meet objectives</p> <ul style="list-style-type: none"> • Support partner organisations to make portfolio decisions that enable Network to meet objectives • Map and monitor resources to deliver the objectives
	3	NIHR CRN Portfolio of Cancer studies serves the full range of cancer types in adults and children	Proportion of adult and child cancer types on the NIHR CRN Portfolio	100%	<p>CRN: East Midlands has a comprehensive disease specific portfolio with recruitment in all disease site Clinical Studies Group (CSG) portfolios.</p> <p>In order to achieve this goal CRN: East Midlands will:</p> <ul style="list-style-type: none"> • Identify gaps in the portfolio by mapping the disease profile of the population of CRN: East Midlands against the current adult, TYA and child portfolio • Map local to national portfolio of adult, TYA and children's portfolio to ensure representative distribution of studies by type, treatment modality and disease stage etc. • Work flexibly with partners across divisions to maximise recruitment • Develop and implement an East Midlands Trial Directory to maximise patient referral pathways • Use the portfolio maps to identify studies to fill the gaps (http://csg.ncri.org.uk/portfolio-maps) • Map and monitor current resources against adult, TYA and child recruitment and disease profiles to identify areas requiring additional resources • Maximise referral to centres of expertise
	4	Cancer patients across England can participate in Cancer studies on the NIHR CRN Portfolio	Shared care arrangements between NHS providers within LCRN geographies	See note ³	<p>CRN: East Midlands has a Children's Cancer Principal Treatment Centre based between Leicester and Nottingham and Paediatric Oncology Shared Care Units at Northampton, Lincolnshire and Derby. In addition, adult MDTs and Specialist MDTs continue to refer patient within and external to CRN East Midlands. Shared Care arrangements for clinical trials are embedded into standard of care within the child, TYA and adult setting.</p> <p>In order to achieve this goal and build on the existing work already underway across the East Midlands, the CRN: East Midlands will:</p> <ul style="list-style-type: none"> • Maintain close working relationship with CYPICS partner organisations

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
					<ul style="list-style-type: none"> • Continue to maintain and develop the current care pathways, which already include trial participation, ensuring that referring Trusts are made aware when their patients do take up the opportunity to participate • Ensure that individual member organisation portfolios are widely available to individual clinicians to enable easy referral for participation • Ensure patients are referred out of region, as required, for appropriate trial participation • Where possible support partner organisations to receive patients back for follow up activities closer to home • Obtain agreement from all partner organisations for a written shared care agreement or memorandum of understanding (as appropriate) for management of trial patients and data flows • Where participants are required to flow across multiple organisations ensure that trial pathway planning is robust and successful
	5	Increase the proportion of NHS cancer care providers recruiting into NIHR CRN Portfolio Cancer studies	Percentage of NHS cancer care providers recruiting into Cancer studies on the NIHR CRN Portfolio	100%	<p>CRN: East Midlands already has 100% NHS Acute Trust level participation in research. In order to maximise other opportunities CRN East Midlands will widen involvement in community partners, Hospices and any other (appropriate) qualified providers. In order to achieve this goal CRN: East Midlands will:</p> <ul style="list-style-type: none"> • Develop existing and create new links with community partners, Hospices and any other (appropriate) qualified providers • Develop existing and new links around workforce development and research awareness in these communities • Develop existing and new links across other divisions as appropriate • Map and monitor resources to support this portfolio development
	6	Increase the proportion of cancer patients offered participation in research	Percentage of patients reporting being offered participation in research through National Cancer Patient Experience Survey	> 32%	<p>There is an overlap between objectives 3 & 6 so actions taken will boost both areas). In order to achieve this goal and increase the proportion of patients being offered participation: CRN East Midlands will:</p> <ul style="list-style-type: none"> • Involve PCPIE members with portfolio planning particularly targeting under represented populations (using data from mapping exercise in objective 3 and results from 2011/12 and

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
					2012/13 National Cancer Patient Experience Survey (NCPES)) <ul style="list-style-type: none"> • Annually cascade results of NCPES to PCPIE members and their access to user groups • Annually cascade results of NCPES to EAGs, Clinicians, CNSs, AHPs, Trust R&D and cancer management, etc. • Continue to engage with EAGs through the research lead for the group by providing recruitment reports, current and future trials portfolios • Include PCPI and NCPES in research staff's induction • Where possible use media to report on research opportunities and results • Develop PCPIE through appropriate channels locally • Where appropriate conduct local patient experience surveys
Cardiovascular Disease	1	Increase the number of Cardiovascular Disease commercial contract studies on the NIHR CRN Portfolio	Number of new Cardiovascular Disease commercial contract studies entered onto the NIHR CRN Portfolio	42	<ul style="list-style-type: none"> • Continue to work with Industry to develop and extend existing relationships, and to work together with the CRN: East Midlands Industry Delivery Manager, Division 2 Manager and other stakeholders to maximise links with Industry. Also to explore commonalities across all specialities within Division 2 and other Divisions. This will facilitate a more cohesive management structure, be attractive to Industry, generate more interest and generate more studies. • Enabling links with the 2 Biomedical Research Units within the Division to all sites across the East Midlands will provide an 'access corridor' to facilitate the conduct of studies that have resulted from research proposals being generated from the original BRU contracts. • Facilitate and support identified research leads across all Acute Trusts in the East Midlands in anticipation of increased research activity. This has already commenced with the setting of bi-annual meetings. • To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators.
	2	Increase access for patients to Cardiovascular Disease studies	Number of LCRNs contributing to multi-centre studies in the 6 Cardiovascular Disease sub-specialities	15	
Children	1	Increase the number of Children's commercial contract studies within the NIHR CRN Portfolio in each	Number of Children's commercial contract studies on the NIHR CRN Portfolio	10%	The Children's theme is composed of the MCRN and paediatric non-medicines portfolios. The national MCRN portfolio has approximately 60% commercial studies and the non-medicines portfolio has <1%. It is expected that 10% is achievable in terms

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
		LCRN			of number of studies with current local activity.
	2	All relevant sites that provide services to children are involved in research	Proportion of relevant sites recruiting to Children's studies on the NIHR CRN portfolio	95%	<ul style="list-style-type: none"> All acute care Trusts in the CRN: EM region are currently active in supporting children's studies. This will be maintained. We will actively promote and seek to involve primary care sites within the region as both active research sites and patient identification centres. Where appropriate we will seek to develop collaboration between acute and primary care sites.
	3	Recruitment of children to NIHR CRN Portfolio studies is undertaken by individuals with appropriate paediatric training and experience, or who are appropriately supervised	Proportion of staff consenting children to NIHR CRN Portfolio studies who are paediatric trained and/or experienced, or who are appropriately supervised	100%	<ul style="list-style-type: none"> All staff involved in recruitment and the consent process will be comprehensively trained in generic research skills to ensure delivery of high quality research. Where specific specialist clinical or administrative skills or knowledge are required for an individual study or trial, appropriate staff will be selected, where possible, according to their clinical training and background and this will be enhanced by study-specific training and supervision. Where suitably trained individual are not available, appropriate training and initial supervision will be provided for all newly recruited staff.
Critical Care	1	Increase the number of intensive care units participating in research	Proportion of intensive care units recruiting into studies on the NIHR CRN Portfolio	80%	<ul style="list-style-type: none"> Adopt a proven model – identify enthusiastic and capable clinicians in smaller non-research active units. Support them in the administrative, financial and practical aspects of opening studies. Explore potential for sharing staffing support e.g. research nurse time for specific projects. Increase the number of NHS Trusts recruiting to Critical Care studies on the NIHR CRN Portfolio (target >95%). Increase the number of Critical Care units in CRN: East Midlands recruiting to Critical Care studies (target >80%). Increase the proportion of eligible patients recruited into critical care studies (target >30%). Aim for critical care units with CRN: East Midlands to be within the top ten recruiting centres nationally for NIHR Portfolio Studies (target = 2 studies).

