



NTW CLRN Operational Plan 2008 – 9
“Securing the baseline and building a platform”

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1 Executive summary

1.1 *The scope of this plan*

This Operational Plan is submitted to UKCRN by CLRN senior management on behalf of the Board of Northumberland, Tyne and Wear Comprehensive Research Network (NTW CLRN). In this document and the Outline use of Resources spreadsheet, we have set out how we intend to deliver the UKCRN agenda within NTW. Our long-term vision is to establish NTW as a destination of choice for studies seeking to recruit NHS patients into NIHR Portfolio studies. We see stable, incremental progression as the key to realising this vision.

The Operational Plan is (by requirement) detailed, implementation-focussed and short-term but we present it as being consistent with a long term investment for strategic development and major change.

1.2 *Immediate imperatives*

The recurrent themes in this 2008-9 Operational Plan are *securing the baseline* and *building a platform*. There is a substantial amount of high quality clinical research within NTW CLRN but there is also much that needs to be done to enhance recruitment to studies and expand capacity.

This plan for our first full year of operation presents our strategy for managing a potentially difficult transitional period. We are effecting a large amount of change quickly and with imperfect information and systems. ‘Doing no harm’ is a priority and, through judicious use of the funding streams available, we will provide a stable infrastructure for research currently under way.

We will also work to improve that infrastructure through working with stakeholders to improve systems and by providing investment and expertise in strategically important areas.

We have prioritised the following *goals for the year* covered by this plan.

- Define the NTW portfolio of NIHR studies and ensure that accrual is reported
- Secure the baseline clinical research infrastructure and capacity
- Build processes for research management and delivery capable of sustaining growth in activity
- Invest effort and resource in priority areas, which have credible strength or potential
- Create an effective local network of research managers in partner organisations and partner networks

1.3 *Work programmes (WPs)*

To achieve these goals we have established the following seven work programmes. These WPs and the resource attached to each are described below. We also set out for each WP



what resource is required, how we will evaluate the outcomes of our interventions and how success is to be defined.

WP1 – Portfolio management

Everything we do is tested against the mantra of ‘how will this help us increase accrual to NIHR portfolio studies?’ There are two components to the work programme specifically addressing management of the NTW contribution to the NIHR portfolio.

Firstly, we need to identify all eligible (non-TRN) portfolio studies, within our Member Organisations and facilitate their adoption onto the NIHR portfolio (if the CI is local). Having identified studies led (or hosted) within NTW CLRN we are establishing mechanisms to ensure that accrual is reported accurately. The Clinical Director, Professor Tim Goodship is leading this part of the WP.

Secondly, we are working with active and potential PIs to encourage recruitment within NTW to established NIHR portfolio studies. This requires that we act as both advocates and facilitators for research, in particular in those areas such as Secondary and Primary Care where there is such potential for capacity to be increased. Two of our other work programmes specifically address this need. The Specialty Group WP led by Steve Robson will interact closely with colleagues in Secondary Care (facilitated by Richard Walker the Secondary Care representative on the Executive) and the Primary Care WP led by Scott Wilkes has the specific remit of accrual within Primary Care.

WP2 – Consultant sessions

In order to secure the baseline of research activity and to effect long-term cultural change by embedding research time in the job-plans of consultant clinicians, NTW CLRN has acted quickly to award 64.5 consultant PAs to 106 consultant physicians and surgeons. The process and proposed performance management of this initiative is described. The Clinical Director, Professor Tim Goodship had led on this WP and our approach has been used by UKCRN as an exemplar in this area.

WP3 – Resource deployment

We present, in this plan and in the attached Outline use of Resources” spreadsheet, a funding model that we believe provides both the stability necessary in the short-term and the basis for long-term growth of activity. It is our explicit intention to move to an activity based funding model. For this we need to improve our insights into activity levels and develop models of funding on this basis. This will be done over the next year in consultation with our Member Organisations and partner Networks.

WP4 – Specialty Groups (SpGs)

In order that we might invest effectively in areas of strength and/or strategic importance, and to avoid spreading available effort and resource too thinly, 15 SpGs have been established. These are in addition to existing partner Networks. For the period of this plan investment of CLRN funding has been almost exclusively confined to these areas. Leadership on SpGs is provided by Professor Steve Robson, the Tertiary Care rep on the Executive.

WP5 – Developing Primary Care research capacity

Although there are pockets of activity, research capacity and activity within Primary Care in NTW is limited. NTW CLRN will invest £80k per year over the next 2 years to secure



active participation of ten practices in reviewing adopted studies and recruiting to at least two new studies each year. These “Local Enhanced Services” (LES) will also contribute to the work of the Specialty Groups. Dr Scott Wilkes, the Primary Care rep on the Executive leads this WP.

WP6 – Network building for Network delivery

The delivery of very significant operational change within the clinical research environment requires highly developed and effective networks of people. The CLRN Senior Manager, Dr Séamus O’Neill is leading on a work programme of engagement with key stakeholders. The work thus far has concentrated on ensuring buy-in from Member Organisation R&D offices, local Topic Networks and the PCRN.

WP7 – Removing administrative barriers

Led by Dr Roger Paxton, the Executive Lead for RM&G and Ms Justine Smith, the Lead RM&G Manager within the core team, this work programme is central to the detailed and complex change required to improve processes around study set-up and delivery. The approaches to the task is set out in section 8 of this plan and the resources assigned to the management of organisational change to facilitate RM&G are detailed in the OuR spreadsheet under “Management”. Management costs are high in this first year (at $\approx 16\%$) however we expect this figure to fall in subsequent years as admin processes are rationalised and front-line activities are prioritised.

These programmes are at different stages of implementation but we believe all are aligned to delivery of the major UKCRN goals.

1.4 Next targets

It is clear that the WPs established do not cover all the areas required. We have, for example much work to do on: our interaction with Pharma; our communications strategy; our roll out of CSP (in common with the rest of the CRN); and on our PPI agenda. These areas will be dealt with in detail in future versions of this Operational Plan as we work up and implement strategies for delivery. We offer the WPs we *have* established as evidence that the NTW CLRN is serious about, and capable of, implementing major change in the local clinical research environment.



