Meeting Date: 30th March 2016

Title: Clinical Research Network: West Midlands (CRN: WM)

Executive Summary:
RWT as Host for the National Institute for Health Research (NIHR) Clinical Research Network: West Midlands (CRN: WM), is responsible for ensuring the effective delivery of research in Trusts, primary care organisations and other qualified NHS providers. The Host is required to submit an Annual Delivery Plan for 2016-17 (which includes an Annual Financial Plan) to the NIHR Co-ordinating Centre (NIHR CC) by 8th April.

The Annual Delivery Plan (Appendix Two) sets out the strategic direction for the local Clinical Research Network (LCRN). It includes the specific activities and strategic initiatives to support the achievement of the performance objectives as set out in the NIHR CRN Performance & Operating Framework 2016-17. The plan has been signed off by the Partnership Group (11.02.16) and should be formally approved by the Host Trust Board prior to submission to the NIHR CC.

The Annual Financial Plan 2016-17 sets out the funding allocations to Partner Organisations and a summary is included at Appendix One.

The report will also provide a general overview and assurance to the Trust Board on progress to date in the CRN: WM.

Action Requested:
1. To sign off the Annual Delivery Plan 2016-17
2. To note LCRN performance to date

Report of: Dr Jonathan Odum, Medical Director
Nominated Executive Lead for CRN: WM

Author: Contact Details: Tel 01902 695968 Email: jonathan.odum@nhs.net

Links to Trust Strategic Objectives
- To build a reputation for excellence by achieving top 25% performance against key measures
- To proactively seek opportunities to improve health services in our local health economy through collaboration and supportive partnerships
- To maintain the financial health of the organisation and seek appropriate investment opportunities that enable further enhancement of patient services

Resource Implications:
- Revenue: n/a
- Capital: n/a
- Workforce: n/a
- Funding Source: n/a

Risks: BAF/ TRR
(designate risk and current risk score) n/a
**Title: Trust Board Report**

<table>
<thead>
<tr>
<th>Public or Private: (with reasons if private)</th>
<th>Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>References: (eg from/to other committees)</td>
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</tr>
</tbody>
</table>
| **Appendices/References/Background Reading** | Appendix One – CRN Summary allocations by Partner Organisation 2016-17  
Appendix Two – CRN: West Midlands Annual Delivery Plan 2016-17 |
| **NHS Constitution: (How it impacts on any decision-making)** | In determining this matter, the Board should have regard to the Core principles contained in the Constitution of:  
- Equality of treatment and access to services  
- High standards of excellence and professionalism  
- Service user preferences  
- Cross community working  
- Best Value  
- Accountability through local influence and scrutiny |
Background Details

1 Under the contract with the DH, RWT as Host Organisation is required to submit an Annual Delivery Plan (ADP) which includes the Annual Financial Plan (AFP) for the Local Clinical Research Network (LCRN). The ADP is based on the Performance and Operating Framework 2016-17 which is part of the DH/LCRN Host Organisation Agreement.

The document includes the High Level Objectives and Clinical Research Specialty Objectives for 2016-17 and it is these national performance objectives, measures and targets which will be used to measure the success of the LCRN. It also builds on the NIHR CRN Performance Management and Reporting Framework.

Annual Delivery Plan 2016-17

2 The Annual Delivery Plan (Appendix Two) sets out the strategic direction and includes the specific activities and strategic initiatives which support the achievement of the NIHR performance objectives. The plans have been streamlined for 2016-17 but also include planning for 2017/18. This has been challenging, particularly given the nature of research, the length of time it can take for research ideas to materialise into studies and having the knowledge of ‘pipeline’ studies coming through the NIHR portfolio.

The 7 High Level Objectives remain unchanged and Specialty objectives reduced to 30.

Section 1 provides reassurance that the LCRN is in full compliance with the DH/LCRN Host Organisation Agreement.

Section 2 of the plan provides the CRN’s baseline performance against the 7 HLOs and provisional recruitment targets for 2016/17 and 2017/18. All LCRNs must submit final targets by end of June. A summary of the plans to support achievement of the HLO’s and specialty objectives are included, with detailed plans in Appendices A and B of the document.

Section 3 provides a high level summary of the initiatives the CRN will be undertaking to support the national CRN priorities which are:

- Delivery of NIHR CRN Portfolio studies to time and target (HLO 2) with a specific focus on commercial contract research (HLO 2A)
- Delivery against the new NIHR CRN strategies – Business Development and Marketing, Communications, Information and Knowledge, NHS Engagement, Patient and Public Involvement, Workforce Development and Working with Life Sciences
- Delivery against the CRN goals – increase recruitment, providing support to researchers, working as a single network, increasing commercial investment, addressing national research priorities

Descriptions of further initiatives are included at Appendix C in the plan.

Section 4 describes other local innovations and initiatives that are planned that have not already been covered eg. New service delivery models, new processes. (Please also refer to Appendix D for additional detail).

Section 5 describes the financial model for allocation of LCRN funding for 2016-17 and our plans for supporting PO’s in their financial management of LCRN funding.

Page 3 of 5
3 The Core Allocation for 2016/17 is £28,529k; this represents a decrease of £1.2m on 2015/16 which had been anticipated. This was due to the performance of Partner Organisations (PO’s) which includes Primary Care in the first 6 months of the Activity based funding (ABF) year (01/10/14 to 30/09/15).

As agreed by the Partnership Group an ABF model has been used to allocate core funding to PO’s. This used a median ABF for 3 years, with a 15% cap on funding change, after which a 2.5% top slice was applied to create a £1.048m Strategic fund (SF). Bids were submitted during December and subsequently £1.373m has been approved with all POs notified by end of January.

Based on an initial plan drawn up before final allocations were notified (09.03.16), CRN estimated a requirement of £28,667k, if CRN honours the initial indicative allocations this would indicate a shortfall of £137k in the funding. In addition NIHR have asked that an element of funding is ring fenced to support Commercial Studies, originally set at £469k but with negotiation is more likely to be around £208k, and this would mean CRN are potentially at risk by £346k. Appendix One provides a high level summary of the 2016-17 allocations to PO’s.

For the past two years the LCRN has seen high levels of slippage (>£1m/year), there are time delays in recruiting research staff and delays in opening of studies, some studies fail to open. Therefore it is considered low risk to approve funding at the indicative levels and manage the £346k risk through slippage. However there are contingency arrangements in place in case the expected level of slippage do not materialise and these were presented to the Finance & Performance Committee (23.03.16).

Trust Board is asked to sign off the LCRN Annual Delivery Plan 2016-17, including the Annual Financial Plan.

4 The CRN remains 1st nationally and 6/15 when adjusted for recruits per million population, 27% ahead of last year’s recruitment and at 98% against the NIHR pro rata 'stretch' target.

Overall the CRN is achieving well against the high level objectives, with a much improved position particularly against HLO 2a and 2b. That is the percentage of studies that have recruited to time and target (closed studies only). Almost all commercial studies that closed at the end of 2015 had achieved the target, currently this is RAG rated amber and achieving 60% (against previous performance of 50% - red RAG rated). For HLO 2b non-commercial studies, we are achieving 86% (green) with 42/49 studies achieving the target; improving the position from November of 50% (red).

Forecast year end position for HLO 7 – increasing patients into Dementia studies, should easily be achieved.

HLO 6 - to increase NHS participation in NIHR portfolio studies; there are now 48% of GP practices recruiting into studies against a national target of 25%.

HLO 5 objective to reduce the time taken to recruit first patient into portfolio studies. This target remains challenging and it will be a focus of attention for 2016-17 with a number of continuous improvement projects being established, working closely with R&D Managers to see how this objective can be improved.

Overall engagement remains very good with senior attendance at Partnership Group
meetings from the majority of partner organisations. A quarterly R&D Managers Forum is well supported across the region with joint working and valuable contributions in developing the Annual Plan and strategic direction for 2016-17.

Quarter 3 Submission reported to NIHR an under-spend “to be allocated” of £428k. This additional underspend is mainly due to further slippage on recruitment, reduction in CCG payments that were expected to materialise, and the release of some provisions within the Host budget that were no longer required. This funding has been re-allocated to PO's in the last quarter to increase recruitment and support the opening of studies (that otherwise would not have opened). Further work has been undertaken with all PO's and any remaining slippage identified and re-distributed; the CRN should return a break even position at year end.
## CRN INCOME ALLOCATION SUMMARY 16/17

### Sum of Total Cost

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<thead>
<tr>
<th>Organisation</th>
<th>2016/17 ABF allocation</th>
<th>Strategic Funding Green Bids</th>
<th>GP payments</th>
<th>CRL CRSL payments</th>
<th>Other</th>
<th>SLA Cont</th>
<th>Grand Total</th>
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<th>Strategic Funding Green Bids</th>
<th>GP payments</th>
<th>CRL CRSL payments</th>
<th>Other</th>
<th>SLA Cont</th>
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### Ringfence Commercial Studies Funding Requirement

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<td>NHR Funding Allocated</td>
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<td>Shortfall in funding (Contingency funding has been identified to address this shortfall if required)</td>
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**Note:** The data provided includes various entries related to different healthcare organizations, funding allocations, and other financial details. The last section includes additional financial requirements and shortfalls, indicating the need for contingency funding if required.
Annual Delivery Plan: 2016/17
CRN: West Midlands

Version: V7
Date submitted: by 8th April
Contents

Section 1: Compliance with the Department of Health / LCRN Host Organisation Agreement
Section 2: Contribution to National NIHR CRN Performance Indicators
Section 3: Contribution to NIHR CRN Priorities 2016/17
Section 4: Other local innovation and initiatives
Section 5: Financial Management

Appendices

Appendix A – s. 2.1 HLO’s
Appendix B – s. 2.2 a & b Specialty Objectives
Appendix C – s. 3.1 National CRN strategic priorities
Appendix D – s. 4.1 Local innovations and initiatives
**Section 1: Compliance with the Department of Health / LCRN Host Organisation Agreement (up to 2 pages)**

1.1. Please confirm that the Host Organisation is delivering the LCRN in full compliance with the DH/LCRN Host Organisation Agreement

Yes  X
No  ☐

1.2. Please confirm if your LCRN is operating in full compliance with Appendix A Performance and Operating Framework 2016/17

Yes  X
No  ☐

1.3. If you have answered no to either of the above, please set out how full compliance will be achieved. Please specify each area of non-compliance and plans to achieve full compliance in 2016/17.

1.4. Please confirm that the enclosed Delivery Plan has been approved by the LCRN Host Organisation Board or is scheduled to be approved by the LCRN Host Organisation Board

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<th>Date when approval was obtained or is expected:</th>
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**Section 2: Contribution to National NIHR CRN Performance Indicators**
This section should summarise the LCRN’s plans to contribute to the CRN’s Performance Indicators.

2.1 2016/17 NIHR CRN High Level Objectives
Please insert local baseline performance in 2015/16 and your LCRN’s planned contribution to each objective in 2016/17 and 2017/18.