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
Dementias and Neurodegeneration (DeNDRoN)	1	Implement arrangements for local use of the "Join Dementia Research system to support study recruitment	A: Proportion of NHS Trusts which provide dementia services, which have put in place generic arrangements for access to medical records, with consent, for the "Join Dementia Research" system users	50%	<ul style="list-style-type: none"> Resourced Project Manager/implementation lead identified/appointed Local project plan in place to implement RAFT to recruit to studies Work with Research Design Service and individuals submitting bids and Research Specialty Groups to use database Work with R&D and IG in Trusts to agree their sign up to Join Dementia Research Local studies eligible for Join Dementia Research regularly identified and linked to website Gain researcher agreement to recruit from Join Dementia Research and support them with information Proactively engage with Memory Assessment Services (MAS) to agree ways to promote research participation and Join Dementia Research to their patients as standard practice Provide support where appropriate to NHS dementia services to access and make use of the implementation and communications toolkit
Dementias and Neurodegeneration (DeNDRoN)			B: Proportion of LCRN staff working on Dementias and Neurodegeneration (DeNDRoN) studies trained to use the "Join Dementia Research" system	60%	<ul style="list-style-type: none"> Nominate a minimum of 2 staff per LCRN for JOIN DEMENTIA RESEARCH training JOIN DEMENTIA RESEARCH accounts created for staff supporting DeNDRoN studies Training delivered to staff supporting DeNDRoN studies Staff are trained and equipped to use JOIN DEMENTIA RESEARCH
	2	Increase the global and psychometric rating skills and capacity of LCRN staff supporting Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio	A: Percentage of research sites covered by at least 2 trained raters who are registered on the national rater database	80%	<ul style="list-style-type: none"> Work towards at least 7 DeNDRoN delivery staff on national rater register Work towards LCRN having at least 3 practice leads for both global and psychometric rating
			B: Proportion of LCRN staff who support Dementias and Neurodegeneration (DeNDRoN) studies who have successfully completed	35%	<ul style="list-style-type: none"> Conduct skills audit and training needs analysis of staff supporting DeNDRoN portfolio Identify staff to attend CRN rater training programme Identify psychometric/global practice lead(s) Provide financial support (cost of training £450 plus travel and accommodation) for minimum of 7 DeNDRoN delivery

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
			rater training and joined the national rater database		staff to attend national psychometric and global rater training in 14/15
	3	Improve access to research for people living in care homes	Proportion of registered care homes participating in NIHR CRN Portfolio studies	20%	<ul style="list-style-type: none"> Identify regional ENRICH leads to ensure local ENRICH development & to participate in national monthly ENRICH Delivery Team meetings Provide project management support to contribute to national programme and implement local delivery of ENRICH Develop and implement an engagement strategy to raise awareness Provide continued research support proactively to engage care home owners/managers and other fora, assisting growth of local and national research ready network
	4	Increase clinical leadership capacity and engagement in each of the main disease areas in the Dementias and Neurodegeneration (DeNDRoN) specialty	Number of LCRNs with local clinical leads in each of the main disease areas (dementias, Parkinson's disease, Huntington's disease and motor neurone disease)	15	<ul style="list-style-type: none"> Identify senior leader in LCRN to take overall responsibility in delivering the dementia plan Identify and appoint clinical research lead in each of the 4 disease areas (Dementia, HD, MND, PD) Include time and costs for post holders to attend monthly teleconferences and national bi-annual meetings Identify / appoint lead research nurse(s) (or other allied health professional(s) / clinical trials officer(s) to provide professional leadership
Dermatology	1	Increase the opportunities for patients to participate in Dermatology studies on the NIHR CRN Portfolio	A: Proportion of health care providers of dermatology services recruiting into Dermatology studies	50%	<ul style="list-style-type: none"> Work with SG lead and CCGs to identify local providers and new care pathway following service transformation. Scope current number of research active providers, provide an outline plan for achieving target. Work with SG lead and CCGs to identify emergency department/minor injury units. Scope current number of research active providers, provide an outline plan for achieving target.
			B: Number of 'wounds' treatment centres recruiting into wounds trials	30	
Diabetes	1	Achieve a minimum level of participation in diabetes studies	Proportion of people with diabetes (prevalence rates) recruited into Diabetes studies on the NIHR CRN Portfolio	0.5%	<ul style="list-style-type: none"> A focus on sites who have recruited less than 50 pats per annum over the previous 2 years to understand their barriers to recruitment, will help to develop a recruitment strategy for these sites to increase recruitment to a level

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
	2	Increase the number of newly diagnosed people with type 1 diabetes in research	Proportion of patients identified via ADDRESS 2 recruited into Diabetes studies on the NIHR CRN Portfolio	5%	<p>that is circa 50% better than their previous annual recruitment numbers.</p> <ul style="list-style-type: none"> Through a wider and more inclusive engagement with CCG's and primary care organisations across the CRN: East Midlands geography will result in greater recruitment activity in primary care and diabetes recruitment overall. This will be achieved by: <ul style="list-style-type: none"> Establish a working relationship with Division 5 with a view to initiatives such as joint posts, increasing patient access, shared resources, shared education and training events, a joint publicity and communication strategy, joint Industry working where possible and exploring how diabetes registries and IS systems are managed and access and how this could be harnessed together for research purposes. To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators
	3	Increase the proportion of NHS providers recruiting into Diabetes studies on the NIHR CRN Portfolio	A: Proportion of primary care providers recruiting participants into Diabetes studies on the NIHR CRN Portfolio	4%	
			B: Proportion of secondary care providers recruiting participants into Diabetes studies on the NIHR CRN Portfolio	83%	
	4	Improve the referral systems in place for newly diagnosed people with type 1 diabetes	Proportion of secondary care trusts with referral systems in place for newly diagnosed people with type 1 diabetes	80%	
Ear, Nose and Throat (ENT)	1	Increase the number of ENT commercial contract studies on the NIHR CRN Portfolio	Number of new ENT commercial contract studies entered onto the NIHR CRN Portfolio	2	<ul style="list-style-type: none"> Currently discussions being undertaken concerning a potential study led by University of Nottingham in collaboration with industry. Nottingham will be a leading site and will engage with partners on the provision of potential participants.
Gastroenterology	1	Increase the proportion of patients recruited into Gastroenterology studies on the NIHR CRN Portfolio	Number of participants (per 100,000 population), recruited into Gastroenterology studies on the NIHR CRN Portfolio	10	<ul style="list-style-type: none"> Objective 1 – achieving 10/100,000 will be dependent on the studies that are available; some are easy to recruit to, others are more challenging. All objectives – closer collaboration between regional partners; propose a half-day meeting open to all GI researchers in the network to encourage them to become more research active, especially newly appointed consultants. Objective 2 – closer collaboration and build on the track
	2	Increase the number of NHS Trusts actively participating in Gastroenterology studies on the NIHR CRN Portfolio	A: Proportion of NHS Trusts participating in Gastroenterology studies on the NIHR CRN Portfolio	90%	

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
			B: Proportion of NHS Trusts participating in Gastroenterology commercial contract studies on the NIHR CRN Portfolio	35%	record across the region
Genetics	1	Increase access for patients with rare diseases to participate in Genetics studies in the NIHR CRN Portfolio	Number of LCRNs participating in multi-centre genetics studies through the NIHR UK Rare Genetic Disease Research Consortium	14	<ul style="list-style-type: none"> CRN: East Midlands has two partner Trusts who are already part of this consortium – Nottingham University Hospitals NHS Trust and University of Leicester Hospitals NHS Trust. Plans are already in place to participate in studies that have become available via this consortium and will be explored for wider regional input from Trusts providing genetics services
Haematology	1	Increase the participation of NHS organisations in Haematology studies on the NIHR CRN Portfolio	A: Number of open Haematology studies in each LCRN	4	<ul style="list-style-type: none"> Current activity in the CRN: East Midlands will be explored and the region is not supporting a minimum of four studies efforts will be made to achieve this target. From data currently available the level of activity is not known.
			B: Number of open Haematology commercial contract studies in each LCRN	1	<ul style="list-style-type: none"> Through collaborative working with the Industry Operations Manager and relevant clinicians we will seek to attract commercial studies of this nature to the CRN: East Midlands.
	2	Increase the involvement of haemophilia centres in supporting Haematology studies on the NIHR CRN Portfolio	A: Proportion of haemophilia centres recruiting patients into Haematology studies on the NIHR CRN Portfolio (comprehensive care)	90%	<ul style="list-style-type: none"> The CRN: East Midlands region will be explored to identify what level of activity currently exists and how these map onto the two types of care settings described. This data will be used to explore options for meeting these objectives.
			B: Proportion of haemophilia centres recruiting patients into Haematology studies on the NIHR CRN Portfolio (large centres)	50%	
Hepatology	1	Increase access for patients to Hepatology studies on the NIHR CRN Portfolio	Number of LCRNs contributing to a multi-centre study in all of the six major study areas (viral hepatitis, NAFLD, autoimmune)	15	<ul style="list-style-type: none"> CRN: East Midlands wide monthly virtual teleconference has been established with minutes circulated. Explore ways in which to replicate the establishing of a network Wide database similar to the one established at