2 NTW CLRN overview

2.1 Key Characteristics of the NTW CLRN

The NTW CLRN covers a population of 1.4 million with dense urban conurbations in Newcastle-Gateshead and Sunderland surrounded by sparsely populated rural areas to the North and West with a natural divide of the North and South areas by the river Tyne. Health care Member Organisations comprise a large acute tertiary teaching hospital (NUTH FT), and four secondary care Trusts (Gateshead, Northumbria, South Tyneside, Sunderland) each with 1 - 3 hospitals providing secondary care as well as a Mental Health and Disability Trust and Ambulance Trust. There are six PCTs – three North and three South of Tyne, one of which is a Teaching PCT. For the purposes of research management, the North and South of Tyne PCTs act as two geographically organised consortia (NoT and SoT).

The majority of the population is White British, but there are sizeable Asian communities within the main cities. Standards of health are poor; the North East has the worst life expectancy of all the nine Government Office English regions. It is also the most deprived region in England according to the 2004 Index of Deprivation. However, there are also pockets of considerable affluence, for example in Northumberland.

2.2 Key Interactions within the NTW CLRN

In addition to the interactions with the Trusts described above, who are our Member Organisations, we will be prioritising work in building links in the following five areas:

TRNs represented within the NTW CLRN include the Northern Cancer Research Network, the North East Stroke Research Network, the North East Dementias and Neurodegenerative Diseases Research Network, the North East Mental Health Research Hub, the North East and Cumbria Diabetes Research Network and the Northern and Yorkshire Primary Care Research Network.

There are **three research active HEIs**, Newcastle University, the University of Sunderland and the University of Northumbria. Newcastle has a large medical school and a very active biomedical research programme. Sunderland and Northumbria also have active research programmes in primary care and allied specialties.

There are several nationally and locally important **units which support clinical research**. NIHR Newcastle University and NUTH FT host a “Specialist” Biomedical Research Centre in Ageing. There is an NIHR Clinical Research Facility based at the Royal Victoria Infirmary and a Wellcome funded Clinical Ageing Research Unit at Newcastle General Hospital. There is an Experimental Medicine Cancer Network Centre based at the Northern Institute for Cancer Research.

The **Centre for Translational Research in Public Health** which starts on 1st June and is funded to the tune of £5.2m by UKCRC (administered through ESRC), is a major and highly competitive centre involving the five North East Universities and the SHA. Prof Martin White at Newcastle University is the Director of the Centre and lead for our Public Health SpG. Professor Charlotte Clarke who is the NTW Board representative for The University of Northumbria is one of four co-directors.



The **NIHR North East Research Design Service (NERDS)**, a consortium of the Universities of Newcastle and Durham, with input from two NHS Trusts is based the Institute for Health and Society at Newcastle University. The Service provides support to local investigators in preparing research proposals for submission to peer-reviewed competition (especially NIHR programmes and UKCRC partners).

2.3 Summary SWOT analysis

The table below summarises key, high-level strengths, weaknesses, opportunities and threats we perceive to be material to our capacity for contributing to the CCRN's overall aims and objectives.

The SWOT analysis will be reviewed and developed as part of ongoing CLRN management. It will be available as a standing item to the Board and the Executive and will be tied closely to the development of a risk register. No distinction is made, at this stage, between issues which are considered to be primarily of significance within NTW and those that are generic.

<p>Strengths</p> <p>S1 Five TRNs in the area covered by CLRN</p> <p>S2 Strong, highly active Medical School with close ties to the major Tertiary Trust</p> <p>S3 Recognised excellence in healthcare provision within Member Organisations</p> <p>S4 Strong support for Network development from stakeholders on the Board</p>	<p>Weaknesses</p> <p>W1 Some LRNs (and CLRN) still in the formative stages of development</p> <p>W2 Lack of strong research culture outside major teaching hospitals</p> <p>W3 Lack of established fora for specialties outside of Topics</p> <p>W4 Inconsistencies in data management and governance processes between Member Organisations</p>
<p>Opportunities</p> <p>O1 CLRN initiative is, itself, a major opportunity for cultural change within the NHS</p> <p>O2 SpG offer major opportunity to address coherence in non-topic specialties</p> <p>O3 Primary Care initiatives can provide a base for a new model of engagement with Primary Care</p> <p>O4 Identification of areas for significant rapid expansion</p>	<p>Threats</p> <p>T1 Tokenistic engagement by Member Organisations could be damaging to the Network <i>and</i> research base</p> <p>T2 Five year horizon for CLRNs and two year funding horizons for some streams creates a sense of impermanence.</p> <p>T3 Responsiveness of key systems (eg time taken to recruit staff) is a concern. These systems are both an object of the change to be implemented and a barrier to establishing the necessary infrastructure.</p>



3 Proposed organisational structure and management arrangements

3.1 The Core Team

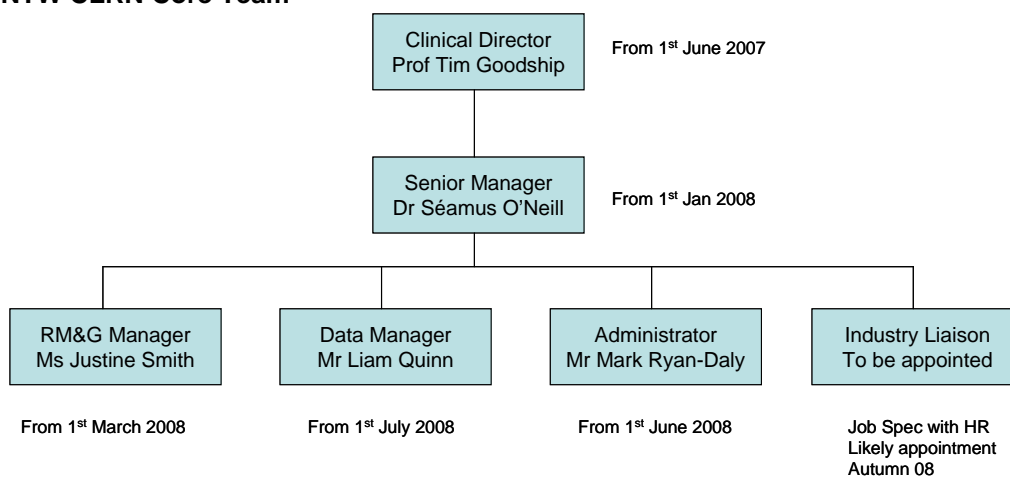
With the exception of the recently released post of Industry Manager, the core team are now appointed (figure 1, below). The mix of personalities, skills and experience is promising and a formal programme of development and team building is planned to ensure success in the formative stages of team development.