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<td>Increase the number of participants recruited into NIHR CRN Portfolio studies</td>
<td>Number of participants recruited in a reporting year into NIHR CRN Portfolio studies</td>
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<td>51644 at month 9 FYE = 66,748</td>
<td>Provisional local target: 51,000</td>
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- Build upon existing Primary Care Patient identification centres (PIC) activity initiative by strengthening the delivery processes to identify PIC sites earlier, ensuring patient recruitment pathways are discussed at EC function and to facilitate and support secondary care recruitment.
- To strengthen the work of our Primary Care Champion to ensure all commercial studies are reviewed and the relevant studies go to...
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<th>2</th>
<th>Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time</th>
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<td>80%</td>
<td>Proportion of commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed Network sites</td>
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<tr>
<td>63%</td>
<td>Local target – 70%</td>
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- Embed the newly developed joint commercial and non-commercial performance management processes across divisions in 16/17.
- To look at recognising PI’s achievements when Targets have been achieved
- The new local portfolio management

Local target – 80%
- By 17/18 our joint commercial and non-commercial performance management processes will be embedded and tested so this year will be about identifying areas that require streamlining and greater performance.
- To enhance performance management escalation process for CRN: WM CI led commercial studies to review failing studies outside of the CRN: WM
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<th>system (LPMS) will support real time recruitment uploads to supply accurate data to performance manage partner organisations (PO’s). - Implement performance management escalation process for all studies regardless of commercial or non-commercial where the CRN: WM lead studies.</th>
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<td>B: Proportion of non-commercial studies achieving or surpassing their recruitment target during their planned recruitment period</td>
<td>80%</td>
<td>88%</td>
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<td>Percentage of the total commercial MHRA CTA approvals for Phase II–IV studies</td>
<td>Local target – 80%</td>
<td>Local target – 85%</td>
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<tr>
<td>4</td>
<td><strong>Reduce the time taken for eligible studies to achieve set up in the NHS</strong></td>
<td><strong>80%</strong></td>
<td><strong>84%</strong></td>
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<td></td>
<td>Proportion of eligible studies achieving NHS set up at all sites within 40 calendar days (from &quot;Date Site Selected&quot; to &quot;Date Site Confirmed&quot;)</td>
<td><strong>Local target – 80%</strong></td>
<td><strong>Local target – 85%</strong></td>
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<td>- Continue to develop the Early Contact and Engagement Service but focussing on communicating the service to our CRN:WM CI, PO's, Local Sponsors and CTU's to support set up of studies in a timely manner. The CRN Study Support Service (SSS) will provide the new national Industry Costing Template Validation process to identify discrepancies to support PO's with timely set up of studies because all activities are listed. - The local LPMS - EDGE, has been customised so that the data collection points defined in the HRA approval process can be reported and performance managed.</td>
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<td></td>
<td><strong>80%</strong></td>
<td><strong>80%</strong></td>
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<tr>
<td>5</td>
<td><strong>Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies</strong></td>
<td><strong>A:</strong> Proportion of commercial contract studies achieving first participant recruited within 30 days at confirmed Network sites (from “Date Site Confirmed” to “Date First Participant Recruited”)</td>
<td>80%</td>
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<td></td>
<td><strong>B:</strong> Proportion of non-commercial contract studies achieving first participant recruited within 30 days at confirmed Network sites (from “Date Site Confirmed” to “Date First Participant Recruited”)</td>
<td>80%</td>
<td>50%</td>
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<tr>
<td></td>
<td>Objective</td>
<td>Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio studies</td>
<td>Local target – 100%</td>
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<td>---------------------------------------------------------------------------</td>
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<tr>
<td>6</td>
<td>Increase NHS participation in NIHR CRN Portfolio Studies</td>
<td>99%</td>
<td>- Link Research Delivery Managers (RDMs) were identified for all POs and the buddying up of POs and the cross region working has occurred due to targeted strategies. This arrangement will continue.</td>
</tr>
<tr>
<td></td>
<td>A: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio studies</td>
<td>100%</td>
<td>99%</td>
</tr>
<tr>
<td></td>
<td>B: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio commercial contract studies</td>
<td>70%</td>
<td><strong>Local target – 75%</strong>&lt;br&gt;- Industry Operations Manager (IOM) to focus on those PO’s not currently delivering commercial research e.g. to encourage PIC sites until more confident in supporting their own commercial research.&lt;br&gt;- To develop and build a local CRN: WM commercial portfolio. This will coincide with greater Sponsor engagement to promote individual PO’s.</td>
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<td></td>
<td>C: Proportion of General Medical Practices recruiting each year into</td>
<td>35%</td>
<td><strong>Local target – 40%</strong>&lt;br&gt;- Key focus is to have flexible recruitment</td>
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<tr>
<td></td>
<td></td>
<td>46%</td>
<td>40%</td>
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<td></td>
<td>NIHR CRN Portfolio studies</td>
<td>Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio</td>
<td>20,000</td>
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<tr>
<td>7</td>
<td>Increase the number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio</td>
<td>On-going identification of potential DeNDRoN researchers and promotion of the CRN, utilising ‘exceptional circumstances’ route where applicable. - Join Dementia Research (JDR) promoted in primary care and through community pharmacies, this will continue. - Working with Division 4 RDM to support commercial Care Homes research by liaising and engage with the CRO’s/ Sponsors in order to bring research within this specialist area.</td>
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</table>
a. Please provide a list of specific activities/initiatives you plan to undertake to achieve your planned contribution.

Summary - (Appendix A - detailed plan)

1. A Proposal to establish a single process for the management of ETCs is being taken to all CCGs (CRN: Wessex model)
2. Full roll out of 'Making studies a success: A feasibility workshop'
3. Continuous improvement workshops on studies that have failed to achieve HLOs
4. PI master class roll out across all 29 PO’s
5. To develop a PI mentoring toolkit
6. Develop partnerships across trusts to submit joint site identifications to increase likelihood of being selected.
7. Working in collaboration with Contract research organisations e.g. MAC / Synexus and Partner Organisations / Primary care
8. Proactive performance management and escalation procedures in place for all commercial and non-commercial studies
9. Target GCP training in RSI practices to enable / facilitate more complex CTIMP studies
10. Engage with the new Vanguard super GP practices in Birmingham and understand how CRN can work with this new type of PO
11. Establish better links with academics to understand pipeline studies
12. Study support service showcase events to raise awareness
13. Improve CRSL involvement in studies going through the early contact and engagement with researchers (ECER) service
14. Trial the use of EDGE for ECER studies
2.2 Plans to support achievement of the NIHR CRN Clinical Research Specialty Objectives in 2016/17 and 2017/18

a. List your priority investments to support the Specialties for development and delivery of the Objectives in 2016/17 and 2017/18

b. Describe any Specific initiatives you plan to undertake in these Specialty areas with your rationale, including identification of opportunities and challenges – (Appendix B – detailed plan)

- Each subspecialty lead to hold an annual educational event to promote the portfolio.
- Launch an Industry collaboration to improve EOI submissions, promote referral pathways and ensure the population across the West Midlands has access to Industry studies.
- Increase genetics trainee involvement in NIHR portfolio recruitment and support research training.
- Working with the academic partners in the region, the CRSL has identified that there are good audits carried out within the NHS that should be developed into funded studies; this will be an initiative taken forward in 2016/17.
- To increase 24/7 research activity through delivery suite midwife champions and O&G trainees
- RAIDPlus is an NHS England test bed for working between the ambulance service, police and mental health urgent care. This is an opportunity for us to explore how this new development can provide research opportunities for service users.
- In 2016/17 we will utilise the newly formed JDR steering group to try and test new ways of promoting JDR and increasing volunteer registration to targeted groups.
- Investment to continue to engage with and increase the number of Community Pharmacies participating in and conducting NIHR CRN portfolio studies
- Extend the use of ‘pop ups’ to identify and screen patients across the CRN, and roll out the EMIS Enterprise initiative, which enables appropriate permissions in place, efficient remote access to GP computer systems for patient identification and data collection.
- With an anticipated increase in Division 6 “Hyperacute” research activity across the West Midlands*, the appointment of a Lead “Hyperacute” Research Nurse should improve delivery to these studies.
- Supporting Trainee Research Networks is linked to improving engagement through Network Speciality Research Events and, by CRN: WM encouraging and promoting trainee participation, research-active trainees can provide and share up to date, practical information

c. Describe how you will facilitate effective working and ensure your local clinical research Specialty Leads are linked-in with the national clinical research Specialty Leads

- Ensure each sub-speciality lead is the research lead for the Strategic Clinical Network Expert Advisory Group and for them to develop

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* See LCRNs Annual Delivery Plan: 2016/17 Guidance Version 1.0
an annual research plan to meet the specialty objectives.

- CRSLs will have a yearly plan for achieving objectives relevant to their specialty and the regional environment. This will be overseen by the CRL and RDM. The main activity will be meeting with clinicians in partner organisations to agree ways of increasing capacity and capability of their team to support delivery of research, in partnership with their Research and Innovation Department.

- CRSL/Subspecialty Leads will lead on chairing and facilitating specialty group meetings. They will also be involved in liaising with study teams to ensure West Midlands is involved in recruitment and advising the portfolio team on feasibility, care pathways and personal contacts in potential sites.

- All divisional leads, subspecialty leads and RDM will meet as a minimum every 3 months to discuss strategic issues and action plans.
- CRSLs will be performance managed by the CRL. The CRL will be performance managed by the CD. Performance report templates have been developed and agreed with the Clinical Leads.

- Regular sessions scheduled to engage with CRL/CRSLs on monthly telecon basis and various meetings to provide support and identify potential issues.

- CRSLs and CRL are involved in project work on an on-going basis.

- Strengthening the role and remit of CRSLs, particularly when sense-checking feasibilities and encouraging individual POs to access expertise when required.

- To increase the number of specialty groups and develop the remit of these groups with defined outputs further. Ensure communication links are in place between R&D Departments and CRSLs/specialty groups.
Section 3: Contribution to NIHR CRN Priorities 2016/17

The agreed CRN priorities for 2016/17 are set out in more detail in Appendix C of the LCRN Annual Delivery Plan: 2016/17 Guidance (v1.0), issued alongside this document; in summary these are:

- Delivery of NIHR CRN Portfolio studies to time and target (HLO 2), with a specific focus on commercial contract research (HLO 2A)
- Delivery against the new NIHR CRN Strategies
- Delivery against the NIHR CRN Goals

3.1 Please describe any initiatives that you plan to undertake to contribute to achievement of the national priorities.

- Please refer to Appendix C for a detailed plan.

HLO2:

- Following a joint strategy planning day with R&D leads from across the region a workshop will be held as part of a CI project to review studies that have not achieved HLO2, or are currently not achieving it, to lead to areas of work to address performance. This is likely to focus on specialties/Divisions that show poorest performance but involving those from specialties/divisions that do perform better to share good practice. Continuous Improvement training will be provided to partner organisations, who have shown a keen interest in receiving this.
- As above, it was agreed with the R&D managers to undertake a continuous improvement project to review the follow-up of patients to see where and how the use of digital technology/smarter working can improve this so that nurse resources can be used more effectively for study set-up and recruitment. It was agreed to undertake a review of 4-5 studies with a number of Trusts volunteering to be part of this project.
- Embed within the Divisions the newly agreed performance management and escalation procedures for all commercial and non-commercial studies developed as a result of a CI workshop in 2015-16.

CRN strategic goals:

- Promotion of Join Dementia Research across the region.
- The engagement of care homes in research to provide residents and staff with research opportunities across all specialties.
- Involvement of community pharmacists to support recruitment of studies.
- Continuous improvement projects in direct communication with service users/patients in GP practices (coffee mornings) and through Macmillan Centres.
Business Development:
- Work in partnership with Trusts to reduce the amount of commercial research undertaken that is not on the CRN portfolio through marketing the CRN and encouraging companies to engage with the CRN.
- To facilitate the sign-up of GP practices to CPRD (see continuous improvement project information).
- To improve the quality of research undertaken through PI Master class training therefore improving our reputation with commercial companies.
- For Trusts to work in partnership to submit site identifications in order to secure UK and West Midlands sites for commercial research.

Engagement and Communication:
- Working with smaller, less research active Trusts to develop capacity and capability for research delivery. This includes partnering organisations to mutually support each other.
- VIP (Values in Practice) Awards - this new staff recognition scheme will be run on a monthly basis throughout the year, with staff invited to nominate colleagues who they view as having gone 'above and beyond' to implement the Network values in their day to day work. Marketing materials - resources to promote the work of the Network will be produced, including a generic brochure featuring the range of activity carried out, success stories and services offered, with an additional version specifically targeted to promote the Network to Industry.
- Raising the profile of the Network by increasing local media coverage;

Workforce, Learning and Organisational Development:
- The CRN: West Midlands Research Academy aims to ensure that research staff and clinical teams supporting research can access high quality locally-provided training which is fit for purpose and meets local needs.
- Develop an HEI engagement strategy to encourage researchers to a) link in with the NHS more but also b) try for grants which result in portfolio status. To deliver joint presentations with the Research Design Service and supported by the ECER team.
- Embed continuous improvement in workforce development coordination and administration functions
- Develop an annual audit programme for the Host employed research nurses in order to provide PO with reassurances around compliance to GCP

Industry Team:
To provide a coordinated and innovative approach to national research priorities - Through the CNR: WM Industry team to develop and utilise EDGE to allow for in-depth timely analysis and reporting of feasibilities; both successes and non-successes. From this collect intelligent data to inform improvements and by working with our PO’s to support greater improvements for commercial research.
**Patient and Public Involvement and Engagement in Research (PPIE):**
- Following the recent pilot and adaption of the course focus, the PPIE team will roll out the Building Research Partnerships (BRP) Programme locally, working with NIHR partners in the West Midlands to deliver the programme.
- Implement initiatives to explore the Patient Experience; develop the Patient Stories pack further, gather case studies in conjunction with the Communications Lead and analyse the results of the Patient Experience Questionnaire to put together an action plan based on findings.

**Business Intelligence (BI) Activities:**
- The BI team will seek to improve overall data-quality through their input into the Portfolio Management Group using the Portfolio Managers' local knowledge to validate data and provide missing data.
Section 4: Other local innovation and initiatives

4.1 Please use this section to tell us about any other local innovations planned for 2016/17 e.g. new service delivery models, implementation of new processes, or continuous improvement projects. (Appendix D - detailed plan).