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
			liver disease, metabolic liver disease).		<p>Nottingham University Hospitals to be ready to make applicable research studies available to patients when they come online: Nottingham has a growing database of auto-immune patents with an expectation that studies will come into the pipeline.</p> <ul style="list-style-type: none"> A number of studies are in the pipeline with potential for all sites to take part in and, hence, access for patients increased. Large number of industry studies in set up that cover a number of different disease areas: viral, metabolic, immunological disease plus links with critical care.
Infectious Diseases and Microbiology	1	Increase awareness of the Infectious Diseases and Microbiology specialty through the identification of a local champion	Number of LCRNs with an identified clinical local champion for infectious disease public health emergencies	15	In development with SG Leads
	2	Increase access for patients to Infectious Diseases and Microbiology studies on the NIHR CRN Portfolio	Number of LCRNs recruiting into antimicrobial resistance research studies on the NIHR CRN Portfolio	15	
Injuries and Emergencies	1	All NHS major trauma centres to support recruitment into NIHR CRN Portfolio studies	Proportion of NHS major trauma centres recruiting participants into NIHR CRN Portfolio studies	100%	<p><i>Ensuring that the number of EDs supporting recruitment into NIHR CRN Portfolio studies increases to nearly a third</i> will involve the continuation and acceleration of work that we have already been doing in identifying and engaging research active and research interested clinicians in units outside the two major centres.</p> <ul style="list-style-type: none"> We have already visited a number of EDs and had face to face meetings with ED clinicians, managers and representatives of R&D from the respective Trusts. Translating good will into recruitment in these centres will require a combination of support and the diversion of some resource for research nurse and potentially consultant time. The CRN can facilitate this by creating an environment where research expertise can be shared and also by helping clinicians in their negotiations with R&D Departments for resources. Set up and recruitment within the Emergency Setting is a

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
					<p>specialised area and one strategy we will be considering will be the sharing of expertise from the bigger centres with units that are at earlier stages in their research infrastructure evolution. An example would somebody like Phil Miller, research manager at NUH travelling to support the set up and running of trials in other EDs and mentoring research nurses in them.</p> <ul style="list-style-type: none"> We also plan to set up a support system for researchers that will involve regular communication and also the development of a virtual communication platform for meetings, backed up by a few face to face meetings. We have a meeting planned for the 11th June at the Attenborough Centre to which research interested clinicians from EDs across the East Midlands will be invited, where these ideas can be explored further and the development of a definitive plan furthered. We have also already had one meeting with critical care colleagues in the East Midlands region who are natural allies In Division 6 around trials in the Injuries and Emergencies portfolio. More meetings are planned to develop this relationship going forward. A major barrier to recruitment is the lack of GCP trained clinicians. Another key component of the CRN strategy over the coming year will be the encouragement of and support for delivery of GCP training to emergency medicine trainees who are rotating within the East Midlands region and to as many consultants, advanced practitioners, nurses etc. as possible. As well as GCP training we will develop strategies to increase awareness amongst trainees, consultants and nursing staff across the region about trials.
	2	Increase the number of NHS emergency departments supporting recruitment into NIHR CRN Portfolio studies	Proportion of NHS emergency departments recruiting into NIHR CRN Portfolio studies	30%	<p>100% of Major Trauma Centres (MTCs) supporting recruitment into NHHR CRN Portfolio studies : - In the East Midlands, NUH as the Major Trauma Centre will be recruiting participants into Portfolio studies and ED will be undertaking any suitable trials focused on our component of the pathway. A major challenge over the coming year will be a development of an understanding that trauma research will necessarily cross departmental and institutional boundaries. This will require close collaboration between all those involved in research across the trauma pathway within the MTC and communication between</p>

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					<p>EMAS, the Trauma Units and the MTC.</p> <p>The CRN: East Midlands will need to support the fledgling Trauma Research Group in the process of being set up at NUH and facilitate communication within NUH and between NUH and stakeholders in the network. Tim has previously circulated a document that identified levels at which communication systems need to be in place for trauma research (most are applicable to all research) including.</p> <p>a) <i>Between researchers</i> – The CRN: East Midlands will need to be able to identify PIs and researchers with in ED and in other specialities involved in Trauma research and to support communication between them. A robust system will need to be in place to disseminate information about studies on the Portfolio.</p> <p>b) <i>Between research nurses and CROs</i> – A component of this, as well as developing the platform for communication to take place, will be the sharing of expertise, whether by support in person or at a distance. The development of standardised working practices and efficient exchange of information will be also be vital</p> <p>c) <i>Between Trust R&D Departments</i> - The CRN can encourage a common approach to key trauma research questions (such as consent for incapacitated patients). This will requires a system to identify common issues in trauma care research and a mechanism by which those involved in granting research permission at a Trust level can meet together, discuss the issues, and come to a common understanding, which can then be communicated to researchers.</p>
Mental Health	1	Increase the number of principal investigators supporting Mental Health commercial contract studies	Number of principal investigators working on open Mental Health commercial contract studies on the NIHR CRN Portfolio	95	<ul style="list-style-type: none"> • Aim to increase to 25 PIs over the next year. • Produce report on the barriers and drivers re: increasing PIs in MH commercial studies • Engage with Trusts, AHSN, PPI and CCGs to take t his forward • Liaise with NIHR to include partnership (with commercial companies) studies to be classed as commercial research as many MH tech studies are partnerships with small

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
					<p>commercial companies</p> <ul style="list-style-type: none"> • Industry Lead to act as mentor for new PIs • Division 4 to continue to organise and support clinician training via WFD Lead • Survey clinicians for special interests and try to match new studies to interest • Continue to open new sites when clinician expresses an interest in a portfolio study • Continue to work with R&D departments to build infrastructure for studies particularly industry • Map for potential growth areas and offer mentoring, training and support
	2	Maintain the skills and capacity of staff supporting Mental Health Portfolio studies in frequently used Mental Health study eligibility assessments (e.g. PANSS)	Number of staff trained in frequently used Mental Health study eligibility assessments	139	<ul style="list-style-type: none"> • Continue to put staff forward for PANSS and other assessments training working in the longer term towards the target. • Identify an CRN: East Midlands WFD Co-ordinator to ensure staff and clinician training occurs and is kept up to date
Metabolic and Endocrine Disorders	1	Support patient access to Metabolic and Endocrine Disorders studies on the NIHR CRN Portfolio	Number of LCRNs supporting established studies of rare diseases in metabolic and endocrine disorders	15	<ul style="list-style-type: none"> • Establishing greater links with Industry through the Industry Delivery Manager to maximise access to studies undertaking trials in complex and rare diseases. • To establish links with theme leads from other CRN's and ensuring that the M&E theme of the CRN: East Midlands is fully engaged with any CRN CC National groups or meetings etc. • To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators.
	2	Increase the number of Metabolic and Endocrine Disorders studies on the NIHR CRN Portfolio	Number of new Metabolic and Endocrine Disorders studies on rare diseases entering the NIHR CRN Portfolio	4	
Musculoskeletal	1	Increase the opportunities for patients to participate in Musculoskeletal studies on the NIHR CRN Portfolio	Proportion of Musculoskeletal service providers recruiting into NIHR CRN Portfolio studies	75%	<ul style="list-style-type: none"> • SG lead to determine numbers of providers. Scope current providers and provide outline plan for achieving target. • Undertake a mapping of current MSK studies and work with SG lead to ensure capacity to support commercial contract studies.
	2	Increase the number of Musculoskeletal commercial contract studies on the NIHR CRN Portfolio	Number of new Musculoskeletal commercial contract studies entered on to the NIHR CRN Portfolio	30	

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
Neurological Disorders	1	Increase the number of NHS Trusts recruiting into Neurological Disorders studies on the NIHR CRN Portfolio	Number of previously inactive NHS Trusts which now are recruiting into Neurological Disorders studies on the NIHR CRN Portfolio	15	<ul style="list-style-type: none"> • Work with AHSN, PPI to engage Acute Trusts • Extend visits by Industry Lead and Managers to Acute Trusts/Clinical Leads/Medical Directors to support Trusts with recruitment • Extend processes, pipeline and staff support to Neurology studies as above • Work with CCGs to recruit to appropriate studies • Work with Trusts to build infrastructure to conduct studies particularly commercial studies.
	2	Increase the number of principal investigators supporting Neurological Disorders commercial contract studies	Number of principal investigators working on open Neurological Disorders commercial contract studies on the NIHR CRN Portfolio	58	<ul style="list-style-type: none"> • Aim to increase to 5 PIs over the next year. • Produce report on the barriers and drivers re: increasing PIs in Neurology commercial studies • Engage with Trusts, AHSN, PPI and CCGs to take this forward • Liaise with NIHR to include partnership (with commercial companies) studies to be classed as commercial research as many MH tech studies are partnerships with small commercial companies? • Industry Lead to act as mentor for new PIs • Division 4 to continue to organise and support clinician training via WFD Lead • Survey clinicians for special interests and try to match new studies to interest • Continue to open new sites when clinician expresses an interest in a portfolio study • Continue to work with R&D departments to build infrastructure for studies particularly industry • Map for potential growth areas and offer mentoring, training and support
Ophthalmology	1	Increase the number of Ophthalmology commercial contract studies on the NIHR CRN Portfolio	Number of new Ophthalmology commercial contract studies entered onto the NIHR CRN Portfolio	4	<ul style="list-style-type: none"> • Objective 1 – engaging more NHS Trusts may have a positive impact on the number of commercial studies on the Portfolio. This must be supported by access to dedicated research staff who can support studies (e.g. one day per week) and less research experienced clinical staff. • Promotion of CRN: East Midlands to clinicians across the EM area, including infrastructure support and increased opportunities for networking.
	2	Increase the number of NHS Trusts participating in Ophthalmology research	Number of NHS Trusts recruiting patients into Ophthalmology studies on the NIHR CRN Portfolio	100	