Tim Goodship is the Clinical Director: Tim is a renal physician who has participated in single and multi-centre clinical trials. He has managed research teams in both the delivery and management of research and was Chairman of the Joint (NHS/University) Research Executive in Newcastle for five years.

Séamus O'Neill is the Senior Manager: Séamus has a background in clinical research and general management; He has a PhD in Genetics, is a qualified Clinical Scientist and has an MBA. Before joining the CLRN he managed research facilities and processes at the University/NHS interface for 10 years.

Figure 1

NTW CLRN Core Team



The NTW CLRN office is in the Biosciences Centre at the Centre for Life right next to the mainline train station in Newcastle.

Contact Biosciences Centre,
Centre for Life,
Times Square,
Newcastle, NE1 3BZ.
0191 241 8842
seamus.o'neill@nuth.nhs.uk



Justine Smith is the Lead RM&G Manager: Justine has worked in the clinical research arena for over 14 years, with roles ranging from laboratory analysis, patient recruitment and follow-up, to management of single and multi-centre international CTIMP trials. Justine has worked in the NHS and in academia and brings to the team extensive experience of collaboration between public sector research bodies and industry. Justine joined us in March 2008 from a trials office at the University of Oxford.



Liam Quinn is the Data and IT Manager: Liam worked for a number of years with the Cancer Research Network locally and since leaving has very successfully provided management information for senior management within the NTW Mental Health Trust.

Mark Ryan-Daly is the CLRN Administrator: Mark has a strong track record of organising information, people and events within the Primary Care arena. He is also a trustee of the local branch of MIND and has a real interest in, and commitment to, PPI.

Our ***Industry Manager*** will be appointed later in the year. The job description is with HR at NUTH for agreement and processing. Discussions are ongoing as to whether this person would be most effectively deployed in the main CLRN office or in the NUTH R&D office (with the CLRN retaining operational and line management responsibilities).

There is a strong argument for deploying the Industry manager at the site of the bulk of the Industry activity. He or she will also work with our other Member Organisations to build capacity and expertise for Pharma activity.

3.2 The CLRN Office

NTW CLRN is hosted by the Newcastle upon Tyne Hospitals NHS FT (NUTH), but the CLRN office is at the International Centre for Life (ICfL). The ICfL is conveniently located next to a metro station and the mainline railway station. This has practical advantages for the core team as they host meetings or travel to Leeds and London and also for the wider CLRN team distributed across the Member Organisations who regularly visit the CLRN office.

3.3 CLRN Board

The NTW CLRN Board is chaired by Sir George Alberti and includes representation from all the major healthcare and health research organisations in the area. A full list of the members and the constituencies they represent are provided in appendix 1

The Board meet three times *per annum* and has met three times under its current Chair; in November 07, January 08 and May 08. Minutes are widely circulated and will soon be publicly available through our website. Attendance lists are kept for each meeting and a policy of nominating deputies has meant that representation for Member Organisations has remained strong.

Notable Board-level achievements thus far in progressing the CLRN agenda have included:

- Establishing an allocation model in advance of robust activity assessments.
- Agreeing the scope of the priority areas and establishing that these would be prioritised in terms of funding and investment.
- Ensuring that hosting and membership agreements were signed promptly
- Gaining buy-in to the principles of administrative cooperation and coordinated change.
- Creating a forum wherein the TRNs, the CLRN, the PCRN, the Member Organisations and the other Member Organisations can set the strategic direction for Clinical Research and fund accordingly.



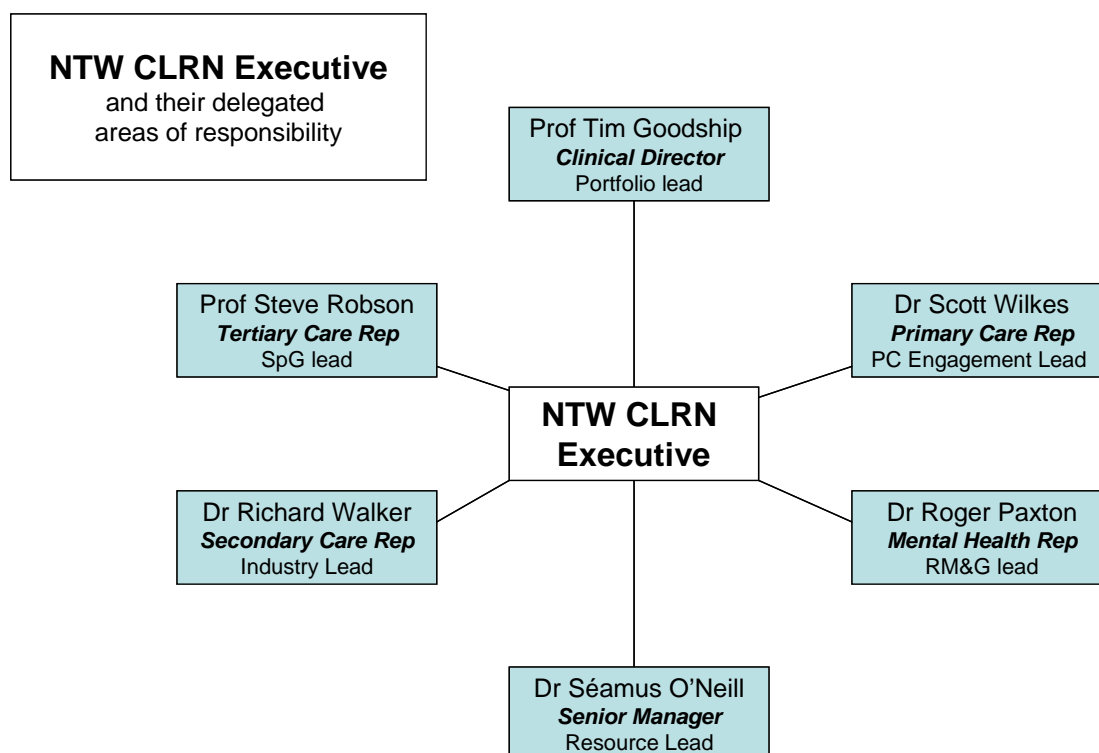
Significant challenges remain, notably overseeing the move to a transparent and agreed model by which funding follows demonstrable activity.