**General initiatives**
- We will be providing access to continuous improvement training for R&D managers in April 2016. R&D managers have expressed an interest in this in order to locally manage HLOs, 70 day benchmark and productivity. This will help embed a culture of improvement and innovation across the region.
- Three posts are currently being recruited to for Band 4 Project Assistant roles (Graduate level roles) to be part of the CRN generic workforce and provide support to POs for study set-up, data management, study co-ordination for failing studies etc. to contribute to the achievement of HLO’s wherever possible.
- PI Master class training will continue to be rolled out where the remaining 25 Trusts have expressed their commitment to doing so.
- The Laboratory Lead is working with a partner organisation on a continuous improvement project to identify ways of increasing capacity through removing wasteful processes and data collection.
- The increased of sign-up to Join Dementia Research for those with a diagnosis of dementia will be a continuous improvement project for 2016/17.

**Primary Care**
- **Integrating the Primary Care Study Support Service and Primary Care Delivery Team** - A new model of delivering Primary Care studies in line with HRA requirements is under consideration. The aim is to better integrate the existing primary Care study support service and delivery teams to work to a more unified model.

**Pathology (Laboratory Medicine):**
- Develop strategies for improving pathology services for research in the West Midlands
- Act as a West Midlands exemplar to support national NIHR CRN pathology engagement in research

**Pharmacy**
- **EDGE**: explore potential for pharmacy clinical trials staff in secondary care to use EDGE to support pharmacy processes
- **CRN: WM Pharmacy data collection tool**: continue to collect regional data re pharmacy approval and set-up times for secondary care and contribute to the national HRA pharmacy readiness project
- **Community pharmacy and primary care**: continue to increase community pharmacy engagement with CRN: WM and identify studies suitable for community pharmacy involvement; continue to explore potential to work with local researchers to develop studies suitable
for community pharmacy involvement; explore potential involvement of pharmacists working in GP surgeries to become involved in research

**Study Support Service**
- **Study Support Service Staff ‘Refresher’ Training** - The Study Support Service team will be providing refresher training to PO and Network staff covering the RM&G proportionate and pragmatic training which was first released over four years ago.
- Getting Academic Sponsors/ Clinical Trials Units (CTU) ready for Assessing and Arranging Capacity (AAC)
- **HRA** - Getting Hospices, Care Homes and other Community providers delivering research
Section 5: Financial Management

5.1 Please describe the model for allocation of LCRN funding in 2016/17
The funding model begins with the previous year’s allocations as a start point. A second calculation is then undertaken to work out the 3 year Median ABF Units % for each organisation and allocate on this basis in relation to the total funds available. The third step is to compare the ABF 3 year Median potential allocation with previous year’s funds and then cap any potential change of moving to the ABF by 15% i.e. capped against the start point; the funds are then allocated on this basis initially. Finally a 2.5% Top Slice is applied which is used towards strategic funding as well as any surplus funding resulting from the ABF Model. The financial figures are then reviewed for any additional factors that need to be taken account with individual organisation discussions taking place and then a final sum to be allocated is derived.

5.2 Describe arrangements within the LCRN Host Organisation for management of LCRN budgets
Host LCRN Budgets have their own set of budget reports, with RDM’s as budget managers, the exception being the Management report and Host supporting costs report which are managed by the CRN COO. Monthly budget meetings are carried out with the relevant accountants and the RDM’s where budgets and spend are monitored and any variances analysed and addressed, with a review of the forecasts undertaken. Monthly meetings also take place with the accountants and the COO to review all reports, both actual and forecasts. Annual budget setting takes place with all budget holders which is reviewed over a period of time before budgets are finally set for the following year. Cost savings through pay and non-pay budgets are re-distributed to POs through an increase to the core allocation.

5.3 Describe arrangements for supporting LCRN Partners in their financial management of LCRN funding
LCRN Partners are supported by the host throughout the year, allocations are communicated initially with full backing details, as we move through the year any underspends notified by the organisations are reallocated across other Organisations within the host, any concerns, and queries are raised and dealt with. A programme of monitoring visits has been taking place whereby assurances are gained and advice is given re any queries partner organisations may have. In addition to monitoring meetings, there will be a concerted drive to support organisations through submitting and uploading their own quarterly returns, this will provide further opportunity to offer advice and support through the process with the added benefit of onsite visits being undertaken. In addition all organisations are free to request assistance, advice, information as they feel necessary to CRN at any time.

5.4 Please provide details of any plans that you anticipate impacting on the use of LCRN funding in 2017/18
There are no plans currently that will impact on the use of LCRN funding in 2017/18.
Appendices

Please attach any supporting information to further illustrate your plans.

Appendix A – s. 2.1 a  HLOs
Appendix B – s. 2.2 a & b  Specialty Objectives
Appendix C – s. 3.1  National CRN strategic priorities
Appendix D – s. 4.1  Local innovations and initiatives

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Appendix A

S. 2.1.a. Please provide a list of specific activities / initiatives you plan to undertake to achieve your planned contribution

HLO1:
1. Development and implementation of a West Midlands Higher Education Institution (HEI) engagement strategy which markets the CRN and eligibility for the portfolio. In addition further collaborators to be identified who are in receipt of portfolio eligible funding (e.g. Accord Group). Roll out in Qu2.
2. The ENRICH initiative was started in the WM in Nov 2014. Since then 80 care homes have signed up to ENRICH. The WM portfolio management team will identify potential studies for recruitment in care homes regardless of the specialty. 2016/17 will focus on the development of these care homes capability to support recruitment of studies and maintaining excellent relationships. Other suitable environments such as Extra Care retirement villages have also signed up to be engaged in research.

HLO2:
1. Partner Organisations receive monthly reports on performance against HLOs at site level even if not lead site. Discussion at a January joint strategy planning meeting between POs and CRN WM led to agreement of a continuous improvement workshop with the aim of improving this. This will lead to 2016/17 priority projects to achieve this.
2. PI Master class train the trainer with the aim that PIs actively provide oversight of a study. This was a greenbelt continuous improvement project. Currently 4 out of 29 Trusts have rolled this out and 40 PIs have received training. All 29 Trusts have committed to rolling this out in 2016/17.
3. To develop a PI Mentoring Tool Kit where for new PI’s conducting commercial research will be supported by the Network and attached to a more experienced PI ‘buddy’. This will support cross PO’s relationships and identify and share good practice.
4. Partnership working between Primary Care and other specialties to improve the quality of GP coding to allow better identification of potential participants for all studies and further develop capability as PICs.
5. Full roll out of ‘Making studies a Success: A feasibility Workshop’. This workshop is a joint initiative between the RDM’s, portfolio managers, Industry and SSS team. The training has been revisited for 16/17 to focus on completing successful feasibilities for both commercial and non-commercial studies along with HRA assess, arrange and capability review. This will ensure internal CRN staff and PO’s are working to same standard; accurate feasibility and successful delivery which will support time to target.

HLO3:
1. Developing partnerships between acute and secondary/tertiary care Trusts so they submit joint site identifications to increase likelihood of being selected E.g. North Staffordshire Combined Healthcare Trust and University Hospitals North Midlands Trust; and, Coventry and Warwickshire Partnership Trust and University Hospitals Coventry and Warwickshire.
2. POs to report commercial studies not on the portfolio to the Industry Operations Manager/RDM to engage with the company to market the CRN.
3. Discussions have started with MAC Plc in Cannock but in 2016/17 we envisage a formal partnership arrangement between MAC and a number of mental health Trusts in order to work together to recruit to the commercial studies they secure.
4. 2015/16 saw a year of establishing the RATER programme and review of the commonly used tests where staff have been submitting frequency of use on a monthly basis. A proposal has been written to embed the programme further to ensure each Trust has 4 raters for dementia studies. This will be implemented in 2016/17. WM has not secured commercial
studies due to being rejected by the CRO because of raters not being accepted. The WM is moving to support more clinical staff members being accepted as raters.

HLO4:
1. A Pharmacy Group has been set up to consider continuous improvement projects, led by Julie Shenton. The first project is ensuring readiness for HRA process and timely set up of studies. The first step is that all Trusts have agreed to collect data as a baseline. Data is being reviewed late February 2016. This will generate improvement projects for 2016/17.
2. A proposal for the management of Excess Treatment costs (ETCs) based on the model from CRN: Wessex will be submitted to the Accountable Officers across all WMs CCGs during February/March. If successful, this should prevent time delays currently experienced by POs when seeking agreement for ETCs.

HLO5:
1. Performance Management and Escalation Standard operating procedures to be reviewed along with LPMS implementation to allow for proactive performance management to identify studies that are ‘Date Site Confirmed’ and support them to do that within 30 days.
2. Support researchers and sites on importance of accurate feasibilities to enable delivery to this HLO by promoting the ‘Making studies a Success: A feasibility Workshop’
3. Facilitating discussions between CRSLs and individual POs where expertise and independent advice is required on feasibilities.
4. Include research teams - CI’s/PI’s in the review of studies which failed to achieve HLOs and in the various continuous improvement projects being undertaken to help achieve HLO’s.

HLO6:
1. The Primary Care Speciality (PCS) plan to continue to further mature the Research Site Incentive (RSI) scheme to increase value for money of the scheme and encourage the increased recruitment by General Medical Practices.
2. Streamline and target Good Clinical (Research) Practice (GCP) training in RSI practices to allow individual practices to conduct a variety of NIHR CRN portfolio studies including the more complex CTIMP studies.
3. PCS have started to initiate early engagement with the newly emerging Super GP practices (Vanguard) to understand how the CRN can best work with this new type of PO.
4. To undertake an exercise calculating the impact of PIC activity as e.g. 19% of the studies included in the PCS forecast for 16/17 are PICs. As PICs, the practices are involved in supporting the delivery of the research and this is utilising scarce resources, just not able to demonstrate direct recruitment.

HLO7:
1. Developing better links with Academics in West Midlands to be aware of pipeline of studies and ensure they are eligible for the portfolio. For example, research is funded by portfolio partners/AMRC organisations but not recruiting through NHS and no NHS ethics therefore being missed as portfolio studies.

Raising Awareness of the Study Support Service
This is a key activity going forward and is likely to be an on-going activity for some time as the new Study Support Services are rolled out and become embedded in current practice. Therefore, it is important that the services that the Study Support Service team provide are clear to stakeholders, PO’s and researchers. This will be done through a number of methods e.g. events, training, meetings, newsletters, and liaising with key stakeholders such as CTUs and RDS.
Study Support Service ‘Showcase’ Events
The Study Support Service team will be identifying various showcase events during 2016/17 where they can demonstrate CRN:WM CI Led studies that has been successfully supported by the Study Support Service across the Research Delivery Pathway to demonstrate the added value of the service and the how it has supported the Network in delivering time to target.

Improving CRSL Involvement in ECER Studies
The Early Contact and Engagement team will be ensuring that the appropriate CRSL is copied into key ECER communications between the ECER Lead, CI and research team and other participating PO’s as part of the ‘explanatory email’ process. This ensures that CRSLs are notified about studies in advance and have the option to contact the local CI or PI’s to provide advice and support to ensure our local Lead studies are a success.

Reporting ECER Studies Using EDGE
The Study Support Service team are currently trialling EDGE for ECER studies to ensure that reports can be pulled off listing the required attributes for RDMs and other stakeholders prior to key meetings, reporting and good news studies regarding delivery within Network newsletters.