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
Oral and Dental	1	Increase the opportunities for patients to participate in NIHR CRN Portfolio studies	Number of Oral and Dental studies on the NIHR CRN portfolio recruiting in each LCRN	1	<ul style="list-style-type: none"> This is dependent on local portfolio requirements. Work with Oral and Dental SG lead and Coordinating Centre to determine opportunities for study roll out in LCRN. To scope and develop capacity to support these studies as required. As East Midlands has no dental school it may be problematic to attract and run studies into the region. However, this will be an area of growth for East Midlands LCRN. Develop capacity locally to support commercial contract studies. Work with SG lead and CC to contribute and ensure a national network of capability. Work with SG lead to determine where studies can be delivered in primary care. Identify and support sites to recruit patients.
	2	Increase the number of Oral and Dental commercial contract studies on the NIHR CRN Portfolio	Number of open Oral and Dental commercial contract studies on the NIHR CRN Portfolio	2	
	3	Offer a balanced portfolio of studies to practitioners and participants	A: Proportion of Oral and Dental studies on the NIHR CRN Portfolio recruiting from a primary care setting	20%	
			B: Proportion of participants recruited from a primary care setting into Oral and Dental studies on the NIHR CRN Portfolio	50%	
Primary Care	1	Increase the opportunities for patients to participate in NIHR CRN Portfolio studies	A: Proportion of GP sites registered as research capable ³	35%	<ul style="list-style-type: none"> LCRN to contribute to national definition of 'registered research capable site' and determine additional local criteria that may apply. Establish % benchmark of current RGCP Research Ready accredited sites and forecast target for year end, together with an outline plan for achieving target. Map current geographical spread of registered research capable sites across CCGs. Forecast target for year end, together with an outline plan for achieving target. For geographical areas rag rated red, work in collaboration with CCGs to establish engagement of member practices and delivery to target. Work to establish a community pharmacy champion, with clear role outline. Draw on existing community pharmacy representation from across East Midlands pharmacy research group.
			B: Proportion of GP sites within any individual CCG registered as research capable	5%	
	2	Improve research engagement with community pharmacy	Number of LCRNs with a community pharmacy Research Champion	15	

³ Registered Research Capable Sites are those sites working with the LCRN which have the capacity and capability to support NIHR CRN activities.

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
Renal Disorders	1	Increase the proportion of Renal Disorders commercial contract studies on the NIHR CRN Portfolio	Proportion of commercial contract studies in relation to the total number of Renal Disorders studies on the NIHR CRN Portfolio	20%	<ul style="list-style-type: none"> N.B. The national objective (1) is intrinsically linked to non-academic recruitment in a step-wise fashion, therefore the more non-commercial studies that are undertaken the greater the number of Industry trials that need to be conducted. It should be noted that In the EM only a few select sties undertake Industry trials due to the areas of specialism in renal research To ensure that all experimental or lab based studies that consent patients are considered for their eligibility onto the NIHR CRN portfolio to maximise recruitment numbers into commercial and non-commercial trials Develop a communications and PPI strategy that will see at least 60% of patients receiving a quarterly newsletter and other promotional material. This material will also be distributed to units that provide a renal service but are not actively conducting research themselves. To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators.
	2	Improve the promotion of research to patients with Renal Disorders	Proportion of renal units actively promoting research to patients	50%	
Reproductive Health and Childbirth	1	Increase the number of Reproductive Health and Childbirth commercial contract studies on the NIHR CRN Portfolio	Number of Reproductive Health and Childbirth commercial contract studies on the NIHR CRN Portfolio	4	<ul style="list-style-type: none"> Through collaborative working with the Industry Operations Manager and relevant clinicians we will seek to attract commercial studies of this nature to the CRN: East Midlands.
	2	Increase engagement and awareness of the Reproductive Health and Childbirth Specialty	Number of LCRNs with an identified midwifery champion to increase engagement and awareness	15	<ul style="list-style-type: none"> We will identify and appoint a Midwifery Champion for the CRN: East Midlands.
Respiratory Disorders	1	Increase access for patients to participate in Respiratory Disorders studies on the NIHR CRN Portfolio	Number of LCRNs recruiting participants into studies in the Respiratory Disorders main disease areas of asthma, COPD and pneumonia	15	<ul style="list-style-type: none"> Maintain infrastructure required to increase recruitment to research databases for asthma, COPD and other respiratory disorders centred across the East Midlands area including Primary, Secondary, Tertiary Care areas, supported by the large Teaching Hospitals.

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
	2	Increase the number of participants recruited into COPD and Asthma studies on the NIHR CRN Portfolio	Percentage of COPD and Asthma participants recruited into Respiratory Disorders studies on the NIHR CRN Portfolio	10%	<ul style="list-style-type: none"> Maintain a pool of respiratory specialist staff with the skill set required to carry out asthma and COPD studies in carefully phenotyped patients which facilitates both commercial and investigator driven studies and also a stratified medicine approach which is increasingly being used for new therapies.
Stroke	1	Increase the proportion of patients recruited into Stroke randomised controlled trials on the NIHR CRN Portfolio	Number of patients (per 100,000 population) recruited into Stroke randomised controlled trials on the NIHR CRN Portfolio	8	<ul style="list-style-type: none"> Build on previous success by maintaining the expertise and current level of resource within the specialty at successful sites – in particular, maintain research staffing levels at LCRN sites and continue to provide support to clinicians to act as PIs. By continuing to build on the success seen by the current topic specific stroke research network with regards to recruiting patients into the hyperacute stroke studies through continued investment and capacity building in providing and building a quality provision for the HSRC in Nottingham. Focus on recruitment to complex studies, with a number of commercial medical technical studies about to open. The experience of the HSRC staff could eventually extend beyond stroke to other specialties where emergency recruitment is desirable and/ or required. Explore areas for working across specialties within the Division (cardiovascular in particular) and across division (Injuries and Emergency) for more efficient working, whilst recognising that some stroke studies (in particular acute recruitment with capacity and communication issues) require specialist skills. Focus and review sites where recruitment has previously been low, (recruited less than 40 patients per annum per 1.0WTE research practitioner) to understand their barriers to recruitment, and develop a recruitment strategy for these sites to increase recruitment to a level that is circa 50% better than their previous annual recruitment numbers. Explore areas for working across specialties within these sites. If recruitment barriers cannot be overcome, review investment opportunities for building capacity at stroke sites
	2	Increase the number of commercial Stroke studies on the NIHR CRN Portfolio	A: Number of new commercial contract Stroke studies on the NIHR CRN Portfolio	5	
			B: Number of new medical technical studies in Stroke on the NIHR CRN Portfolio	2*	
	3	Increase the proportion of NHS Trusts, providing acute Stroke care, recruiting to Stroke studies on the NIHR CRN Portfolio	Proportion of NHS Trusts, providing acute Stroke care, recruiting participants into Stroke studies on the NIHR CRN Portfolio	80%	
	4	Increase activity in NIHR CRN Hyperacute Stroke Research Centres	A: Number of patients recruited to hyperacute Stroke studies on the NIHR CRN Portfolio in each NIHR CRN Hyperacute Stroke Research Centre (HSRC)	50	
B: Number of patients recruited to complex hyperacute Stroke studies on the NIHR CRN Portfolio in each NIHR CRN HSRC			15		

Specialty	Ref.	Objective	Measure	Target	LCRN actions to achieve objective(s)
			C: Number of HSRCs recruiting to Stroke commercial contract studies on the NIHR CRN Portfolio	8	<p>elsewhere in LRCN. However, to maintain >80% of sites involved in stroke research within the CRN: East Midlands.</p> <ul style="list-style-type: none"> To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators. <p>*The 2 med tech studies are part of the overall target of 5</p>
Surgery	1	Increase the number of NHS Trusts supporting Surgery studies on the NIHR CRN Portfolio	Proportion of acute NHS Trusts recruiting patients into Surgery studies on the NIHR CRN Portfolio	75%	<p>Objectives 1 & 2:</p> <ul style="list-style-type: none"> 100% of acute Trusts admitting patients for elective surgery participating in Portfolio research. To have at least one surgeon in each specialty in each Trust trained in GCP. To increase the proportion of surgical patients involved in clinical trials by 20%. <p>Generic actions to support the above achievement:</p> <ul style="list-style-type: none"> Increase delivery of GCP, make it easier to access online courses (equitable provision across the East Midlands region). Ensure that support follows recruitment and make sure that support not only goes to the Trust but filters down to the PIs involved. Trusts are required to provide evidence of support and action is taken by CRN: East Midlands if this support is not forthcoming. <p>Specific actions:</p> <ul style="list-style-type: none"> Nominate a surgical lead in each specialty in each Trust and provide them with GCP training in a manner that is convenient for them. Set up specialty specific cross-regional groups. Monitor performance and take interventional action as appropriate in cases where delivery is not being achieved.
	2	Increase the proportion of surgery patients recruited into Surgery studies on the NIHR CRN Portfolio	Number of participants (per 100,000 surgical admissions) recruited into Surgery studies on the NIHR CRN Portfolio	50	

NIHR Clinical Research Network: East Midlands

Presentation to UHL Trust Board: Annual Plan 2014/15, Financial Plan 2014/15 and Governance Framework

Background

The NIHR Clinical Research Network (CRN) is the clinical research delivery arm of the NHS in England, with 15 Local Clinical Research Networks (LCRN's) responsible for delivery and championing clinical research in the NHS at every level. UHL is the host organisation for the East Midlands LCRN (also known as NIHR CRN: East Midlands) and is responsible for overseeing effective transition, delivery and on-going governance and performance of the LCRN. Previously, there were 10 NIHR research networks in the East Midlands; establishing the East Midlands LCRN requires the transition of these networks into one entity. The LCRN became operational on April 1, 2014 but full transition is not expected or required until the end of this financial year. We are presenting for discussion and approval three important documents which are mandated by NIHR to be approved by the Trust Board: (i) Annual Plan 2014/15; (ii) Financial Plan 2014/15; and (iii) Governance Framework.