Negotiations with the Member Organisations, the TRNs and the PCRN are formally conducted at Board level. Similarly, accountability for funding and performance management resides with the Board. However, there is an obvious need for engagement with the key stakeholders outside the Board meetings and the Clinical Director and Senior Manager have, on behalf of the Board, established a rolling programme of quarterly meetings with the Topic and PCRN Leads (Clinical Directors and Managers of the LRNs) and the Member Organisations (R&D Directors and R&D Managers). The significant deliverable of the first round of these meetings has been a relatively painless prioritisation of funding both for Key Service Support and within the Member Organisation allocations.

3.4 CLRN Executive

The operation of the Executive has been one of the very encouraging elements of the early stages of CLRN development. The group is small (see figure 2 below), with the minimum level of representation required, but has already proven to be highly effective.

Figure 2



Key work programmes already established by the Executive are:

- Consultant sessions: £800k *per annum* of consultant sessions awarded in open competition
- Primary Care initiative: Local Enhanced Services (LES) being established for Primary Care, (again as an open competition) in collaboration with NYREN



through membership of the Primary Care Working Group led by the CLRN. This WP is described in depth in appendix 2

- Specialty Group leadership: Established and coordinated by the Executive. Three local leads to apply for national Chairs of SpGs.

The Executive meet every three weeks. Attendance is very good, we cancel meetings if two people are not able to attend and we have only had to cancel or move two meetings this far. A full list of Board and Executive meeting dates is provided in appendix 1.

The Executive reports to the Board through the Clinical Director and the priorities set by the Board to a large extent determine the work of the Executive. However, the Executive are all active researchers in their own right and there is real leadership evident in identifying and addressing barriers to clinical research locally. One issue highlighted in other CLRNs has been overtly territorial or acquisitive behaviour at Board and Executive level. This has not been a significant problem for NTW. There was an explicit acceptance early in the process that the members of the Executive were representing their broader constituencies rather than their own discipline or Trust. Any conflicts of interest that have arisen within the NTW CLRN Executive have been managed well. No member of the Executive has felt inclined to comment on the unfairness of any decision.

3.5 Links with our Host Organisation

The senior management of the CLRN work closely with NUTH as both a host organisation and as our most active member organisation. There are potential tensions which could arise should the CLRN initiative be perceived to be unduly favouring any part in the agreement. NUTH as both a member and the host organisation are aware of the need for transparency.

To this end, Brian Stevens, Deputy Chief Executive and Wendy Jones, Assistant Director of Finance at NUTH are our regular contacts for host issues. The R&D Office led by Professor Gary Ford is our point of contact on issues relating to NUTH as a member organisation. It is a separation of duties we requested at the outset and it works well.

One area in which we appreciate that we must be seen to be acting transparently is in the management and distribution of funds. This is a host function and we have access to dedicated staff in the NUTH finance team with responsibility for research funding. These staff manage our accounts. We are building an effective working relationship with them and the reporting for the annual report this year (though simple) went smoothly. They have also been advising us on budgeting, account structure, sign-off responsibility, the distribution of funding and the dangers in moving money close to year end.

The finance team operate independently from the R&D Office which represents NUTH as a Member Organisation. We are therefore satisfied that no undue influence is being brought to bear. NUTH has been a very supportive host.

3.6 Communications strategy

The communications strategy for the NTW CLRN is being developed as an extension of the Network Building WP. The approaches being adopted to communication are relevant to both delivery and management issues and at this early stage of establishing the CLRN,



while we are having success in building the team required for network delivery, we have a substantial work to do in raising the profile of the initiative within the broader NHS context.

Communication strategies aimed at the audiences necessary for Network delivery are developing rapidly. We have contact lists and/or regular meetings in place for

- Member Organisation R&D (and RM&G) managers
- Specialty Group leads
- LRN Clinical Directors and Managers
- Clinicians with CLRN sessional support

In addition, a standing item on the Executive agenda requires individual members to report on their recent activity in promoting awareness of the CLRN. This serves to reinforce the importance of widely disseminating information about the CLRN. Such awareness-raising is pivotal as we seek to increase capacity, particularly in areas which are not currently research active but have potential for expansion.

The Executive and Core team have presented to a wide range of audiences on the role of the CLRN, these include staff meetings, directorate clinical meetings and LRN annual meetings.. Another initiative to raise awareness and provide resources through which communication can be facilitated is the production of local guides. Building on the information provided by UKCRN

Short guides are planned which will provide a simple overview with a local flavour on

- The CLRN initiative – purposes, staff, organizational structure
- The new funding streams and how they affect CIs and PIs
- The importance of accrual and how to record it as a CI or PI
- How the CLRN can help at each stage of the project life-cycle

These guides will also provide the basis of a FAQ section on the Network website. On a similar theme we are planning a quarterly newsletter to promote understanding of the CLRN remit and activity. Establishing the guides, the newsletter and the website as both channels of communication and repositories of information is a priority for this year.