HRA ‘Exemplar’ Study
Currently the HRA Approval and assess, arrange and capability processes and Study Support Services are still being embedded (CRN:WM had already provided feasibility training to their R&D Departments) but Study Support Service Team wishes to identify a HRA ‘exemplar’ study where CRN:WM and PO’s will work together to re-evaluate these new processes and try to identify any possibilities of a leaner process to improve communications with setting up and delivering portfolio studies. This is where the CNR: WM is providing practical support to PO’s to make clinical research happen and that it is delivered to time to target.
2.2. a&b. Plans to support achievement of the NIHR CRN Clinical Research Specialty Objectives in 2016/17 and 2017/18

Division 1

- Continue to hold weekly teleconferences with CRL, deputy CRL’s, RDM, Locality managers, Portfolio managers and lead cancer research nurse to ensure communication is optimised, performance is managed, opportunities are maximised and issues are identified and resolved in a timely manner.
- Continue to hold annual meeting to review annual performance, celebrate successes and discuss challenges and opportunities for the year ahead.
- Ensure each sub-speciality lead is the research lead for the Strategic Clinical Network Expert Advisory Group and for them to develop an annual research plan to meet the speciality objectives.
- Each subspecialty lead to hold an annual educational event to promote the portfolio.
- Launch an Industry collaboration to improve EOI submissions, promote referral pathways and ensure the population across the West Midlands has access to Industry studies.
- Develop distribution lists for each subspecialty to include the Chair and/or research lead for each MDT.
- Work with colleagues in Primary Care to increase collaboration.
- Each subspecialty lead to meet with Div. 1 teams annually to review performance against annual plan.
- Nationally work with other Div1 RDMs to develop the role of “Link CSG RDM” in order to lead the coordination of the sub-speciality leads and the national CSGs.
- Continue to develop the role of the cancer research locality managers. Bi-monthly locality managers’ meetings to continue which share best practice, develop patient pathways, review commercial performance, explore the portfolio, monthly site visits to gather local intelligence.
- Dedicate resource to map and communicate complex patient pathways.
- Appoint a portfolio manager to identify studies which meet the speciality objectives, horizon scanning and liaising with Sponsors and the national portfolio team to speed up the time to set up studies.
- Develop portfolio maps to reflect the local portfolio of open studies which will be distributed monthly to all cancer teams.
- Identify populations for each Provider Organisation providing cancer care, in order to provide intelligence around expected recruitment to achieve speciality objectives.
- Follow-up on the Macmillan cancer research information project to ensure Macmillan information centres across the West Midlands have access to up to date relevant information regarding clinical trials available to patients.
- Continue to Host the Macmillan Acute Oncology Nurse and collaborate on new developments around standard care for acute Oncology.
- Continue to contribute to the national Geriatric Oncology group.
- Continue to deliver an annual programme of educational events for cancer research staff.
Division 2
Cardiovascular
We continue to have CRSLs covering all 6 sub-specialties including Paul Clift (Birmingham) who is one of three national leads. Whilst CRN:WM has successfully run studies in all 6 sub-specialties, the areas of Congenital Heart disease and Pulmonary Artery Hypertension (PAH) have little Portfolio activity and there are only 7 PAH centres in the UK, none being in the West Midlands. Growth will be targeted within the Prevention sub-specialty, through acute Trusts but also importantly community Trusts and primary care. Funding for preventive services such as smoking cessation, dietary advice and exercise schemes, is from Public Health England to Councils, who we will engage with alongside GP practices including practice nurses / AHPs.

Diabetes
There are 4 CRSLs covering diabetes. The West Midlands has a diverse demographic suitable for conducting diabetes research and we aim to attract new immuno-therapy studies for recent onset Type 1 diabetes through University Hospital of Birmingham. The region is research active with early onset and gestational diabetes and we aim to build on recent successes in this area and primary care to increase research activity related to prevention of diabetes. As with cardiovascular prevention much of the services are centred on GP practices and the wider community and in this instance focus on obesity and weight loss. We have begun to attract commercial diabetes research studies to the region.

Metabolic & Endocrine
We have a good pipeline for metabolic and endocrine rare disease studies including where we are Lead CRN. We have requested the reassign of the Pathfinder study (UKCRN ID 17588) from Genetics to M&E (unconfirmed). We aim to expand this study to other rare diseases in 2016-17 and if successfully reassigned this will be a key driver for increasing M&E recruitment.

Good progress has been made with increasing the profile of laboratory research and we will continue to build on good engagement between the laboratory and various clinical colleagues.

Renal
All 8 main renal units have achieved recruitment in 2015-16 with 5 of these undertaking commercial research studies. We wish to build on this success by firstly defining which areas of the specialty will attract future commercial funding and secondly establish the scope for viability of recruitment at more renal satellite units. We remain strong in CKD research and cardiovascular disease related to CKD. There is a need to examine the scope building on the success of a recent peritoneal dialysis study and also look at further opportunities around hospitalisation related AKI.

Stroke
We have the highest recruiting Hyperacute Stroke Research Centre (HSRC) in England at UHNMs who currently recruit 24/7 supported by strategic funding from the CRN. This has helped achieve very high levels of acute stroke patients being recruitment into trials (circa 20-25%) . We wish to build on this success at other centres including University Hospital of Birmingham where there is further potential for expansion following local organisational and care pathway changes. We have a strong portfolio, including locally derived studies such as the Health Technology Assessment (HTA) funded MAPS2 study that is expected to start recruitment in early 2016-17 financial year. There is a good balance in our portfolio between hyperacute, acute, rehabilitation and prevention. There is a need to secure new leadership and growth in the south of the region with the imminent loss of Professor Cappuccio as one of our Stroke CRSLs.
Division 3
Children
Objective: 90% of relevant sites that provide children’s services to recruit into Children’s portfolio studies

The portfolio management and research delivery teams work closely together to identify studies into which children are eligible for recruitment across a range of therapeutic disciplines, and support POs with relevant clinical services to open these studies. We also actively seek to open studies in the smaller / DGH sites, and assist these Organisations with extra support from the CRN core research nurse team. This strategy has proved highly successful in 2015/16 with the portfolio being open wider across the LCRN than in previous years. The approach will be continued in 2016/17 and underpinned by the active training programme on Paediatric Communication and Consent that the Children’s nurses deliver, in order to provide the competency and confidence for all research staff to approach children and families to consent to studies. We have actively engaged with CAHMS and the Div 4 workforce, and have started to support paediatric mental health studies with a plan to expand this support to the Mental Health portfolio in 2016/17, in addition to retaining focus on the disciplines in which the West Midlands CI’s are research active. We have initiated a GCP training programme for the children’s Acorns hospices in the West Midlands, making them research ready, in the hope that a suitable portfolio study is identified but in the meantime we are also engaging with researchers in the LCRN to write a protocol suitable for delivery in the hospice setting.

Three main priorities in the West Midlands for 2016/17 are:
1. Creation of a paediatric trainee’s forum
2. To engage with Forward Thinking Birmingham as the mental health services are reconfigured, seeking opportunities to deliver portfolio research in this changing clinical services setting
3. Deliver research in the Acorns Children’s Hospices

Genetics
Objective: Recruit into multi-centre Genetics studies through the West Midlands Regional Clinical Genetic Unit/West Midlands Regional Genetics Laboratory.

The CRN: WM is recruiting to five open studies approved under the Musketeer’s Memorandum, with 306 recruits from three Trusts at Q3 in 2015/16, the second highest LCRN. We will continue to support the WM Chief Investigators and local NIHR Research Fellows to ensure that Rare Disease studies are supported under the MM. In addition Dr Larissa Kerecuk is the Rare Disease Lead at Birmingham Children’s Hospital and is developing the Rare Disease Centre which will support suitable portfolio studies. The Birmingham Clinical Genetics Unit is well established as a national centre of excellence and has developed a successful genetic test for Duchenne and Becker Muscular Dystrophy (DMD/BMD) in pregnancy, and this will be reported in 2016/17 and will translate this non-invasive prenatal diagnosis (NIPD) into clinical practice. Ensuring that the regional genetics unit is sufficiently resourced to support the changing healthcare delivery as personalised and stratified medicines become more prevalent is key to initiatives pertinent to the Musketeer’s Memorandum.

Three main priorities in the West Midlands for 2016/17 are:
1. To increase commercial studies
2. Encourage more collaborative projects between genetics and other specialties
3. Increase genetics trainee involvement in NIHR portfolio recruitment and support research training
**Haematology**

Objective: Named haematology trainee identified and involved in supporting recruitment to portfolio studies

The CRSL is actively engaged with the national initiative to engage trainees, and will deliver this initiative in the West Midlands. Although recruitment to main specialty haematology studies is lower than previously, West Midlands recruitment to co-sponsored studies is ranked 2nd/15 LCRNs nationally, representing good support to the haematological oncology portfolio. We will aim to involve this workforce in the non-malignant haematology studies in 2016/17. Specific focus in 2016/17 will be to engage with the London study teams running the Haemoglobinopathy studies in order to promote the large sickle cell population in the West Midlands. Working with the academic partners in the region, the CRSL has identified that there are good audits carried out within the NHS that should be developed into funded studies; this will be an initiative taken forward in 2016/17.

Three main priorities in the West Midlands for 2016/17 are:

1. To increase research practitioner / nurse support for the portfolio
2. To maintain recruitment to all 4 sub-specialties and to expand studies in transfusion and haemoglobinopathy
3. To identify and support region-wide trainee audits

**Reproductive Health & Childbirth (RH&C)**

Objective: Network of sites within the LCRN supporting reproductive medicine studies

The midwife champion role is well established within the LCRN and there is an active community of RH&C research delivery staff. Ongoing activities include the identification of examples of practice that positively impact upon delivery of portfolio studies, and workshop sessions run at regional research midwives forum with focus on feasibility input and HLOs. The professional / workforce development activities also underpin the network of sites and in 2016/17 the aim is to expand the induction pack for new staff, and to facilitate a programme of shadowing/mentoring to make best use of skill mix within the region. The midwife champion is also engaged with the national initiatives, including online communication to facilitate an integrated, collaborative approach to delivery of studies in the one national network, and raising the profile of research within the Nursing & Midwifery Council and Royal College of Midwives.

24/7 recruitment on delivery suite is recognised as an important factor in successful delivery of the midwifery portfolio, and will be addressed by having GCP-trained shift leaders to enable consent ‘out-of-hours’. Engagement of trainee doctors will also be a focus in order to promote GCP training and research involvement, both on the wards and by engagement with the Obs & Gynae trainee forums.

Reproductive Medicine assisted conception services are research active in the West Midlands, with leading infertility Units recruiting to portfolio studies. The Birmingham Women’s Hospital and University Hospitals of Coventry & Warwickshire are engaged with the national specialty in order to ensure that the IVF portfolio will be run in 2016/17 under a national agreed strategy, such that the planned studies do not compete for patients within each Centre.

The Tommy’s charity is to open the UK’s first national clinical research centre dedicated to early miscarriage on 1 April 2016. The National Early Miscarriage Centre will comprise a partnership of three universities: The University of Birmingham, The University of Warwick, and Imperial College London. The three sites will run specialist clinics enabling 24,000 women per year to access treatment and support and participate in research studies. In the centre’s first five years Tommy’s
commits to researching: Genetic causes including a possible connection to damaged DNA in sperm; The role of bacteria in miscarriage and early pregnancy outcomes; Predicting the risk of miscarriage by developing sophisticated computerised risk prediction models that pull together clinical data from across the UK; and Identifying the best ways to support women who have experienced miscarriage. In 2016/17 the opening of this early miscarriage centre will support increased research activity and portfolio study delivery.

Three main priorities in the West Midlands for 2016/17 are:

1. To increase 24/7 research activity through delivery suite midwife champions and O&G trainees
2. To focus on the assisted conception services and the IVF studies
3. To engage with the Tommy’s UK first early miscarriage centre opening April 2016 in Birmingham, Coventry and London.

Division 4
DeNDRoN - in order to optimise use of JDR for recruitment to dementia studies we plan on doing the following:

1. In order for researchers to use JDR effectively more volunteers need to be signed up who have a diagnosis of dementia. Currently delivery staff are using multiple systems to recruit as JDR alone is not sufficient. A JDR steering group, involving JDR champions, delivery staff and representatives from primary care will steer in-year action plans to achieve this.
2. A specialty group will be started in Q1 bringing together clinicians and researchers in the area of ageing and dementia.
3. In 2015/16 Divisional portfolio team members and workforce development lead delivered face-to-face training to improve the use of JDR by researchers (CRN delivery staff). This will be improved further in 2016/17. We will also be contributing to the coordinating centre review of training and contribute to this. We will continue to liaise with JDR researcher administrators at each site to discuss audits of effective use, in line with the service promise to volunteers.
4. When marketing the CRN to Higher Educational Institutions JDR will also be promoted as a tool to use for recruitment with the aim that we increase the number of dementia studies registered on JDR.
5. We have two flexible members of the delivery workforce managed directly by Division 4 Portfolio Manager. 2015/16 has required them to support partner organisations where staff have left and where recruitment to these posts was limited due to in-year funding. Now POs have been informed of indicative funding, it is envisaged that these members of staff will be able to support more the promotion of JDR across the region and support POs in using JDR as a recruitment tool.

The subspecialty lead roles for CAMHS and neurological disorders (MS and Infections) will be appointed to early 2016.

2015/16 has been a year of liaising with partner organisations to identify key clinicians engaged in research. 2016/17 will be a year for developing specialty groups and bringing people together to facilitate sharing of good practice for research delivery and building capacity and capability within their clinician teams to support research. These groups will also have a remit of bringing together clinicians and academic researchers so research design is informed by NHS practice and engages clinical teams right from the beginning.
RAID is the Rapid Assessment, Interface and Discharge service. This places liaison psychiatry within acute hospitals. To-date we feel this is a missed opportunity for identifying potential participants at the earliest stage possible for Division 4 studies. In 2016/17 we will work with the regional RAID team to better understand how we can recruit to mental health and dementia studies in organisations other than typical mental health trusts. RAIDPlus is an NHS England test bed for working between the ambulance service, police and mental health urgent care. This is an opportunity for us to explore how this new development can provide research opportunities for service users.