Annual Plan 2014/15

The plan is indicative and no doubt will change to some degree after consultation with NIHR and in response to events during the year. Broadly, it describes how far we have progressed on the road to transition and our next steps, who is doing what at this present time, what we feel our recruitment targets should be, and other issues such as patient and public involvement. The document itself is a template where we are asked specific questions with a requirement insert brief text in answer to them. Some of the present arrangements are interim and there is an emphasis on increasing recruitment despite the challenges of the transition process. A one page Executive Summary gives an overview of our mission, vision, challenges and immediate and mid-long term priorities.

Financial Plan 2014/15

As host, UHL has responsibility for the effective and transparent financial management of the LCRN budget. The Financial Plan includes an account of our planning principles and indicative allocations to partner organisations. The allocation for 2014/15 has been confirmed as £21.5m, and will involve collaborative working with 15 NHS organisations, 19 CCGs and multiple Independent contractors from across East Midlands, together with academic organisations. It is expected that we will fund over 1,000 research posts across the East Midlands.

The allocation received represents a £1.1m (4.8%) reduction against the original indicative allocation of £22.6m. This raises a significant financial challenge for 2014/15; it is the

operational responsibility of the LCRN Chief Operating Officer, Clinical Director and Senior Network Team to manage this risk. However, as the legal entity receiving these funds, UHL has the ultimate duty to ensure that the budget is managed effectively.

Our financial planning principles include: submission of a realistic budget which can be accommodated with the allocation provided; ensuring a realistic vacancy factor (5%); retention of present staff; retention of non-pay and overheads for partner organisations; active budget management e.g. monthly reporting, frequent meetings with partners, enhanced performance management, flexible funding when required; improving value for money; and central approval of all new and replacement posts.

Governance Framework

This document outlines the governance framework for the LCRN as hosted by UHL. It includes the purpose the network, general principles, senior officers, scheme of delegation, governance structure, Host Board controls and assurances, assurance framework, business continuity arrangements, risk management processes, escalation processes and monitoring of action plans.

Trust Board will be asked to review and/or sign off information on the following LCRN activities: LCRN annual plan; LCRN annual report; submission of the annual 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; quarterly report to Trust Board on the work of the LCRN alongside the quarterly report on UHL R&D; inclusion of LCRN data in the monthly Trust Board Quality and Performance Report.

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

**National Institute for Health Research
Clinical Research Network: East Midlands**

GOVERNANCE FRAMEWORK

**Incorporating
Scheme of Delegation, Assurance Framework, Escalation
Process and Risk Management System**

March 24, 2014

Change Control

Version	Changes made
1.0	Original document – approved by UHL Executive Strategic Board 01.04.14
1.1	More detail on roles of the Clinical Research Divisional Leads and additions to section 7.1. 08.04.14

NIHR CLINICAL RESEARCH NETWORK: EAST MIDLANDS

Governance Framework

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NIHR CLINICAL RESEARCH NETWORK: EAST MIDLANDS

Governance Framework

1. INTRODUCTION

- 1.1 The National Institute for Health Research (NIHR) Clinical Research Network (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 partners 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 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 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 Operating Framework which is concerned with (i) the transition of 10 NIHR research networks into the NIHR CRN: East Midlands and (ii) the hosting of the LCRN after fully transitioned.

2. PURPOSE

- 2.1 This framework describes the LCRN's scheme of delegation, Board controls and assurances, assurance framework and 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;
 - 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;
 - Assurance framework and risk management system;
 - Escalation process;
 - LCRN Leadership and Management Groups.
- 3.3. NHS patients, carers and the public are the key stakeholders in NIHR CRN research, and are to be included in LCRN governance arrangements. Patient, carer or public representatives have been included in the agreed membership of the Partnership and Executive Groups.
- 3.4. LCRN governance arrangements are required to be formally signed off by the Trust Board and by the national CRN Coordinating Centre.

4. ACCOUNTABLE OFFICER AND NOMINATED EXECUTIVE DIRECTOR

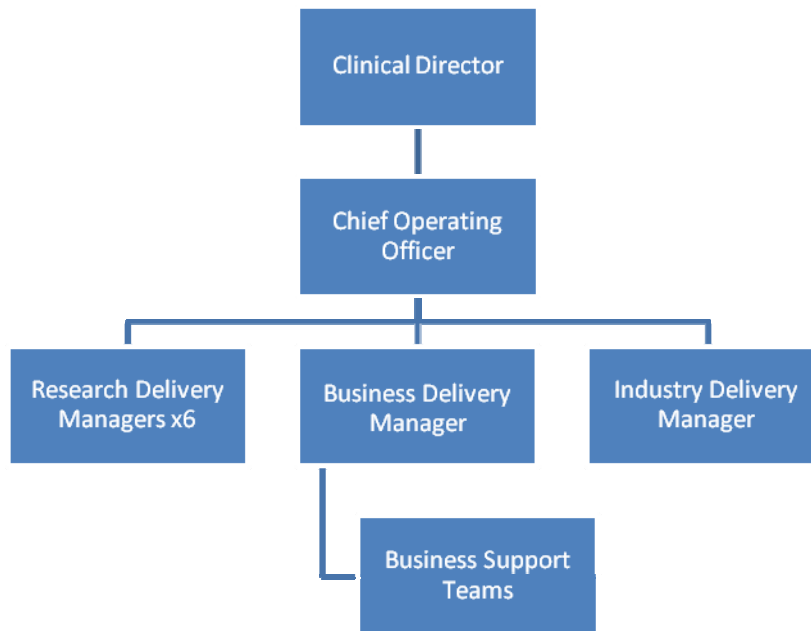
- 4.1 The LCRN Accountable Officer is the Trust's Chief Executive Officer, John Adler.
- 4.2 The Nominated Executive Director for the LCRN is the Trust's Medical Director, Dr Kevin Harris.

5. SCHEME OF DELEGATION

- 5.1 Informed by the LCRN draft contract and Performance Operating Framework v0.5, the Trust Board has agreed a specific scheme of delegation of authority to the LCRN leadership team to ensure good governance of the LCRN.
- 5.2 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.
- 5.3 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.
- 5.4 The Trust will appoint **LCRN Divisional Research Delivery Managers** (day-to-day operational management of research activity in each of the six operational divisions), an **Industry Operations Manager** (responsible for commercial research within the LCRN), and a **Business Delivery Manager** (responsible for management themes that cross cut the divisions).
- 5.5 The Trust has appointed six **LCRN Clinical Research Divisional Leads**. These clinicians will represent the clinical activity interests of all specialties within their Research Delivery Division, liaising with the Clinical Research Speciality Leads. They will be members of the LCRN Clinical Research Leadership Group (see below) and work closely with their Divisional Research Delivery Managers and other members of the Operational Management Group (see below). Their responsibilities include: (i) addressing resource allocations and the balance of the LCRN portfolio across specialties, sites, patient groups and study composition; (ii) providing clinical intelligence and advice to support research delivery within the division, including a view of the clinical implications of national policy locally, and supporting Clinical Research Specialty Leads with the identification and development of research communities within the LCRN area.