3.7 Process for ongoing review and development

The processes by which we will review and develop the activity of the NTW CLRN are still formative. They will, however, be based on the principles underpinning this plan. The key goals will be established (both short to medium term, and strategic) and work programmes will be put in place to deliver these goals. For example, the relationship between the work programmes and the goals for 2008-9 as defined in the Executive Summary are set out below.

2008-9 goal	Principal associated WPs	Key measures of success	Key dependencies and risks
Define the portfolio and report accrual	WP1, WP3	All eligible studies identified, adopted and accruing by end of 2008	To be worked up as part of WP



Secure baseline infrastructure	WP2, WP3, WP4	SpG and Board feedback on resource deployment is positive	documentation
Build research mgt processes	WP3, WP6, WP7	Barriers to study development and processing identified and plans to address worked up by end of 2008	
Priority areas	WP2, WP4, WP5	> 95% of funding to priority areas, > 85% of funding in 2009-10 to be for delivery SpG requirements identified in 2008 and addressed in 2009-10 budgets	
Build the network	WP6, WP7	Full engagement of Member Organisations and LRNs with the programme of CLRN work. Deliverables include timely and appropriate contribution to CLRN reports and appropriate management of devolved resource.	

Key to WPs:

WP1 – Portfolio management

WP2 – Consultant sessions

WP3 – Resource deployment

WP4 – Specialty Groups (SpGs)

WP5 – Developing Primary Care research capacity

WP6 – Network building for Network delivery

WP7 – Removing administrative barriers

Appropriate risk management strategies will be put in place in due course at both WP and Network level



4 Network-building for Network-delivery

4.1 *Building on established networks*

We believe that the long-term success of the NTW CLRN is dependant on building a collegiate culture. The structures we put in place and the way we manage our interactions with stakeholders must be supportive of our aims.

The interaction with stakeholders happens at a variety of levels. The Board and Executive level interactions has been dealt with previously but the operational implementation of the Network requires broad facilitation and intensive management of information flow. Two communities key to this are the Trust-based R&D (and RM&G) managers and the LRN managers.

We established that the leadership and information flows within and between these groups were not adequate for the range of interventions expected of us (for example the coordination of research infrastructure funding or the implementation of passports and CSP).

We have, therefore, obtained agreement that the CLRN will lead groups as required to implement specific initiatives. Rather than set up new fora we sought, where possible, to use existing meetings.

4.2 *Bringing Member Organisation R&D managers into the CLRN team*

We have had some success already. The Regional R&D and RM&G managers meetings had been very ‘support and information’ orientated rather than ‘action’ or ‘change’ focussed. They now function as a means of addressing key issues within the CLRN agenda. This has been made explicit and the proportion of these staff funded by CLRN has been one driver that has been important in making this happen. The other impetus for the interaction is the need to appropriately devolve and account for funding. We have called these our “First Tuesday Meetings”. The continuity afforded by the timetabling helps us to reinforce the CLRN focus in the region and the meetings are fast becoming our primary mechanism for securing and retaining buy-in from the Member Organisations at the operational level. Details of the meetings timetabled for this year are provided in appendix 3

4.3 *Securing LRN manager input to strategy and delivery*

Prior to the CLRN being established, LRN Managers locally had a quarterly meeting of interested parties across the North East. Again, this was reported by many who attended to be ineffective and we were asked to host a regular CLRN-limited meeting so that LRN managers could have access to first hand information (on funding in particular) and also contribute to discussions on strategy and priorities. The major success from these meetings has been in the focussed use of CLRN funding to address capacity issues experienced by the established networks.

This intervention is detailed in this plan through, in particular, the use of our Key Service Support streams which was heavily informed by a consultation exercise carried out by the Senior Manager, involving LRN Managers, Member Organisation R&D Managers and Specialty Group Leads. Following production of the an agreed assessment of need, the



CLRN and LRNs brokered agreements with each Member Organisation on how their allocation might be used most effectively to overcome barriers.

The meetings with the Member Organisation R&D Managers are chaired by the CLRN Senior Manager and the CLRN RM&G Manager attends. The business of these meetings is to ensure that at an operational level, the Member Organisations' activities are aligned with the overall aims of the CLRN. Issues to be addressed include: Reporting requirements such as Schedule 1 submission to inform the operational plan

4.4 Including the Specialty Groups

We see SpG-led increase in recruitment (mainly to established trials) as being pivotal in increasing volume. Embedding recruitment to NIHR portfolio trials as a key element of NHS activity is dependant on a establishing a broader research culture and base than currently exists. NHS consultants (particularly those in secondary care) are our main target in this.

Through the SpGs and their leadership we will create a broadly based network of contacts. Through these contacts (and under the leadership of our Executive reps for Secondary Care and SpGs) we will identify and promote NIHR trials to which NTW consultants within the SpGs can recruit.



5 Overview of existing UKCRN portfolio research activity in Member Organisations

5.1 An initial assessment

An estimate of potential NIHR portfolio activity was undertaken in November 2007 using the databases of the Member Organisations R&D departments. A detailed breakdown of the number of active studies reported by Member Organisations (by TRN or funder) is provided in appendix 4. A summary to indicate our first insight into the relative scale of the activity in the organisations is provided below.

Northumberland, Tyne and Wear NHS Trust	25 studies (3 commercial)
Northumbria Health Care Foundation Trust	32 studies (0 commercial)
Newcastle upon Tyne Hospitals NHS Foundation Trust	433 studies (170 commercial)
South Tyneside NHS Foundation Trust	22 studies (0 commercial)
Gateshead Health Foundation Trust	39 studies (0 commercial)
City Hospitals Sunderland NHS Foundation Trust	123 studies (29 commercial)
Primary Care Trusts	37 studies (6 commercial)

The insight afforded by this assessment was limited and there were numerous barriers in terms of availability of information. However the exercise did allow the CLRN Board to establish a (percentage based) funding algorithm which recognised both the need for baseline coverage in all Member Organisations and also to allow highly active organisations to cope with the costs associated with volume and service support.