JDR is a great opportunity but a focus is required on promoting to people with dementia and their carers/family members volunteering on their behalf. Leaflets and local newspaper articles has had little impact. In 2016/17 we will utilise the newly formed JDR steering group to try and test new ways of promoting JDR and increasing volunteer registration to targeted groups. Delivery staff also need to use this effectively to provide a customer focussed service for the volunteers. Division 4 staff will monitor this and intervene where necessary, ensuring the staff have all of the knowledge and support they need.

CRSLs will have a yearly plan for achieving objectives relevant to their specialty and the regional environment. This will be overseen by the CRL and RDM. The main activity will be meeting with clinicians in partner organisations to agree ways of increasing capacity and capability of their team to support delivery of research, in partnership with their Research and Innovation Department.

CRSL/Subspecialty Leads will lead on chairing and facilitating specialty group meetings. They will also be involved in liaising with study teams to ensure West Midlands is involved in recruitment and advising the portfolio team on feasibility, care pathways and personal contacts in potential sites. All divisional leads, subspecialty leads and RDM will meet every 3 months to discuss strategic issues and action plans.

CRSLs will be performance managed by the CRL. The CRL will be performance managed by the CD. Performance report templates have been developed and agreed with the Clinical Leads.

Division 5
- We aim to further develop collaborations with Division 4 colleagues and the West Midlands Dementia Lead to explore opportunity for a joint Ageing and Dementia Specialty meeting.
- The Orthopaedic Specialty Group with lead CRSL has a wider network approach for collaboration and its remit is to identify research opportunities that can be adopted on to the portfolio for delivery in the West Midlands.
- Investment to continue to engage with and increase the number of Community Pharmacies participating in and conducting NIHR CRN portfolio studies in order to increase the access for patients into NIHR CRN portfolio studies in the Primary Care setting via community pharmacy.
- Extend the use of ‘pop ups’ to identify and screen patients across the CRN, and roll out the EMIS Enterprise initiative, which enables appropriate permissions in place, efficient remote access to GP computer systems for patient identification and data collection.
- Scope out those organisations / services with whom engagement has been low or not yet been explored with Primary Care, i.e. HEIs that might possibly contribute studies to the NIHR portfolio if encouraged and supported to do so; service providers such as ‘out of hours’.
- Continue to strengthen participation in cross boundary/speciality collaboration to identify new studies that can run in the Primary Care setting. Maximising the Primary Care potential for those studies where patients are naturally seen in the Primary Care setting.
There is regular attendance at national Primary Care Specialty Group meetings by the CRL for Primary Care, when other Primary Care CRSLS and CRLs are present, and regular email and telephone with group members.

- Regular sessions scheduled to engage with CRL/CRSLs on monthly telecon basis and various meetings to provide support and identify potential issues.
- CRSLs and CRL are involved in project work on an on-going basis.

**Division 6**

1. **DEDICATED “HYPERACUTE” RESEARCH DELIVERY SUPPORT** – supporting critical care, injuries & emergencies, anaesthesia, respiratory, hyperacute stroke, surgery

CRN: WM Division 6 currently has nearly 30% of its actively recruiting studies crossing different Specialties that include some “hyperacute” characteristic, i.e. they concern conditions that are briefly extremely serious and severe. The main Specialties these studies fall within are: Critical Care, Injuries & Emergencies, Anaesthesia, Respiratory, Surgery, but will also include (hyperacute) Stroke and possibly Cardiovascular disease. The West Midlands region has 4 major trauma units and 18 critical care units across 13 Trusts.

With an anticipated increase in Division 6 “Hyperacute” research activity across the West Midlands*, the appointment of a Lead “Hyperacute” Research Nurse should improve delivery to these studies. The aim is to promote unit engagement and participation by improving and coordinating local site identification and effective feasibility assessment that enables swift local site set-up. The post will mitigate against the current risk of inadequate “hyperacute” study/site monitoring and the resultant inability to detect and highlight failing studies early enough to direct effective resources to implement remedial actions.

[*As an example, there are 6 critical care studies, including Industry, funded and in set up across the West Midlands; and a further 6 studies in development. Of these 12 studies, 8 have a local investigator being a named co-applicant or chief investigator, and all have challenging targets for interventional studies that will require dedicated expert research nurse support to achieve recruitment to time and target.*]

2. **IMPROVING ENGAGEMENT THROUGH NETWORK SPECIALITY RESEARCH EVENTS, LINKED TO NATIONAL CLINICAL RESEARCH SPECIALTY GROUP OBJECTIVES**

Where pressure on NHS and its resources impact on engagement efforts and clinicians resist participation, research is not always viewed as an equal service for prioritisation. The aim of these events is to communicate the added value that research brings to patients and the NHS by focusing on activities that capture the value of research or being research active to patients and the NHS. Following a CPD approved format, each Specialty Group will hold network specialty research events, open to clinicians working within a disease speciality from across the West Midlands.

Presentations will be provided on working with the Clinical Research Network, and include the importance of research in the NHS & Working with our life science partners. Consultants and Chief or Principal Investigators from the Speciality also present studies that are open and recruiting, in feasibility or set up, or that have published results. Then through a series of workshop activities/talks and discussion, barriers to research and ideas of how to build research capacity within their area explored.

Working with commercial partners and participating in clinical trials, in line with the NIHR aims to “maximise the research potential of the NHS through the life sciences industry”, and where appropriate representatives from industry partners are invited to participate.

Sharing best practice amongst clinical professionals from the region, offers an opportunity to gain peer support, identifies new opportunities for growth and increases the chance for patients to participate in, and benefit from, research. By introducing the concept of extending joint working with the NIHR partners, CRN and the AHSN aims to accelerate the implementation of research outputs into NHS practice and further research opportunities.
3. SUPPORTING TRAINEE RESEARCH NETWORKS/COLLABORATIVES, LINKED TO NATIONAL CLINICAL RESEARCH SPECIALTY GROUP OBJECTIVES

Engagement of NIHR partners, including clinicians and academics, is key to the NIHR agenda. The Trainee Research Networks/ Collaboratives have been recognised nationally as a way to deliver high quality research, while at the same time building research capacity and giving trainees access to research success. Led by trainees themselves, these Networks provide a framework for peer and mentor support, but they need to have access to local support and expertise to succeed, which will be provided through Division 6 CRSLs.

Supporting Trainee Research Networks is linked to improving engagement through Network Speciality Research Events and, by CRN: WM encouraging and promoting trainee participation, research-active trainees can provide and share up to date, practical information and advice for those wanting to set up their own specialty trainee networks or want to take time out to do larger projects or higher degrees.

4. INCREASE PATIENT ACCESS TO RESEARCH STUDIES ACROSS THE BREADTH OF SURGICAL SUB-SPECIALTIES BY IDENTIFYING SURGICAL SUB-SPECIALTY LEADS (SSSLs) in each of the following 15 subspecialties: breast, cardiac, colorectal, endocrine, general, head & neck, hepatobiliary, neurosurgery, orthopaedics, plastics and hand, transplant, trauma, upper GI, urology, and vascular.

The principal aim of this role is to ensure that the CRN West Midlands has an active and successful portfolio of research, meeting the priorities and needs of the local population and contributing to the national research agenda. SSSLs will promote surgical research among colleagues and at regional meetings and educational events. Encourage colleagues to participate in research relevant to their patient populations, and advise on study placement and referral pathways for studies, including providing clinical intelligence or study feasibility assessments as required.

SSSLs will attend annual meeting to lead discussions about clinical research, agreeing priorities and implementing improvements as appropriate, interact with the CRN: WM team, e.g. Research Delivery Manager, CRSLs, Cancer Subspecialty Leads, Chief Operating Officer, Clinical Director; and interact with CRSLs to plan Cross-Network delivery of studies for rare populations of patients or for studies with complex interventions.

SSSLs will be provided with administration support and travel expenses, as they may be required to attend at least one full-day national meeting per year to network with the relevant Subspecialty Leads from other Networks.

5. INDUSTRY SPONSORED RESEARCH AND EXPERIMENTAL MEDICINE

An increased engagement with commercial research and improved delivery to target is a CRN priority and a high level target for NIHR. Dr Simon Fletcher, Industry Lead NIHR CRN Critical Care National Specialty Group has recently announced that the majority of new commercial trials within critical care will be targeting infection and aimed at developing antimicrobials and other compounds to tackle multidrug resistance. The trials will often be shared between Critical Care and Infectious disease portfolios.

To ensure CRN: WM effectively participate in these trials, centres must show that they can undertake the sort of trial proposed but also have the appropriate case mix including infective spectrum. Research capacity is also important, particularly with the potential for multiple trials examining a similar population. The CRN: WM will be working with Trusts obtain some quite detailed information on individual units’ research interests, capabilities (complexity of trial) and supporting resources and creating a database of research active clinicians/researchers who can then be matched to suitable studies.
S. 3 Contribution to National CRN Strategic priorities

HLO2:

- Following a joint strategy planning day with R&D leads from across the region a workshop will be held as part of a CI project to review studies that have not achieved HLO2, or are currently not achieving it, to lead to areas of work to address performance. This is likely to focus on specialties/Divisions that show poorest performance but involving those from specialties/Divisions that do perform better to share good practice. Continuous Improvement training will be provided to partner organisations, who have shown a keen interest in receiving this.

- As above, it was agreed with the R&D managers to undertake a continuous improvement project to review the follow-up of patients to see where and how the use of digital technology/smarter working can improve this so that nurse resources can be used more effectively for study set-up and recruitment. It was agreed to undertake a review of 4-5 studies with a number of Trusts volunteering to be part of this project.

- Through Early Contact and Engagement with Researchers the Study Support Service team will be engaging with researchers earlier in the Research Delivery Pathway and explaining all elements of the Study Support Service via a various different communication channels - newsletters, meetings, CRL/ CRSLs, local academic Sponsor, RDS etc. As parts of the Study Support Service are mandatory for eligible studies such as the Effective Study Start-Up and the National Study Delivery Assessment, researchers will be seriously advised to meet with an Early Contact Lead (despite ECER being an optional process) to discuss their study. This will ensure their study maximises its full potential to delivery to time to target.

- Strengthening the role and remit of CRSLs, particularly when sense-checking feasibilities and encouraging individual POs to access expertise when required. To increase the number of specialty groups and develop the remit of these groups with defined outputs further. Ensure communication links are in place between R&D Departments and CRSLs/specialty groups.

CRN strategic goals

- Promotion of Join Dementia Research across the region.
- Working across organisational boundaries where acute Trusts and mental health trusts support each other in recruiting to Division 4 studies.
- The engagement of care homes in research to provide residents and staff with research opportunities across all specialties.
- Working across regions. We are currently exploring setting up studies in Hereford in Division Although the Trust falls under an adjoining CRN, we are working with that Trust and partner CRN to agree a way of ensuring the population can access research due to being able to access delivery staff support in a highly rural area.
- Involvement of community pharmacists to support recruitment of studies.
- Continuous improvement projects in direct communication with service users/patients in GP practices (coffee mornings) and through Macmillan Centres.

CRN Strategies

Business Development:

- Work in partnership with Trusts to reduce the amount of commercial research undertaken that is not on the CRN portfolio through marketing the CRN and encouraging companies to engage with the CRN.
- To work in partnership with companies such as MAC Plc to facilitate access to potential participants through the NHS as PICs.
- To facilitate the sign-up of GP practices to CPRD (see continuous improvement project information).
To improve the quality of research undertaken through PI Master class training therefore improving our reputation with commercial companies.

For Trusts to work in partnership to submit site identifications in order to secure UK and West Midlands sites for commercial research.

CD and CRL link with the clinical trials programme of the AHSN. AHSN also sit on the ENRICH steering group due to care home work.

Communications:
- Local radio and press articles regarding care home research and dementia research.
- The use of patient stories to increase the number of localised specialty specific stories regarding taking part in research.
- To utilise national/international health awareness events to promote specialty research.

NHS Engagement:
- VIP awards accessible to CRN funded staff within partner organisations.
- Working with smaller, less research active Trusts to develop capacity and capability for research delivery. This includes partnering organisations to mutually support each other.
- Joint R&D Managers/CRN meetings every 3 months.