5.6 Figure 1, illustrating the management structure, is included below:

Figure 1 - CRN: East Midlands Senior Management Structure



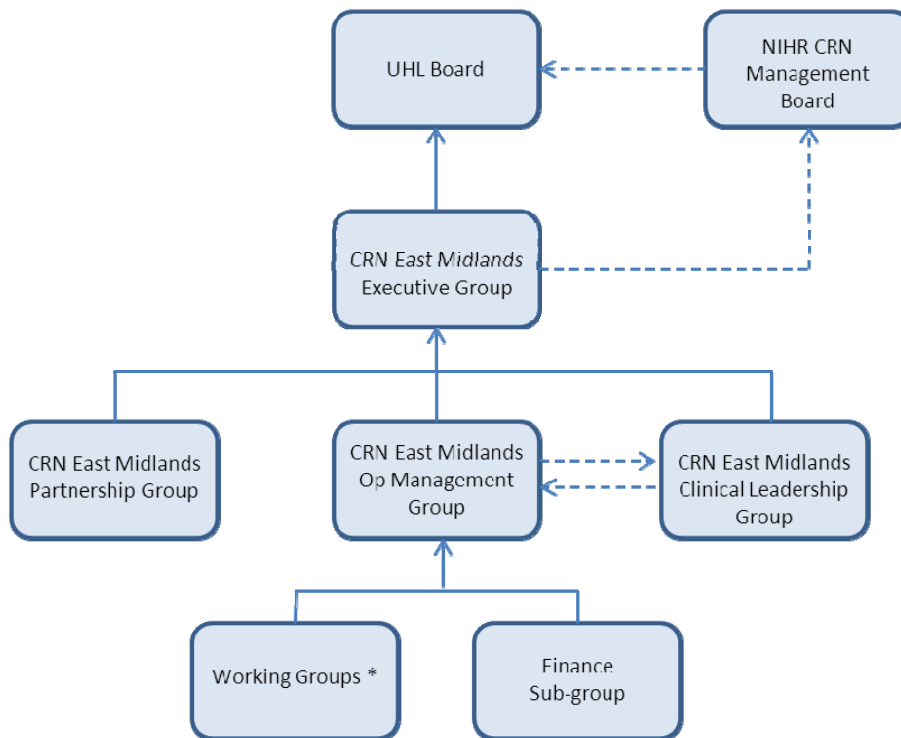
6. LCRN GOVERNANCE STRUCTURE

6.1

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

A

Figure 2 – CRN: East Midlands Governance Structure



- 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.
- 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 Human Resources Lead, LCRN Financial Lead, and Trust Head of Communications and Engagement. Its purpose is to oversee and deliver good governance of the LCRN as defined by the Host contract and LCRN Operating Framework.
- 6.4 The Trust has established a **LCRN Operational Management Group** chaired by the Chief Operating Officer (or Clinical Director until the Chief Operating Officer commences duties) and reporting to the LCRN Executive Group. 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. Membership includes all LCRN senior operational managers.
- 6.5 The Trust has appointed a **Clinical Leadership Group** consisting of the Clinical Director, LCRN Clinical Divisional Leads and the designated leads representing clinical specialities. The Clinical Leadership Group will work closely with the Operational Management Group; 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 plan, from the Executive Director, for approval;
 - Receipt of an LCRN annual report, from the Executive Director, for approval;
 - Submission of the annual 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 data in the monthly Trust Board Quality and Performance 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. ASSURANCE FRAMEWORK

- 8.1 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.
- 8.2 This section describes the structure and systems through which the LCRN Leadership and Management Groups, and the Trust board receive assurance.
- 8.3 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

- 8.4 An issue is defined as a relevant event that has happened, was not planned, and requires management action.
- 8.5 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 1

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

8.6 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 accordingly 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 appropriate response. However the response must always be:

- timely
- proportionate
- comprehensive
- inclusive
- effective.

8.7 The LCRN will follow a five step procedure for issue management and control (table 2). This procedure will be followed by the LCRN Senior Management who comprises the Operational Management Group.

Table 2

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

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

Table 3

Internal Sources of Assurance	External Sources of Assurance
Performance review meetings	Patients, carers and the public
Portfolio performance reports	UHL Audit Programme
Internal audit (review of internal systems and processes)	CRN Coordinating Centre
Executive Group	Stakeholder feedback and engagement
Partnership Group	Stakeholder and public survey results
Operational Management Group	
Clinical Leadership Group	
Staff surveys and exit interviews	
UHL Board	
Quality and Performance reports	

- 8.9 T
 he LCRN is launched on 1 April 2014 and will be adopting new assurance sources throughout 2014/15. Assurance systems have been identified for development within the Annual Plan to be submitted to the CRN Coordinating Centre. It is anticipated that a means of tracking performance monthly against a series of performance measures set out in a "performance measures dashboard", will be adopted.

LCRN Host Organisation Annual Review

- 8.10 The Trust must review its role in discharging the Department of Health contract for hosting the LCRN and provide a report on this within the LCRN Annual Plan. This report must be shared with the LCRN Partnership Group.

LCRN Auditing Arrangements

- 8.11 The Trust is obliged to ensure that LCRN activity is included in the local internal audit programme of work. The LCRN Clinical Director has instigated these arrangements with the Trust's Interim Director of Finance and PwC UK.

9. BUSINESS CONTINUITY ARRANGEMENTS

- 9.1 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.

- 9.2 The
 LCRN will create a separate Business Continuity plan in the 2014/15 finance year. However in the interim, in the event of an unpredicted medical emergency or condition, the LCRN will adopt the recommendations from the Leicestershire, Northamptonshire and Rutland Comprehensives Local Research Network (LNR CLRN) Contingency Plan v2.0 (October 2013) and the Trent CLRN Pandemic Planning (July 2013).

10. RISK MANAGEMENT PROCESS

- 10.1 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.
- 10.2 T
The LCRN has implemented an interim risk management framework, based on the Trust framework, which includes an action plan and risk register. The action plan documents the work required of the host organisation in the establishment of the LCRN. In addition, a risk register has also been created by the LCRN. Both documents are reviewed monthly the LCRN Executive Group.
- 10.3 B
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.
- 10.4 The LCRN, however, recognises the need to develop a risk management framework which reflects the strategic and operational requirements of the LCRN, as these differ from those of the Trust. This framework will be created by LCRN Senior Management within 2014/15.

11. ESCALATION PROCESS

- 11.1 T
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 Operating Framework.
- 11.2 T
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) L
CRN Clinical Director – Professor David Rowbotham
 - 2) N
Nominated Executive Director – Dr Kevin Harris
 - 3) T
The Trust Chief Executive Officer – John Adler
 - 4) N
National CRN Coordinating Centre – Management contact TBC
- 11.3 T
The LCRN plans during 2014/15 to formalise a range of trigger points or thresholds, linked to finance, service and contractual performance measures which will be used as the principal means against which the LCRN Senior Management is held to account.

These will relate to the measures set out in the CRN Performance and Operating Framework 2014/15.

- 11.4 T
he 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.

12. MONITORING OF ACTION PLANS

- 12.1 T
he Trust has developed a common action plan template. All action plans developed by the LCRN are in accordance with this model.
- 12.2 T
he LCRN has created an action plan which documents the work required of the host organisation in the establishment of the LCRN. The action plan is reviewed monthly by the LCRN Executive Group.

13. REVIEW

- 13.1 T
he Governance Framework will be subject to further development as the Trust hosting requirements and LCRN arrangements become embedded.
- 13.2 T
he 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

24 March 2014

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: TRUST BOARD

DATE: 24th April 2014

REPORT FROM: PROFESSOR ROWBOTHAM, CLINICAL DIRECTOR
CRN: EAST MIDLANDS

AUTHOR: MARTIN MAYNES – RESEARCH & DEVELOPMENT
FINANCE LEAD

SUBJECT: CLINICAL RESEARCH NETWORK: EAST MIDLANDS
FINANCE PLAN 2014/15

1.1 Background

In September 2013 the National Institute for Health Research (NIHR) announced the organisations which are to host the 15 new Clinical Research Networks (CRNs) across England. The CRN: EAST MIDLANDS is to be hosted by UHL. This followed a rigorous selection process to ensure that potential hosts are committed to developing research, and have a track record of working collaboratively with other organisations.

The Networks are an essential element in the national strategy to increase the opportunities for patients to take part in research, and to ensure that research is carried out effectively.

Starting on 1st April 2014 the 15 hosts will be awarded five year contracts from the Department of Health to act as the Network's local branch and to raise the profile of research across the NHS.

UHL has responsibility for the successful management of all aspects of the CRN: EAST MIDLANDS. The first key duty is to oversee the transition process from the existing CRNs and Topic Networks to CRN: EAST MIDLANDS.

The purpose of this paper is to set out the draft 2014/15 Finance Plan for CRN: EAST MIDLANDS.

1.2 Financial Overview

CRN: EAST MIDLANDS is a significant financial undertaking. The allocation for 2014/15 has been confirmed as **£21.5m**, and will involve collaborative working with 15 NHS organisations, 19 CCGs and multiple Independent contractors from across East Midlands, together with Academic organisations. It is expected that CRN: EAST MIDLANDS will fund over 1,000 research posts across the East Midlands.

The allocation received represents a £1.1m (4.8%) reduction against the original indicative allocation of £22.6m. This raises a significant financial challenge for 2014/15, as this comes on top of the 10% reduction that most Research Networks in the East Midlands experienced in 2013/14.

It is the operational responsibility of the COO and Senior Network Team to manage this risk. However, as the legal entity receiving these funds, UHL has the ultimate duty to ensure that the budget is managed effectively.