5.2 Refining our insights

While these early data sets provided some useful initial insights, high quality information was difficult to obtain. Since November 2007 we have been examining, in greater detail, the databases of the Member Organisations. We have initially concentrated on the Newcastle upon Tyne Hospitals NHS Foundation Member Organisation as the most active member organisation, but are now extending the analysis to other Member Organisations. We have identified a range of studies in the following categories

- a. Studies listed on the NIHR portfolio as potential but where there is an incomplete dataset. The Clinical Director, Professor Tim Goodship, has personally contacted the CI/PI for each study and helped in the completion of the proforma.
- b. Studies listed on the NIHR portfolio where there is a local PI but no evidence of accrual. Again the Clinical Director, Professor Tim Goodship, has personally contacted the PI for each study to identify who the CI and accrual contacts for the study are. He has then contacted the CI to ask him/her to complete the proforma.
- c. Studies listed on the database of Member Organisations which look to fulfil the criteria for adoption onto the portfolio. Again, the Clinical Director, Professor Tim



Goodship, has personally contacted the CI/PI for each study and helped in the completion of the proforma.

Currently the monthly accrual data shows there to be 11 active CCRN studies with recruitment taking place in the NTW network. 10 studies have in May 2008 been adopted onto the portfolio and accrual figures back to April 2007 will be submitted in the next few weeks. A complete dataset for a further six studies has been submitted and adoption of these onto the portfolio is expected (appendix 5). This iterative process will continue, with responsibility for it being taken over by Liam Quinn, our recently appointed information manager. However, the initial accrual figures would suggest that the initial estimate of potential portfolio activity was optimistic.



6 Local research priority areas

6.1 Our priority areas

Priority areas (outwith the five Topic Networks and PCRN presence in the CLRN) and the local clinical leads for NTW CLRN are listed below.

Priority areas (Non-TRN)	Clinical Lead
Cardiovascular	Professor Bernard Keavney
Clinical Genetics	Professor John Burn
Ear, nose and throat	Professor Janet Wilson
Musculoskeletal	Professor John Isaacs
Ophthalmology	Mr Scott Fraser
Oral & Dental	Professor Jimmy Steele
Hepatology	Professor David Jones
Renal	Professor Neil Sheerin
Reproductive Health and Childbirth	Professor Steve Robson
Respiratory	Professor Paul Corris
Dermatology	Professor Nick Reynolds
Paediatrics	Professor Allan Colver
Age and Ageing	Professor John O'Brien
Health Services Research	Dr Robbie Foy
Public Health Research	Professor Greg Rubin Professor Charlotte Clark
Priority areas (TRNs)	Clinical Lead
MHRN	Professor Nicol Ferrier
Diabetes (DRN)	Professor Mark Walker
DeNDRoN	Professor John O'Brien
SRN	Professor Chris Gray
Primary Care (PCRN)	Professor Greg Rubin

The factors that were taken into to account in determining these areas include

- a. Programmes that were scored as “strong” or “moderate” in the annual R&D reports of the Member Organisations. These are listed in appendix 6.
- b. Areas of strength identified in the 2008 RAE submissions from the three HEIs



6.2 Strategic funding based on priority areas

Of the resource allocated by the Executive (£750k in Consultant Sessions and £415k in Key Service Support) only one session (£11.5k) was awarded outwith the Priority areas identified above. This session was awarded to a team of Urological Surgeons who are very active in portfolio trials, but do not map to a local SpG or TRN.

Within the devolved allocations, all the resource deployed was credibly reported as being used in support of priority areas. An in-depth analysis of the use of funding by TRN and SpG will be conducted by the Senior Manager and will form part of our annual report for 2008-9.



7 Portfolio management

Participation in CCRN portfolio studies in NTW is likely to follow three patterns

- a. Single or multi centre studies initiated and led by a local CI. Our current data suggest that the number of these will be relatively small (<100). Through both our member organizations and HEIs we are attempting to increase the number of applications for NIHR funding at the same time as maintaining our research council and national charity funding.
- b. Participation in multi-centre studies initiated and led by a CI from another site. We will screen the NIHR portfolio to identify studies that are open to other centres and directly contact clinicians (especially those with CLRN funded sessions) to solicit interest in participation
- c. Participation in commercial studies. Through our local Specialty Groups we will identify clinicians who are willing to participate in commercial studies.

We will encourage clinicians working in all disciplines (including those which are not currently identified as priorities) to participate in b and c particularly.

We will carefully assess the NHS support costs that will be necessary to support such activity. It is possible that growth in activity in such areas may in the future result in them being adopted as local priority areas. The executive will monitor which portfolio studies are supported locally and what the resource implications are for Service Support.

Our assessment of the evidence from Member Organisation registers of studies (see appendix 5) would suggest that there will be relatively few studies in NTW which will lie outside of our TRNs and SpGs. Current initiatives to enhance recruitment include:

- The award of 64.5 clinician sessions,
- The funding of at least 10 GP practices to act as “beacon” sites for CLRN activity in primary care,
- The pump-priming of Member Organisations with a low research activity,
- Giving the Specialty Groups a remit for expanding recruitment to extant NIHR studies



8 CLRN research management

Figure 3 – the CLRN RM&G Team, a devolved model for funding and management with clear accountability



8.1 RM&G Team

Through the work programme being developed on RM&G streamlining, NTW CLRN is implementing a devolved model for NIHR Portfolio RM&G. We are building on the high level of expertise currently available across the Member organisations. Specific RM&G staff will be employed in the larger and more active Member Organisations, with R&D staff providing this function elsewhere.

The funding allocated to Member Organisations in the OuR to support the RM&G role will pick up part of the salaries for current R&D and RM&G staff and allow additional posts to be created to increase turnaround times and build capacity. The CLRN RM&G



Team is illustrated in figure 3 above. The remaining portion of salaries will be met by the Member Organisation to cover non-portfolio work, although this workload is expected to fall over time.