Workforce Development:
- Working with Partner Organisations to implement the Rater plan. This will be that each site will have at least 4 members of staff (research/clinical) as raters who upkeep their experience of assessments. This will hopefully secure more sites within the West Midlands for commercial companies.
- Mental health and dementia awareness training provided for all delivery staff across the west midlands as appropriate. For example for primary care staff working on mental health and dementia research, generic nurses.
- The CRN: West Midlands Research Academy aims to ensure that research staff and clinical teams supporting research can access high quality locally-provided training which is fit for purpose and meets local needs. It aims to support the provision of training which meet the three NIHR CRN priority areas for organisational and workforce development. In 2016/17 we will be progressing equity of access to Academy training across the region by fostering locality-based training collaborative and encouraging participation in workforce development (see page 3 for the proposal to deliver research-related training).
- Develop an HEI engagement strategy to encourage researchers to a) link in with the NHS more but also b) try for grants which result in portfolio status. To deliver joint presentations with the Research Design Service and supported by the ECER team.
- To improve delivery we need to try different ways of accessing the public. A social media working group has been set up. This group will look at ways we can better recruit through using social media.

Provide a coordinated and innovative approach to national research priorities - Through the CNR:WM Industry team to develop and utilise EDGE to allow for in-depth timely analysis and reporting of feasibilities; both successes and non-successes. From this collect intelligent data to inform improvements and by working with our PO’s to support greater improvements for commercial research.
NIHR CRN: WM Research Academy

Proposal for the delivery of research-related training 2015 - 2017

Prepared by Hannah Reay & Suzanne Sumara, CRN: WM Workforce Development Leads

September 2015

trainingCRNWM_generic@uhb.nhs.uk
This strategic summary outlines the purpose and functions of the CRN: West Midlands Research Academy and proposes a collaborative locality model to support regional training. The document outlines the purpose, vision and values, mission and strategic priorities for the period 2015 – 2017.

1. **Background**

Everyone involved in conducting clinical research must be suitably trained and experienced to undertake their particular role and tasks (ICH 1996). NHS organisations have a statutory duty to meet the learning needs of their research workforce (DH 2005, DH 2012). However the burden for any single organisation to provide appropriate in house or external training may be prohibitive.

Pre-existing training collaboratives (e.g. WMS CLRN Academy; BRTC) have proved to be a cost effective model to overcome the shortfall of suitably experienced trainers and meet the demand for research training from small groups of staff in diverse organisations.

Building on these previous successes, the CRN:WM Academy invites collaboration from all research active organisations within the CRN:WM geographic region. A collaborator is an organisation within this region which commits to deliver and host Academy training and contribute to a shared programme of research-related training within their locality. Collaborators may include primary, secondary and specialist NHS Trusts/Organisations, Clinical Trial Units and Universities.

2. **Purpose**

The CRN:West Midlands Research Academy aims to ensure that research staff and clinical teams supporting research can access high quality locally-provided training which is fit for purpose and meets local needs. It aims to support the provision of training which meet the three NIHR CRN priority areas for organisational and workforce development:

- Regulation and Safeguarding;
- Delivering Network Business (business delivery/study support)
- Specialty Specific/Responsive training

3. **Vision and Values**

Using a locality collaborative model (see appendix 1) the CRN:WM Academy aims to support reciprocal access to training for the research workforce across the region and provide a forum whereby collaborating organisations can share best practice, pool learning resources
and promote local initiatives in partnership with the Network. It aims to complement the activities of other research and training structures in the West Midlands.

The Academy and its collaborators believe every patient choosing to take part in research deserves to be cared for by highly trained and suitably qualified staff. Research-related training should be fit for purpose and meet local need; the delivery of training should be to a consistent standard and quality-assured to permit recognition of training between collaborating organisations. Each training programme will be overseen by a regional ‘programme lead’ and criteria for trainers will be developed to ensure they are suitably experienced to deliver sessions to a common standard.

The CRN:WM Workforce Development Strategy Group will provide strategic oversight for the Academy and its constituent locality collaboratives. Locality Collaboratives will provide the operational leadership to support the delivery of Academy training within their member organisations; each locality collaborative will have representation within the strategy group.

4. **Remit**

The CRN:WM Academy will oversee a portfolio of training which meet the needs of the West Midlands research workforce regardless of role and level of experience. This will include both national and locally-developed training programmes (current programmes and courses are listed in appendix 2).

Locality-based collaboratives will agree annual programmes of training for which they will take shared responsibility for delivering, hosting and supporting staff to attend. They will agree terms of reference (TOR) which support them to share training opportunities, participate in cross-site developments and contribute to the strategic direction for Academy training and workforce development initiatives. An example TOR is provided in Appendix 3.

The Academy’s training portfolio will be fully embedded in each partner-organisation’s local processes for research-related training. The need for new local training initiatives and/or development of new training programmes within each locality-based collaborative will be channeled through the Academy to enable network-wide working.

5. **Resources**

Academy training is free at the point of delivery to all participants from CRN:WM partner organisations and affiliated HEIs. The Academy is a ‘not for profit’ entity; it works on the premise that reciprocal core training sessions are cost neutral. Collaborators are required to contribute by providing a nominated representative for the locality collaborative (with a commitment to attend 4-6 meetings/yr and act as a primary point of contact through which
information will be disseminated to and within the organisation), suitable trainers and/or venues as per Academy course requirements.

Full day and/or specialist programmes may incur additional hosting costs (trainer/venue/catering) which will be agreed on a case by case basis. The CRN:WM will provide centralised administrative support for locality collaboratives and trainers/resources for specialist courses such as facilitator development programmes.

6. **Strategic priorities**

The strategic priorities for the CRN:WM Academy over the period 2015-2017 will include:

- Fostering relevant locality-based research training collaboratives, whereby existing groups are maintained and developed and new collaboratives formed to facilitate the delivery of the Academy’s training portfolio
- Encouraging and supporting participation in workforce development by:
  - Enabling experienced research staff to become trainers
  - Providing access to facilitator training
  - Building the training delivery workforce to enable succession planning
- Coordination of periodic region-wide workforce training needs analysis to ensure that local needs are met
- Robust evaluation of all courses and programmes as a whole to ensure that course materials are fit for purpose and trainers meet the required standards
- Fostering a working relationship with the West Midlands AHSN and Health Education West Midlands (LETB) whereby the Academy is recognised as the partner responsible for research delivery-related training in the West Midlands
Appendix 1: Locality Collaborative Model

Other proposed Collaboratives (expressions of interest):
North Midlands: UHN; SSSOTP; Burton; SSSSFT; Keele CTU
Staffs & Shropshire: RJA; SATH; RWT
South Midlands: UHCW; C&WPT; WMAS; CRN:WM SLA Trusts
<table>
<thead>
<tr>
<th>CRN:WM Academy courses currently being delivered</th>
<th>NIHR CRN Strategic Priority Area</th>
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<tbody>
<tr>
<td>Adverse Event &amp; Safety Reporting - Clinical Trial Pharmacovigilence</td>
<td>Delivering network business</td>
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<tr>
<td>Commercials Trials Workshop</td>
<td>Delivering network business</td>
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<td>Continuous Improvement Foundations</td>
<td>Delivering network business</td>
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<td>Cost Attribution Training</td>
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<td>DenDron RATER Training</td>
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<td>Feasibility Training</td>
<td>Delivering network business</td>
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<tr>
<td>Fundamentals of Clinical Research delivery for potential PIs</td>
<td>Delivering network business</td>
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<tr>
<td>Good Clinical Practice (Introduction / refresher / e-learning)</td>
<td>Regulation &amp; safeguarding</td>
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<tr>
<td>Introduction to Clinical Genetics &amp; Research – an overview</td>
<td>Specialty specific</td>
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<td>Introduction to Clinical Research</td>
<td>Delivering network business</td>
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<td>Introduction to Imaging in Clinical Research</td>
<td>Specialty specific</td>
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<tr>
<td>Introduction to IRAS and Research Management in the NHS</td>
<td>Delivering network business</td>
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<tr>
<td>Introduction to Medical Terminology for Research Staff</td>
<td>Delivering network business</td>
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<td>Introduction to Radiotherapy</td>
<td>Specialty specific</td>
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<tr>
<td>Introduction to the Valid Informed Consent Process</td>
<td>Regulation &amp; safeguarding</td>
</tr>
<tr>
<td>IRAS/CSP – seeking NHS permission for research</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Let’s Talk Trials</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Making IRAS work for your research amendments</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Monitoring - how to make it pain-free (well, almost!)</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Network responsibilities for sense checking of costings and contracts</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Paediatric Communication and Consent Training</td>
<td>Regulation &amp; safeguarding</td>
</tr>
<tr>
<td>Patient Pathway Planning</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Performing Quality Control Checks to Ensure Accurate Data Collection</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Preparing for Audit &amp; Inspection</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Site File Management &amp; Delegation of Duties</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>What did the monitors, auditors and inspectors find?</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Writing SOPs - A Workshop</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>New and courses in development</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>PI Oversight Masterclass</td>
<td>Delivering network business</td>
</tr>
<tr>
<td>Fundamentals of Clinical Research Delivery for Laboratory Staff</td>
<td>Regulation &amp; safeguarding</td>
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<tr>
<td>Fundamentals of Clinical Research Delivery for Chemotherapy Nursing Staff</td>
<td>Regulation &amp; safeguarding</td>
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<tr>
<td>Fundamentals of Clinical Research Delivery for Imaging Staff</td>
<td>Regulation &amp; safeguarding</td>
</tr>
<tr>
<td>Fundamentals of Clinical Research Delivery for Dispensing Staff</td>
<td>Regulation &amp; safeguarding</td>
</tr>
</tbody>
</table>
Appendix 3: Example of a Locality Collaborative Terms of Reference (based on the current BRTC terms of reference – for local discussion and agreement)

1. ACCESS

The Birmingham region Research Training Collaborative (BRTC) invites collaboration from all research active organisations within the Birmingham region (Birmingham / Solihull / Sandwell / Dudley / Walsall). A Collaborator is an organisation within this region which commits to deliver and host training.

The geographical region in which Collaborators are identified collectively forms the ‘delivery footprint’ for BRTC. Recipients of BRTC training will be from Collaborator organisations (within this delivery footprint) but may also attend from other partner organisations in the CRN:West Midlands region. The geographical region from which recipients of training may travel to attend BRTC courses (where similar courses are not available within their own organisation / locally) will be referred to as the ‘access footprint’ for BRTC. See Appendix I.

Research Staff within Collaborator organisations will be eligible to access BRTC events on a priority first come first served basis. Staff within the access footprint region will be eligible to access BRTC events if places are available. External applicants (from outside the access footprint) will be considered on an exceptional basis.

2. MEMBERSHIP

Each BRTC Collaborator will nominate one representative to be a BRTC “Contact” who will be a primary point of contact through which information will be disseminated to & within their organisation (not individual departments). This nominee (or their delegate) will represent the organisation within the BRTC Operational Group and agree to the terms of this group (see below). Each Collaborator will deliver and/or host BRTC training and will commit to these Terms of Reference (TOR) which will be reviewed annually hereafter.

BRTC will be managed by Strategic and Operational Working Groups with membership drawn from Collaborating Organisations. Chairs will be nominated to lead each group (see Appendix 2 for nomination process). The term of office is 2 years unless specified otherwise. The respective Chair will be responsible for managing meetings, progressing decision making and liaising with their Co-Chair to deliver the BRTC mandate. BRTC will continue to be serviced and supported by an administrative Co-ordinator within CRN:WM

Failure to:
   a) deliver training (by identifying suitable trainers within the collaborating organisation and enabling them to commit to delivering training) and/or
   b) host training (provision of a suitable room & equipment or providing equivalent resource to enable hosting in an alternative venue) and/or
   c) support staff employed within the organisation to attend appropriate BRTC training (advertising BRTC courses and study leave arrangements as applicable)

will result in continued membership of the collaboration to being reviewed by the Strategic Working Group

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1 Sample text; appendices not included in this document
3. ReMIT

The BRTC Collaborators will share ideas and best practice related to research training and education and provides a communication forum where local events can be shared.

Collaborators will:

- determine and set the overall strategic direction for BRTC-related education and research training ensuring it is responsive, up to date and complementary to that of other research training provision in the region
- network together to share training opportunities and support cross-site developments
- contribute to / host core BRTC Training sessions (minimum one per year)
- identify / contribute to / host specialist BRTC programmes
- agree to support BRTC training events (see finances & resources section)

CRN:WM WD Strategic Group
This group is responsible for the strategic oversight of all Academy activities. It will comprise 8 – 10 nominated individuals who will represent multiple stakeholders; each locality collaborative will nominate a representative to join this group. 60% member attendance is required for the meeting to be quorate. It will identify a 5 year strategy for the Academy and its constituent Locality Collaboratives. Failure to attend (or nominate a deputy) two meetings in succession will require continued membership to be agreed by the chair.