A major factor in the reduction is this year's allocation is the relatively poor recruitment in some Partner Organisations (POs) in our region. Recruitment represents the majority of the funding calculation in the budget summary as can be seen in Table 1 below. Addressing this issue needs to be a priority for CRN: EAST MIDLANDS to avoid future budget reductions..

Table 1: Breakdown of main funding allocation for NIHR CRN: East Midlands

Funding Element	Allocation 2014/15 £'000
Leadership and Management	782.4
Per Capita	4,696.4
Project Related Funding	1,253.4
Performance Related Funding	281.8
Recruitment Related Funding	14,456.0
CRN Specialty National Leads	69.4
Total Main Funding Allocation 2014/15	21,539.4
<i>Hosting (within Total Main Allocation 2014/15)</i>	400.0
RCF Allocation 2014/15	tbc

Details of the various elements which make up this allocation are shown in Appendix 1.

1.3 Timetable

Action	Responsibility	Key Date
Develop Financial Planning Principles	Interim Operational Management Group	21/03/14
Approve financial plan and indicative organisational budgets.	CRN: EAST MIDLANDS Exec Team UHL Trust Board CRN: EAST MIDLANDS Partnership Group (via email)	10/04/14 10/04/14 10/04/14
Submit Detailed Financial Plan to NIHR via Finance Tool	Cathryn Love Rouse, Project Advisor - CRN: EAST MIDLANDS	09/04/14
Issue draft 14/15 indicative budgets/finance pro formas to all partner organisations	Cathryn Love Rouse, Project Advisor - CRN: EAST MIDLANDS	11/04/14
NIHR review of submitted plans	NIHR	April 2014 (tbc)
Confirmation of 2014/15 CRN: EAST MIDLANDS Finance Plan.	NIHR	April/May 2014 (tbc)

1.4 Planning Principles

Given the reduced budget and the need to ensure that research activity continues across the East Midlands it is essential that there is a robust and transparent methodology for budget setting. The CRN: EAST MIDLANDS

Executive Team therefore wished to establish a number of clear financial planning principles to inform the detailed budget setting process.

In terms of process the ET mandated the Interim Operational Management Group to develop the planning principles. The OMG set up a panel of experienced Network Managers to draft these, and have worked with the Host Finance Team and Partner Organisations (POs) to refine them over the last few weeks. The principles agreed are:

Balanced Budget

The CRN: EAST MIDLANDS is committed to submitting a realistic budget which can be accommodated with the allocation provided. Therefore the budget submitted will reconcile with the allocation.

Vacancy Factor

The Vacancy Factor is recognised by NIHR as a way of reflecting the fact that staff turnover will reduce the number of funded posts as the financial year progresses. It is recommended that a maximum 5% Vacancy Factor will be applied. 5% is a realistic maximum based on experience in previous years. This will need to be managed carefully throughout the year to ensure that a minimum 5% saving is actually achieved.

The 5% Vacancy factor will be applied to individual organisational financial allocations and managed at that level. The level of delivery will be monitored and reported monthly to the Senior Team. In addition, Network Managers will monitor progress through regular face to face meetings to ensure delivery of the savings required.

Retention of Staff

Wherever possible CRN: EAST MIDLANDS wishes to ensure funding is available for staff who are currently research active in the East Midlands. This is seen as offering significant assurance to Partner Organisations that funding will continue during the transition period into the new Network. Therefore, as far as possible, the financial plan will reflect the staff actually in post at March 2014, and make provision for 12 months funding. This does not include staff who are funded via other budgets, for example Research Capability Funding (RCF) or commercial funding. The risks associated with RCF funding are discussed in the Risk section of this paper.

Non Pay and Overheads

The feedback from POs was very strongly in favour of retaining realistic percentages for Non Pay and Overheads. Therefore the draft budget reflects an across the board allocation of 5% for Non Pay and 4% for Overheads, this being the average amounts funded in 2013/14. Given that there was reduced funding overall this was paid for by reducing the amount of pay funded for each post. This approach has been discussed with PO's. The Non Pay and Overheads budgets will form part of the allocation of funding made to PO's.

Budget Management

The feedback from POs also indicated that there was a desire for greater flexibility and joint working in terms of managing CRN: EAST MIDLANDS budgets at organisational level. This will be accommodated as far as possible, and any change to budgets will be made in partnership with POs. However, final decisions on budgets have to remain the responsibility of the COO and Network Managers (working closely with, and advised by, the CD and Divisional Clinical Research Leads) to ensure that the ability to move funds wherever required remains. In return for more financial collaboration, it is expected that POs will:

- only make changes to budgets following consultation with, and the agreement of, the COO and senior Network Managers with input as required from the CD and Divisional Clinical Research Leads. Agreement and discussion should also take place in advance of any changes being made.
- manage within the funding allocations made (including Vacancy Factor)
- ensure that all expenditure is fully accounted for at the level of detail specified by the Network
- accept an increased emphasis on performance management within the context of devolved organisational budgets.

In addition there will be regular formal performance management meetings held with POs.

Flexibility

There is a recognition that 2014/15 is very much a transitional year. Therefore, it is expected that funds will need to be used flexibly in order to achieve the step change in performance required. Because of this the budgets can only be regarded as indicative at the beginning of the financial year. This gives the Network and POs the opportunity to seek better value for money by using resources to the maximum effect possible. It is essential that there is a fundamental review of how network finances are used during the early part of 2014/15.

Vacancy Management

Because of the requirement to achieve a 5% Vacancy Factor and to deliver greater flexibility in the use of funding it is essential that there is a process to review all posts which become vacant – a process is in place to ensure this. Therefore it should not be assumed that all vacant posts will automatically be filled. This will give an opportunity to assess whether the funds saved by staff leaving should either be used to contribute towards the Vacancy Factor savings, be reallocated to an area of greater impact, or reinvest the funding in a like for like replacement.

Financial Monitoring

It is essential that the Network maintains strict financial discipline throughout transition and beyond. As Host, UHL will transact all the business of the Network through the main finance ledger. It is therefore essential that there is strong financial control over Network income and expenditure. Therefore the following conditions will apply to funding allocations..

- Monthly detailed reporting will be required from POs at individual post level – submissions to be made via approved spreadsheet
- PO ledgers must match allocations and financial returns. Evidence will be required to support this.
- Monthly payments will be made to POs based on returns submitted
- Any changes made in use of funding by POs must be documented in financial return, including evidence regarding how any changes will contribute to improved performance
- Monthly Network Finance Reports to OMG and ET, and Trust Board

Other Budgets

Budgets for Service Support Costs and Primary Care will be maintained at 13/14 levels. Again, this will be subject to ongoing review. There is also provision of £135k within the budget to replace the Local Portfolio Management System.

Communication and Engagement

It will be important for there to be regular dialogue between the Network and POs. Therefore it has been agreed that a Finance Forum will be established which will ensure that there is a continuing focus on financial issues. This will build upon the very successful Finance Forum already operating in Trent locality and CRN: EAST MIDLANDS will invite the finance lead from each partner to attend regular meetings. The Terms of Reference are to be agreed, but are likely to include:

- Detailed financial planning process
- Communicating requirements for financial reporting
- Agreeing standards of financial governance/financial assurance statements
- Dissemination of midyear and full year financial reporting requirements
- Discussion of budget adjustments

In addition CRN: EAST MIDLANDS will schedule a number of regular formal and informal meetings with partners to monitor progress against plans, and this will include discussions regarding financial performance.

1.5 Indicative Budgets

Organisation	Indicative Budget 2014/15 £'000
CHESTERFIELD ROYAL HOSPITAL NHS FOUNDATION TRUST	431.0
DERBY HOSPITALS NHS FOUNDATION TRUST	1,494.8
DERBYSHIRE COMMUNITY HEALTH SERVICES NHS TRUST	65.7
DERBYSHIRE HEALTHCARE NHS FOUNDATION TRUST	241.1
EAST MIDLANDS AMBULANCE SERVICE NHS TRUST	30.9
KETTERING GENERAL HOSPITAL NHS FOUNDATION TRUST	401.6
LEICESTERSHIRE PARTNERSHIP NHS TRUST	466.2
LINCOLNSHIRE COMMUNITY HEALTH SERVICES NHS TRUST	111.9
LINCOLNSHIRE PARTNERSHIP NHS FOUNDATION TRUST	305.0
NHS LEICESTER CITY CCG	96.0
NORTHAMPTON GENERAL HOSPITAL NHS TRUST	823.2
NORTHAMPTONSHIRE HEALTHCARE NHS FOUNDATION TRUST	404.8
NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST	6,554.1
NOTTINGHAMSHIRE HEALTHCARE NHS TRUST	1,035.4
SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST	717.1
UNITED LINCOLNSHIRE HOSPITALS NHS TRUST	1,219.7
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST (see Note 1 below)	7,140.9
TOTAL FUNDING	21,539.4

NOTE 1

UNIVERSITY HOSPITALS OF LEICESTER ANALYSIS	Indicative Budget 2014/15 £'000
UHL Staffing & Non Pay	5,510.5
Hosting	300.0
Service Support Costs (central budget)	819.9
Research Sites Initiative Funding (Primary Care)	324.0
LPMS Replacement	135.0
Central Training & Other Budgets	51.5
TOTAL FUNDING	7,140.9

As well as organisational budgets it is also possible to show the budget by subjective heading as follows.