Where there are gaps in staffing, due to staff turnover or insufficient resources to support new staff, the CLRN funded team will be deployed across organisational boundaries. The arrangements with Member Organisations in relation to the deployment of CLRN resource in this area has been explicit about the need for staff to operate across organisations when required.

However, for the purpose of continuity, staff will have a main Organisation within which they will operate and for our largest Trust, NUTH we will deploy a full-time RM&G manager who will be based at NUTH.

RM&G Leads have been selected to represent Member Organisations currently undertaking NIHR portfolio work (8 currently) and form part of a team who meet on a regular basis to discuss all areas of RM&G. Other RM&G staff will be invited as appropriate. Discussions will be against a standard agenda covering all NIHR/UKCRN initiatives, implementation plans and standardised areas of governance and quality assurance.

This team-orientated approach will be the basis of Network-building and also a real strength in delivery as it grows into a support network. It will be led by the Lead RM&G Manager and will have the capacity and remit to provide cover for absence (annual leave, sick leave and staff movements), both in the short and medium term. To allow cross-cover, team members will be paired/grouped to allow sharing of experience, being selected on type of research undertaken in their Trust.

The period of this Operational Plan will see the RM&G role become more prominent and stable within Member Organisations. Member Organisation staffing levels will initially grow, but we will look in the medium term for synergies and opportunities for rationalising provision as activity patterns become clearer. Within the CLRN-funded roles, we will also seek to provide opportunities for professional development to ensure retention of experienced and high quality staff.

This structure proposed will ensure consistent access to RM&G expertise across the CLRN for portfolio work - to undertake governance checks and achieve sign off against set targets, with continued monitoring of studies, maintaining a high quality standard.

8.2 CSP

The RM&G team are committed to the introduction of NIHR CSP and are convinced of its benefits. The move to allow cover for governance checks across different Member Organisations in the CLRN will be introduced over the next 6 months as the team develops and experience is shared, resulting in a shared goal and enabling trust.



The flow of work will be as outlined in flowcharts included as appendix 7, with governance checks split as follows:

NTW CLRN Proposed Delegation of Responsibilities

MULTI-CLRN STUDIES	SINGLE-CLRN STUDIES	SINGLE CENTRE STUDIES
GLOBAL CHECKS		
CSP Unit	Lead RM&G	Lead RM&G
LOCAL GLOBAL CHECKS/CLRN LEVEL CHECKS		
Lead RM&G/Trust	Lead RM&G/Trust	Lead RM&G/Trust
LOCAL/MEMBER ORGANISATION LEVEL CHECKS		
Trust	Trust	Trust

This table introduces a new level of checks titled 'Local Global'. These checks map to the green shaded areas on CSP ReDa. The concept is consistent with a Trust-based member of the CLRN RM&G Team taking on responsibility for certain governance checks, on an NIHR study, where they do not employ the Chief or Principal Investigator i.e. on behalf of another Trust. This will help to share the load of trials across the CLRN, ensuring a more consistent turnaround of allocated studies. There still remains the need for local checks and sign off at each participating Trust, as finance and contracting will remain at each Trust. However, the move will reduce the burden of more standardised checks on high volume Member Organisations, and, in time, the number of checks that can be done by another Member Organisation will increase, as experience and trust are gained.

This will be a flexible and efficient model under which CSP can be successfully implemented and produce consistent improvements in turnaround times.



8.3 Implementation of CSP

The Lead RM&G Manager has attended a training session on CSP ReDa and hosted a CSP specific meeting of the RM&G team to discuss local implementation details. The next steps are as follows:

Task	Relationship and dependencies					
UKCRN provide Superuser license						
Superuser familiarised with CSP ReDa using eggs set by CSPU						
UKCRN provide licenses for RM&G team						
External training arranged for RM&G team						
RM&G team to practise on system using e.g.s examples*						
Active version of CSP ReDa released						
Study allocated to NTW CLRN						
RM&G staff undertake first set of governance checks*						
Full implementation across CLRN**						

Key

* One-to-one on-site support provided by Superuser

** Once all RM&G staff undertaken governance checks using CSP

CSP implementation will be monitored through the regular RM&G team meetings, with regular reports run by Lead RM&G Manager to monitor turnaround times and reasons for clocks stopping. Weekly reviews of study status will be run, with more regular reviews during the implementation stage and for the next six months.

Once all staff are familiar with the system, targets for turnaround will be set and regularly reviewed at team and individual and team level.

8.4 Honorary Research Contracts and Passports

Current procedures and processes for issuing honorary contracts and letters of access vary widely across the CLRN. The CLRN team are acting as brokers in the change management process required to rationalise the provision of HRCs and Passports. As a first step, the Member Organisations, who have signed up to this implementation must come to a common understanding of the requirements and establish accepted, efficient processes across the Member Organisations and HEIs. Each Member Organisation has been asked to provide details of people locally who will be involved in these discussions – the key people who will take this concept forwards into practise.

There is agreement that such a process needs to be implemented and that current arrangements are not working, but some areas are understood differently or felt to be too open to interpretation. The areas on which the CLRN will broker agreement, under guidance from UKCRN, are as follows:

- CRB checks – frequency, who needs them, level required, time since carried out



- Who needs an HRC (detailed decision on all common types of research taking place in CLRN)
- Who should be issuing them/signing them off and monitoring them
- Indemnity
- How will supervision be checked
- What training will be provided or induction required.
- Standardised checks done once only in Occupational Health
- Conflict with current guidance and internal SOPs

As well as taking guidance from national sources, we are building on best practice locally. The North of Tyne PCT has a procedure in place to implement this process, which it uses as the basis of the consortium agreement between partners in the Primary care RM&G Consortium. This approach is being circulated for review and possible refinement for use across all Member Organisations.

Until the scheme is fully operational, the barriers and delays in issuing contracts is being monitored.