Locality Collaborative Operational Working Group
This group comprising a representative nominated from each Collaborator is responsible for day-to-day BRTC activities to ensure the high quality delivery of courses that meet the training needs of research staff within Collaborator organisations. It will propose an annual plan and support it’s delivery; it will report to the strategic group on an quarterly basis. Failure to attend (or nominate a deputy) two meetings in succession will require continued membership to be agreed by the chair.

BRTC Administrative Coordinator

The role of the BRTC Administrative Co-ordinator will include:

- the management of membership lists and contact details
- convene meetings, consult members and prepare agendas
- record meeting attendance and apologies for non-attendance; ensure quorum prepare and distribute minutes as soon as possible
- carry out actions from each meeting in liaison with the respective group chair (to include but not limited to: identifying and booking venues for meetings & training; liaising with trainers and collaborators; advertising and managing the course booking process; preparation of course materials and feedback summaries; preparation of reports)

4. FINANCES

BRTC training is free at the point of delivery to all participants from organisations within the BRTC access footprint. BRTC is a “not for profit” organisation; it works on the premise that reciprocal core training sessions (usually 2hr sessions) are cost neutral. Collaborators are
required to contribute by providing suitable trainers, venues and or refreshments as per BRTC course requirements.

A necessary additional contribution is made by the CRN:West Midlands. In their capacity of enabling the delivery of NIHR portfolio research which includes the appropriate training and development of the research workforce, they provide trainers, administrative support for BRTC and resources for specialist courses such as NIHR GCP training.

Full day / specialist programmes may incur additional hosting costs (trainer/venue/catering) which will be agreed on a case by case basis. Where additional costs are incurred by Collaborators, there may be a charge of up to £50.00 made to those who book a place and then do not attend/cancel their place or send a deputy in their place. Any external applicants accessing BRTC events (excluding NIHR GCP) may incur the following charges (on a course basis agreed in advance by the strategic group):

<table>
<thead>
<tr>
<th>Duration of Training Session</th>
<th>Cost to External Applicants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Day Training Session</td>
<td>£50</td>
</tr>
<tr>
<td>Half Day Training Session</td>
<td>£25</td>
</tr>
<tr>
<td>Cancellation Standard Charge Rate</td>
<td>£50</td>
</tr>
</tbody>
</table>

Applicants within the access footprint will take priority over external applicants. All fees will be payable to BRTC and used for hosting events. Any surplus at the end of each year will be reviewed by the Strategic Group and retained for future training events as applicable or used to reduce future contributions from collaborators.

**BRTC Cancellation Policy**

If delegates fail to attend a BRTC training session and have not cancelled their place or provided us with a valid reason for late cancellation their organisation will be notified. Failure to attend 2 BRTC courses in succession may lead to the exclusion of this delegate on future courses in discussion with their Collaborator’s BRTC Contact.

**5. MEETINGS**

The Strategic Group will meet at least twice per year. More frequent meetings will be required initially to drive the reconfiguration of the Academy and formulate the next five year strategy. Failure to attend (or nominate a deputy) two meetings in succession will require continued Collaborator membership to be agreed by the chair.

The Operational Group will meet at least quarterly with course specific working groups convening on a more frequent basis as required (these may include working group representatives or nominated deputies according to topic of interest). Failure to attend (or nominate a deputy) two Operational Group meetings in succession will require continued Collaborator membership to be agreed by the chair.
Appendix D

Section 4 – Other local innovations and initiatives

General initiatives
We will be providing access to continuous improvement training for R&D managers in April 2016. R&D managers have expressed an interest in this in order to locally manage HLOs, 70 day benchmark and productivity. This will help embed a culture of improvement and innovation across the region.

Generic nurse workforce - following a review of the teams and outputs, a CRN staff principles paper has been approved which outlines the purpose of these team and introduces a process for ensuring ABF/salary costs are identified and re-invested into research, (page 7).

Three posts are currently being recruited to for Band 4 Project Assistant roles (Graduate level roles) to be part of the CRN generic workforce and provide support to POs for study set-up, data management, study co-ordination for failing studies etc. to contribute to the achievement of HLO’s wherever possible. These are fixed term posts and a Master’s degree is offered with the aim of growing future research staff that are non-clinical. The CRN are also exploring Band 1 Apprentice roles to provide administrative support for back-office functions.

In 2015/16 a region-wide R&D Managers Forum was set up. These will continue to facilitate region-wide working, sharing best practice as well as jointly agreeing strategic issues and action plans to further develop the West Midlands research activity, delivery and performance.

With CRN intervention the number of CCG GP practices signed up to CPRD rose from 20% to over 90% in the North of the region. As a continuous improvement project this is now being rolled out to other CCG areas.

A problem with Principal Investigator oversight of research delivery led to a green belt continuous improvement project. The outcome was that PI Master class training was provided for cascade within Partner Organisations. To date 4 out of 29 Trusts have rolled this out with 44 people being trained. In 2016/17 this will continue to be rolled out where the remaining 25 Trusts have expressed their commitment to doing so.

The Laboratory Lead is working with a partner organisation on a continuous improvement project to identify ways of increasing capacity through removing wasteful processes and data collection. The aim of this is to increase the time available to support research.

The increased of sign-up to Join Dementia Research for those with a diagnosis of dementia will be a continuous improvement project for 2016/17.

The portfolio management group have undertaken two continuous improvement events in order to provide a standardised and streamlined process for maximising the number of WM sites for portfolio research and for managing performance. In 2016/17 these will be measured and monitored to embed the process as well as continually improve. The portfolio management meet as a group on a monthly basis.

Each RDM has been assigned to a small number of organisations as Link RDMs in order to communicate effectively and maintain relationships. Each Trust has also been assigned a lead CRN finance accountant and in 2016/17 this will be extended to CRLs.
Patient and Public Involvement and Engagement in Research (PPIE)
- Following the recent pilot and adaption of the course focus, the PPIE team will roll out the Building Research Partnerships (BRP) Programme locally, working with NIHR partners in the West Midlands to deliver the programme. The Young Person’s Steering Group (YPSG) will also continue to review the course content with a view to delivering the course to young people.
- Implement initiatives to explore the Patient Experience; develop the Patient Stories pack further, gather case studies in conjunction with the Communications Lead and analyse the results of the Patient Experience Questionnaire to put together an action plan based on findings. Continue to work with the YPSG on these initiatives for use with children and young people.
- After undertaking a scoping exercise the Patient Research Ambassador (PRA) Initiative will be taken forward by working with partner organisations and supporting them in the implementation and development of the PRA role, with YPSG input.

Business Intelligence (BI) Activities
- The plan to implement EDGE as the Local Portfolio Management System for the network will continue into 16/17 and all partner organisations interested in using EDGE as their LPMS are scheduled to go live by July 2016.
- BI training will focus on Google Hub, EDGE and ODP using a community of locally trained Champions.
- The BI team will seek to improve overall data-quality through their input into the Portfolio Management Group using the Portfolio Managers’ local knowledge to validate data and provide missing data. This will result in more robust analysis and metrics to assist RDMs in identifying where action is needed to improve overall performance.

Communications
- A second survey of staff attitudes will be carried out; the aim is to track staff culture within the Network and identify areas for engagement/improvement, and to measure the success of initiatives taken in 2015/16 as a result of staff feedback. Further staff engagement initiatives will be developed based on the results.
- VIP (Values in Practice) Awards - this new staff recognition scheme will be run on a monthly basis throughout the year, with staff invited to nominate colleagues who they view as having gone ‘above and beyond’ to implement the Network values in their day to day work. The aim is to recognise, reward and share best practice, and publicise good work. This is one of the outputs resulting from last year’s survey.
- Marketing materials - resources to promote the work of the Network will be produced, including a generic brochure featuring the range of activity carried out, success stories and services offered, with an additional version specifically targeted to promote the Network to Industry.
- Raising the profile of the Network by increasing local media coverage; working more closely with our partner organisations to identify patient stories and other good news, and targeting national campaign weeks and creating press releases for local print and broadcast media. Increased use of social media (including within the YPSG meetings) and the Network website will also contribute to this initiative.
Workforce Development

- In collaboration with Lead nurses, support the roll-out of NMC revalidation across our registered workforce
- Implement an online induction module for LCRN staff
- Embed continuous improvement in workforce development coordination and administration functions
- Develop explicit routes for career progression and development of LCRN staff with a particular focus on non-patient facing roles, patient facing roles delivered by non-registered staff and primary care staff. Explore the implementation of Apprenticeships within the Business Delivery Services team.
- Work with partner organisations to support leadership and development of CRN funded staff
- Develop an annual audit programme for the Host employed research nurses in order to provide PO with reassurances around compliance to GCP
- Continue to develop links with Primary Care to ensure nurse contracts are held within NHS organisations (Host) and have access to support, training and education from the Host

Primary Care

Integrating the Primary Care Study Support Service and Primary Care Delivery Team - A new model of delivering Primary Care studies in line with HRA requirements is under consideration. The aim is to better integrate the existing primary Care study support service and delivery teams to work to a more unified model. The two teams currently work together to deliver their individual elements of the feasibility and assurance functions. The proposal to integrate the teams more closely intends to develop a unified model that will encompass the ‘assess, arrange and confirm’ functions that are required by HRA and offer a more seamless service to researchers, sponsors and Primary Care partner organisations.

Pathology (Laboratory Medicine):

1. Raise awareness of pathology contributions to research:
   a. Projects to identify pathology activity in clinical trials including using EDGE and open study visualisation tools
   b. Internal CRN engagement with team members such as the Study Support Team (eg. ECER), Portfolio Managers Team and Workforce Development

2. Develop pathology engagement with the CRN: WM – build on local work to promote engagement with the CRN: WM from pathology staff and continuing the novel and successful initiatives to identify new PIs, develop researchers and potential CIs from these professional groups. Examples include initiating the West Midlands Laboratory Medicine Research Group and working with the Association of Clinical Biochemistry and Laboratory Medicine, the IBMS Training and Development group and the West Midlands Consultant Microbiologist Group.

3. Develop strategies for improving pathology services for research in the West Midlands – build on local initiatives to promote improved service provision from pathology departments such as the delivery of training (e.g. Shipping of Dangerous Goods and Fundamentals of Clinical Research Delivery for Laboratory Staff) and the strategically funded Northern Pathology Research Delivery Alliance and Coventry and Warwickshire Pathology Services research contacts exercise and the development of the CRN: WM Research Advisory group for Pathology In research Delivery (RAPID).

4. Act as a West Midlands exemplar to support national NIHR CRN pathology engagement in research:
a. National Professional Body Engagement – Supporting the National CRN Lead for Support Services in the engagement of professional associations and organisations that represent the pathology workforce in research

b. Development of National Pathology Research Workforce Survey – Keele University Benchmarking Service

c. Develop local support in the West Midlands for the CM-Path initiative to develop academic histopathology research which is funded by the NCRI

d. Support the roll out of the National NIHR CRN training package: Fundamentals of Clinical Research Delivery for Laboratory Staff

Pharmacy

Collaborative working among pharmacy clinical trials staff: continue to develop collaborative working among pharmacy clinical trials staff working in secondary care through quarterly regional meetings and the development of the CRN: WM pharmacy Google site

EDGE: explore potential for pharmacy clinical trials staff in secondary care to use EDGE to support pharmacy processes

GCP training: address workforce development needs of pharmacy staff involved in the delivery of clinical trials by developing training including consolidation workshops to complement NIHR GCP for Investigational Medicinal Products management e-learning and research awareness training materials

HRA pharmacy technical assurance: support pharmacy staff involved in the delivery of clinical trials with the implementation of the HRA pharmacy technical assurance process

CRN: WM Pharmacy data collection tool: continue to collect regional data re pharmacy approval and set-up times for secondary care and contribute to the national HRA pharmacy readiness project

Community pharmacy and primary care: continue to increase community pharmacy engagement with CRN: WM and identify studies suitable for community pharmacy involvement; continue to explore potential to work with local researchers to develop studies suitable for community pharmacy involvement; explore potential involvement of pharmacists working in GP surgeries to become involved in research

Radiology

Develop further Radiology engagement within the CRN: WM-support, promote and build on local engagement initiatives with radiology stakeholders, to include the AHPRN’s, Consultant radiographers group, WM Medical Physics group, Research radiographers group and West Midlands imaging Dept. Managers group. Identify and signpost potential radiology and radiography CI’s and PI’s. Continue to engage with CRN: WM core team.

HRA Radiology technical assurance-inform, update and support radiology clinical trials staff throughout the implementation of the HRA radiology assurance process.