SUBJECTIVE ANALYSIS	Indicative Budget 2014/15 WTE	Indicative Budget 2014/15 PA	Indicative Budget 2014/15 £'000
Clinical Delivery	280.8	217.2	12,288.5
Host Cost	5.4	0.5	300.0
Non Clinical Delivery	104.4	0	2,718.9
Management	15.7	6.0	583.7
Research Management & Governance	34.1	0	1,074.5
Supporting Clinical Services	66.0	18.8	3,222.6
Other	5.7	0	1,351.2
TOTAL FUNDING	512.1	242.5	21,539.4

1.6 Risks and Opportunities

The current budget carries a number of risks and opportunities, and these, together with actions required, may be summarised as follows.

Risk	Mitigating Action
No provision for incremental pay progression/pay awards	<p>Delegate budgets to POs to manage flexibly.</p> <p>Monitor staff leaving, as well as those which progress through pay scales.</p>
No fund set aside for new developments or training	<p>Seek opportunities to use staff more flexibly.</p> <p>Seek to use non pay budget to offer more training</p> <p>Reinvest savings identified into new areas of development</p>
No contingency funds in place	<p>Seek opportunities to use staff more flexibly as they arise</p> <p>Reinvest savings identified into new areas of development</p>
Vacancy Factor not achieved	<p>Regular monitoring of financial position to identify issues and address them promptly</p> <p>Performance management of PO budgets</p> <p>Reduce PO allocations if no savings identified</p>
<p>Research Capability Funding (RCF).</p> <p>During the planning process it became clear that there are a number of posts funded in 13/14 by RCF which would normally be funded from Core Network budgets. At mid year this equated to 14.5wte with an annual cost of £330.6k. At present there is no confirmation that this funding will continue in 14/15</p> <p>Formally this risk lies with POs but there will be a case made that the Network should fund these individuals should funding cease.</p>	<p>Ensure any 14/15 RCF funding is used to mitigate this risk where possible.</p> <p>Consider transferring RCF funded staff to Core funding as and when possible</p> <p>Consider not filling vacancies when staff funded by RCF leave.</p>
Cross Border Posts	<p>During the planning process UHL were notified that a number of staff employed in POs actually carried out work in another Network Region,</p> <p>Seek NIHR guidance on the treatment of Cross Border staff</p> <p>Ensure budget for cross border staff</p>

eg Sheffield. There is a risk that if TUPE applies then the Network receiving the funding will also request a transfer of funding. At present this risk has not been quantified.	remains in CRN:EAST MIDLANDS financial plans for 14/14 while this issue is resolved at national level.
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Opportunity	Action Required
Identify funding which can be released for investment elsewhere.	COO to lead major exercise to review all CRN: EAST MIDLANDS budgets and relate them directly to performance Review Network management and admin costs to ensure maximum efficiency Review organisational budgets and relate more directly to activity and performance
Develop Divisional Budgets and Reporting	Divisional Managers to identify resources across Divisions and begin to manage these as a single resource.
Maximise commercial income	CRN: EAST MIDLANDS to focus on developing capacity within the region to carry out more commercial activity. This will generate additional income which may be reinvested in research.

1.7 Recommendations

The Trust Executive Committee is asked to:

- Approve the Financial Planning principles
- Approve the indicative budgets outline in Table 2, subject to review by NIHR
- Note the financial risks and opportunities identified, together with the mitigating actions
- Authorise the circulation of detailed draft Financial Plans to Partner Organisations after NIHR submission

APPENDIX 1 – ALLOCATION FUNDING DETAILS

1. LCRN Leadership and Management funding element

The LCRN Leadership & Management funding element is defined as funding to meet the costs of specified LCRN leadership and senior management posts based upon the structure set out in the CRN Performance and Operating Framework (v0.5):

- Clinical Director
- Chief Operating Officer
- Divisional Research Delivery Manager x 6 (one per division)
- Cross-divisional Research Delivery Manager
- Industry Operations Manager

The CRN CC has calculated indicative costs for these posts based on the expected NHS band for each post, taken at the top of the NHS salary band.

A funding allocation capped at £782,383 per LCRN is available to support leadership and management costs in 2014/15. An additional 8% for direct non-staff costs (travel, equipment, etc.) is included in the calculations.

2. Per Capita Population element

Per capita population based funding was introduced as a foundation element of NIHR Comprehensive Local Research Network (CLRNs) funding at the inception of CLRNs in the 2007/08 financial year. This element of funding was introduced in order to provide a degree of stability for the networks by providing a minimum amount of funding not dependent on levels of research activity or performance. The per capita population allocations are based upon Office of National Statistics (ONS) Resident Population estimates of the resident population within each LCRN geography.

NIHR LCRN funding has retained a per capita allocation for 2014/15, maintaining the allocation at the 2013/14 total national level (£57m, to nearest £1m); this equates to 20% of the total CRN allocation of £284.6m.

3. Project-related element

A funding element for “Project-based” activity was introduced in the funding allocations model in 2013/14. This element of funding referred to all CLRNs services where the level of resource

The NIHR Clinical Research Network

Supporting research to make patients, and the NHS, better needed to deliver the service relates to the number of research projects processed through the service, rather than the number of participants in the research projects.

The key activities identified in this domain in 2013/14 were:

a) Activities related to the NIHR Coordinated System for gaining NHS Permission (CSP)

The CSP-related allocation is awarded based on the number of local reviews and study-wide reviews undertaken by each CLRN in 2011/12 (commercial and non-commercial combined) and then weighted according to the study complexity (based on IRAS category). Study-wide reviews are given an additional weighting of 68% over local reviews.

b) Lead CLRN network services

The Lead CLRN allocation is awarded based on the number of study-wide reviews undertaken by each CLRN in 2011/12.

For 2013/14, 7% of CCRN funding has been allocated on the basis of project-based activity equating to the average CLRN spend on these activities.

For 2014/15 this element remains unchanged from the 2013/14 model; this includes retaining the funding allocated to this element at £17, 060, and 08.

The numbers of CLRN local and study -wide reviews carried out between October 2012 and September 2013 have been mapped to the new LCRN boundaries and this new mapping has been applied to the funding model in order to calculate this element of funding in 2014/15.

4. Performance-related element

The 'Performance Premium' was introduced as an element of the funding model for NIHR Comprehensive Local Research Networks in 2013/14 as an allocation of funding on the basis of good study delivery performance i.e. CLRNs meeting recruitment targets within agreed timeframes. In the 2013/14 model, CLRNs received performance-related funding for each commercial contract study within the CLRN conducted to 'time and target'.

The CRN CC has used the same calculation methodology for this element as was used for 2013/14, however the proportion of NIHR CRN funding assigned to this element is doubled from £1.75m (2013/14) to £3.5m (2014/15).

5. Recruitment-related element

As in previous years, the 2014/15 CRN funding model allocates funding in proportion to recruitment activity, with study complexity addressed utilising three weighted study bands.

6. CRN Specialty National Leads

From 2014/15 the Clinical Research Network Portfolio will be mapped to 30 CRN Specialties. Each CRN Speciality will have a CRN Specialty National Lead; these Leads are the senior external-facing clinical face of the Clinical Research Network, engaging with specialty-specific stakeholders (e.g. charity funders) and promoting intra-NIHR collaboration. CRN Specialty National Leads maintain an overview of the national portfolio for their CRN Specialty and support the optimal delivery of commercial contract and non-commercial portfolio research.

In 2013/14, National Leads for 24 CRN specialties were funded through NIHR Comprehensive Local Research Network budgets; the six other CRN Specialty National Leads are resourced through funding to the national Coordinating Centre.

7. LCRN Host organisation Corporate Support Services

From 2014/15 LCRN Host Organisations will be required to provide Corporate Support Services as set out in the CRN Performance and Operating Framework.

In order to reach an estimate of the cost of provision of LCRN Host Organisation Corporate Support Services, the CRN CC analysed expenditure data from previous years for these activities. These data included expenditure related to hosting, as reported on the CRN Finance Tool, and expenditure on other staff posts that were required to deliver the hosting function, such as host-employed Finance posts.

As this is the first year of operation of the new LCRNs, the CRN CC is setting as guidance, an allocation for Corporate Support Services at 2% of an LCRN's total allocation or £400,000, whichever is the lower. Please note that funding for Corporate Support Services is not defined as a separate funding component in Table 2 above as this is included in the main funding allocation; the table shows the maximum permissible spend on Corporate Support Services for each LCRN Host Organisation.

Please note that LCRN Host organisations that consider the LCRN Leadership and Management funding element and/or the Corporate Support Services funding element to be insufficient to meet genuine and legitimate costs, then any additional expenditure above the allocation will need to be justified, considered and approved in advance by CRN CC.