Society of Radiographers-continue to sit on the Radiographers Professional research board, to represent the interests of the NIHR and to cascade national initiatives, to key stakeholders. Build on the recent SOR Research survey.
EDGE: explore potential for radiology clinical trials staff to use EDGE to support diagnostic and therapeutic radiology research processes.

GCP training-work in conjunction with the CRN: WM workforce development team to design tailored GCP training for radiology clinical trials staff

Study Support Service
Study Support Service Staff ‘Refresher’ Training
The Study Support Service team will be providing refresher training to PO and Network staff covering the RM&G proportionate and pragmatic training which was first released over four years ago. In addition to this, staff will also receive refresher training on cost attribution which will be delivered by the Network’s AcoRD Specialists. This training will ensure that those being trained regardless of area of speciality has the appropriate knowledge to protect our patients by ensuring any feasibility conducted are as robust and safe as possible within their local areas.

Getting Academic Sponsors/ Clinical Trials Units (CTU) ready for Assessing and Arranging Capacity (AAC)
The Study Support Service team will be working closely with Academic sponsors and CTU staff to ensure they understand the focus of the new UK policy framework on Health and Social Care and the HRA’s expectation of sponsors communicating study information to research teams. Since the Network provides a Performance Management role we are keen to ensure communication regarding studies is clear, effective and timely which will support NIHR objectives. To support these aims, we will be hosting a number of meetings between the LCRN, HRA and Sponsor representatives throughout 2016/17 until the new HRA processes have been confidently understood and embedded.

Study Support Service Collaboration with Local Academic Sponsors and CTUs
A key challenge during 16/17 is to ensure our local academic Sponsors and CTU’s are engaged with the Study Support Service team as early as possible, particularly with the decommissioning of CSP on the horizon. The Team would like to work with our Academics/ CTU staff to ensure any relevant SOPs they follow encourage closer collaboration. This will only be achieved by the team demonstrating the effectiveness (added value) of the Study Support Service and how it can benefit them in delivering effective studies. This will be achieved via the current CRN Academic/ CTU group that has been set up to support these organisations through HRA changes.

HRA - Getting Trusts Ready for AAC
The Study Support Service team will be redefining training to PO’s, Local Sponsors and CTU’s regarding new HRA studies by updating our existing training modules to deliver a one stop shop on IRAS developments due to changes because of HRA, CSP ceasing and CRN Study Support Service. The emphasis at these sessions will be to ensure key stakeholders support early discussions regarding studies before IRAS submissions. This will help all objectives because it will give the CRN time to project manage studies they are lead or participating to ensure recruitment is effective as possible and identify any missed opportunities.
The Study Support Service Team will be developing small working groups with PO’s in identifying appropriate HRA related SOPs to support consistent Set Up and Delivery within the region. This will help researchers who may work across PO’s. These SOPs will be piloted via CRN:WM SLA Team who provide research management and support for numerous different types of organisations so not to burden PO’s with early implementation.
HRA - Getting Primary Care ready for AAC
The Primary Care Study Support Service Team have been putting arrangements in place to ensure preparedness for HRA since the phased implementation. The Primary Care element (Cohort 2) of HRA Approval implementation went live in August 2015; however the number of Primary Care studies coming through nationally has been low, therefore the opportunity for the CRN:WM: Primary Team SSS team to work on HRA studies and to establish a clear new process has to date been limited. In order to address this, the West Midlands HRA Change Lead has been requested by the Primary Care Research Support Manager to provide training to the team based on experience of Primary Care HRA applications in other LCRNs; this will enable the team to start to get a feel of how the new process will actually work. This will facilitate the development of any new procedures required to support Primary Care research within the West Midlands.

HRA - Integrating the Primary Care Study Support Service and Delivery Team
To develop a new model of delivering Primary Care studies in line with HRA requirements. The aim is to better integrate the Primary Care Study Support Service team who will focus on assess, arrange and confirm with the Delivery Team. Currently they work together to deliver their individual elements of the feasibility and assurance functions but this new integration will develop a unified model to offer a more seamless service to researchers, Sponsors and Primary and Community care sectors.

HRA - Getting Hospices, Care Homes and other Community providers delivering research
To establish a process to support new engagement with private, charity and voluntary NHS service providers who are supporting portfolio research. This will be an iterative process that will be developed on a ‘case by case’ approach. Portfolio studies destined to take place in the hospice and care home settings will be triaged between the Palliative Care support and the Primary Care Study Support Service Team and signposted to the appropriate speciality/organisation to receive the necessary support required to get the study underway eg feasibility, training, or providing nursing/data management support.

Study Support Service - EDGE - Trust and the Network utilising whilst supporting with AAC
The EDGE Study Support Service working group (made up of CRN:WM and PO’s staff) will implement the core AAC data collection fields within the EDGE system. In addition with new attributes it will ensure that the data collected supports the requirements of both the CRN and PO’s. Additionally the working group will investigate ways the CRN:WM can utilise EDGE that will enhance its business processes, such as the use of EDGE Workflows and the creation of a user manual.

HRA Amendments and Information Governance Processes
CRN:WM is in a fortunate position where one of the Networks Study Support Service Managers’ is on the DH ‘Champions for Research’ Group. It ensures that any new areas of work/information gets properly disseminated to PO’s but also CRN:WM activities are aligned. For 2016/17 the Manager will be supporting the HRA Amendments Stakeholder and Information Governance Group so any changes needed from that the Network can be implemented.
Principles of prioritising CRN: WM research staff support to Partner Organisations

1. Introduction

It should be recognised that, while the Clinical Research Network (CRN) and the Partner Organisations (POs) have a common goal in delivery of the NIHR portfolio, there are inevitably some differences in focus. Having a shared understanding of the focus or priorities for each respective organisation is essential for effective working relationships. This document is provided as a basis for the dialogue needed between the CRN and Partner Organisations.

– Guiding principles for NHS Trusts and Any Other Providers (AOPs)

Partner Organisations each aim to deliver a portfolio of studies to meet the needs of their patient demographics, the relevant patient care pathways, and the interests of their investigators. Feasibility assessments and setting of site targets aim to maximise research activity, and to maximise the associated funding to both deliver the research activity and to embed this as a core activity for the Organisation.

– Guiding principles for the CRN WM

The CRN aims to ensure that a balanced portfolio is delivered across the West Midlands region, such that NIHR income to the LCRN is maximised for provision to the Partner Organisations to deliver the studies. The focus for the CRN is achievement of the NIHR’s High Level Objectives (HLOs) and specialty objectives, against which the success of the LCRN is measured nationally.

– Benefits of a mixed model to POs and the CRN WM

The CRN WM operates a mixed model, with provision of direct funding to Partner Organisations and also the opportunity to provide additional clinical research support staff on an ‘as-needs’ basis. Requests for research staff support for defined studies or defined time periods will generally be considered against a set of criteria (see below) and will in general have the remit of helping a PO to set up a study in a timely and robust way, to focus on achieving the HLOs (namely increasing total recruitment, first patient recruited within 30 days, and achieving the site recruitment target) i.e. to push timescales for swifter study delivery and achieving of HLOs. The corollary of this is that once the HLOs have been met, the CRN staff would plan to provide any study-specific training to departmental research or
clinical staff for the on-going follow-up activities, releasing the CRN staff to set up the next study or support another Partner Organisation. It is important therefore that expectations are clear at the outset, and there is the expectation that two-way discussions are held at key milestones e.g. if a study is extended or alternatively planned to close early when national or international targets are met etc.

2. **Principles for providing CRN staff support to POs**

1. **Task force for service support core nursing / midwifery activities:**
   - Screening databases, clinic attendance records, ward admissions to identify eligible participants
   - Taking or facilitating consent
   - Maintaining the investigator site file
   - Promoting research and engaging with clinical staff
   - Linking with all relevant departments e.g. pharmacy, labs, radiology
   - Helping to overcome barriers to recruitment
   - Liaison with Trust/site lead staff and R&D
   - First point of contact for research participants
   - Capacity building – Delivery of clinical studies in accordance to protocol. This will be agreed prior to commencement with the CRN: WM staff/midwife line manager or CRN: WM Lead Research Staffs.
   - In exceptional circumstances, after discussion with CRN:WM staff line manager, support for feasibility and set up of clinical trials prior to delivery of trial specific activity

2. **Delivering to the Industry mandate**

3. **Prioritising West Midlands CI-led studies**

4. **Focus on new study set up, pushing timelines and planning screening activities**

5. **HLO attainment**

6. **Addressing specialty measures defined in the annual plan**
   - e.g. national specialty mandate; local high priority area / study; development of new research initiative;

7. **Peaks & troughs of workload**
   - e.g. extra support for busy research clinics; covering vacancies to maintain research activity; providing critical leave and sickness cover

8. **Value for money**
   - recognising that all resources are limited, CRN staff support to POs will be considered against a set of criteria to help determine workload allocation within the CRN:WM clinical research staff team (see later section)
9. **Training of Trust staff**
   - Supporting research naïve PIs and study teams
   - Provision of GCP training with specialty focus via CRN WM Academy, or study-specific training
   - Sharing of best practice for studies opening at other sites across the LCRN

10. **Funding**
   - The principle that no organisation should receive double-funding for studies has been agreed by the Partnership Group
   - Where nursing and midwives have been involved in the recruitment of commercial studies and which attract income, the WTE input will be assessed on a monthly basis and Trusts will be invoiced accordingly. Alternatively the PO and CRN may agree for funding to be re-invested to support non-commercial studies.
   - For staff supporting non-commercial studies, which attract ABF units, an agreement must be reached and reviewed at 6 months between the CRN and PO as to reimbursement for WTE or alternatively for funding to be reinvested to support other research studies.

3. **Criteria to determine site and/or study support workload allocation within the CRN WM research staff teams**
   - Interventional (ABF x14) over observational (ABF x3) to maximise income for the LCRN
   - Lead CRN study (i.e. Chief Investigator in the West Midlands)
   - New studies and sites opening to help ensure that HLO5 is achieved (i.e. FPFV <30 days)
   - Studies not yet at target over those where site target has been achieved
   - Studies with competitive recruitment (i.e. likely to recruit ahead of time and close early, and therefore need maximal early support)
   - Studies closing to ensure that HLO2 is achieved at each site (i.e. RTT)
   - Commercial contract studies (to deliver for the Life Sciences Industry)
   - Assistance with non-consenting studies / cluster randomised trials / ‘rare’ studies etc. to ensure delivery of a balanced NIHR portfolio within the LCRN
   - Studies by main specialty over co-supported specialties, to ensure that NIHR national specialty measures are achieved (e.g. one of the Haematology specialty measures requires each LCRN to recruit to each of the four sub-specialties; Dementia research is a national priority etc.).

4. **Expectation from Trust/site for CRN research staff working in a PO**
   - To arrange and organise letters of Access
   - Proportionate Trust / departmental induction
   - Access to appropriate on-site mandatory or study-specific training
   - ID badge and access to appropriate research/clinical areas
   - IT logon incl. emails, ordering patient notes, screening databases, EDC systems
• Suitable work station
• Agreement on appropriate allocation of study-specific duties for the CRN:WM staff
• Agreement on expected duration of study support
• Engagement with site intelligence and target setting
• Access to administration and data management support for studies as and when available at partner organisations.
• Access to MDT and relevant clinical teams to ensure that the assigned clinical research staff is incorporated in patient care and provided access to medical notes/clinics and databases
• Engagement with any discussions in terms of study extension or early closure
• Direct recovery of commercial income for the CRN:WM for tasks carried out by CRN:WM staffs/midwives
• Car parking provision
• If a Trust policy states that those working within the organisation must wear a Trust approved uniform, the cost, and timely provision, of the uniform to the CRN: WM member of staff will be met by the R+D department
• CRN: WM staffs/midwives will be line managed by CRN: WM Lead Research Staffs or CRN: WM RDM managers. CRN: WM Lead Research Staff/RDM managers will work closely with Trust Lead Staffs/R+D Managers to ensure safe, effective practice.

If a cause for concern is identified or an incident occurs involving a CRN: WM staff we will expect timely communication between the members of staff’s line manager and the partner organisation to enable appropriate actions to be taken.

5. **Partner Organisations Expectations from CRN: WM**
   1. CRN: WM will provide access to NIHR training, as provided through the CRN: WM training academy, for our staff/midwives, as appropriate, and support to ensure the safety of patients is of paramount importance.
   2. CRN: WM will work with Sponsors/R+D Departments/PI’s to ensure trial specific training is provided before the commencement of delivery of research to maintain quality of care and robust scientific data
   3. CRN: WM will discuss and agree with Partner Organisations trial specific activities that staff will support prior to commencement including treatments, follow up visits and specific research related activities.