8.5 Standardising Procedures

A review of processes by which governance checks are undertaken in each Member Organisation is also under way, along with the collection of documents used by Member Organisation R&D when managing studies throughout their life cycle. This information will allow an overview of current practice and an assessment of how consistent the approach is across the CLRN.

Once this information is collated it will provide a starting point for the discussions within the RM&G team meetings around standardisation. These discussions will focus on what processes need to change and what the appropriate quality assessments. This standardisation will enable cross-cover to a high quality across the CLRN. Other areas for consideration within the work programme are:

- Audit
- Risk Assessment
- SOPs
- Training requirements

8.6 Advice Service

The CLRN will work alongside the new North East Research Design Service (NERDS) to provide advice and support to researchers through the grant application process and beyond as contracted. Investigators with a research idea likely to be a portfolio study will be referred to NERDs.

Advice to local CIs and PIs is already available across the CLRN, with R&D staff taking on the role of supporting investigators as they progress through the approvals process and systems.



Member Organisations provide help in different ways, including one-to-one coaching sessions, leaflets, presentations and documents on intranet. It is planned to pull together all study set-up documents and merge these into one set of guidelines and teaching aids. This set of documents will be accessible online for all local researchers, with details of the site advertised in newsletters and mailings.

The Trust-based RM&G Team will be the first point of contact for the majority of researchers, with queries being passed to the Lead RM&G Manager for resolution where outside their remit or experience. The Lead RM&G Manager takes queries and provides advice to the Trust-based RM&G team and topic specific network staff, with this role expanding as more individuals become aware of role,

The Lead RM&G Manager will gain advice or resolve queries by contacting relevant bodies, e.g. MHRA, NRES and UKCRN as necessary, passing queries to experts within the CLRN where available e.g. for disease or population specific advice.

This network of advisors will utilise the expertise available within the CLRN efficiently, with coordination of response to queries through the CLRN office.

8.7 Feasibility and Delivery

Feasibility and delivery are closely linked. A thorough feasibility assessment will result in a realistic target and therefore deliver to target.

Details of patient populations in the region are available via the PCTs and Member Organisations, with local experience providing additional data for assessment of local recruitment potential. As assessments are done, details will be collected and accrual monitored against original estimates for informing future studies and targets.

A pilot project will be run in selected Member Organisations to collect data on patients screened but not entered into studies, to look for trends e.g. too tight eligibility criteria, no patients with specific condition. These will then be fed back to the CI and local researchers to enable studies to be designed for the local population, as well as to Member Organisations to improve feasibility estimates. Should this pilot be successful and provide useful feedback, then this will rolled out across the CLRN.

Monthly reports of accrual into portfolio studies will be uploaded onto the portfolio database, with CLRN staff pulling off regular reports to monitor recruitment rates locally. Where slow or no recruitment is noted, CLRN staff or the RM&G lead for the site will contact the researchers to find any reasons for low accrual, offering advice and tackling any barriers faced.

8.8 Monitoring and Issue Resolution

All initiatives and implemented systems/processes relating to the life cycle of portfolio studies will be monitored to ensure compliance and effectiveness. Discussion of metrics will take place within the various regular CLRN meetings, with any issues arising being dealt with by working groups, with solutions found and put into practise, or escalated upwards for consideration by the board or to UKCRN.

The Membership Agreements in place as the basis of the CLRN provide a framework for the majority of local issues to be resolved where non-compliance with CLRN processes is found.



9 CLRN infrastructure and management

As described in sections 4 and 8, the NTW CLRN management model is a devolved one. There is significant expertise within Member Organisations and, with stability as a priority, the CLRN will secure the component of this expertise necessary to deliver high quality management of NIHR portfolio activity. Similarly in terms of securing staff and non-staff support for research (as service support or clinical time) the approach taken for the first year of CLRN operation is to devolve funding to Member Organisations and work with them to ensure that the funding is used in line with CLRN strategic imperatives.

A distinction is made below between funding allocated to Member Organisations through initiatives managed by the CLRN Executive and those managed locally by the Member Organisation's R&D offices.

9.1 Using funding for Network Delivery

The NTW CLRN has clear objectives in its use of funding in support of the work programmes established and being developed. We will seek to ensure that:

- Adequate funding follows portfolio activity
- Funding is used primarily to support priority areas
- Areas identified as strategically important for growth in the CLRN will be pump-primed
- In the initial rounds of funding, the maintenance of the existing research base is prioritised
- All funding streams are managed transparently and fairly
- Funding is used in line with UKCRN guidance
- Collaboration with neighbouring CLRNs allows cross-CLRN funding where necessary

The "Outline use of Resources" (OuR) submitted with this document (appendix 9) details a coordinated plan applying funding across Member Organisations in line with expected need and priorities for growth. It also addresses the requirement that we establish an effective infrastructure of research personnel and service support to allow recruitment into portfolio studies.

£2.96m of activity and *per capita* funding is available for Network delivery in the financial year 2008-9. £1.64m of this is to be devolved to Member Organisations, to be used for locally prioritise sessions, service support and RM&G functions associated with NIHR portfolio activity. Approximately £1.16m of funding has been committed to two major Executive led initiatives, (Clinician Sessions and Key Service Support) and the use of these funds is described below. The remaining funds (approximately 5% of the total) are being reserved as a contingency.



9.2 Executive managed funding

9.2.1 Clinician sessional support

It was decided that, in order to secure the baseline of activity and to make a clear statement about the role of research in clinical practice, significant resource would be put into the support of clinician sessions. Furthermore, in order ensure consistency and alignment with strategy, the process of awarding the sessions was managed through the Executive. Appendix 8 gives the detail on the strategy, process and outcomes. In short, 64.5 sessions were awarded to 106 clinicians, an investment of £741,750 *per annum*. The stated expectation, supported by the Board, is that Member Organisations will incorporate these sessions into job plans as protected research time. Recipients of the sessions have been informed that the sessions have been awarded for two years but there will be annual, accrual based performance management of this investment.

9.2.2 Key Service Support (KSS)

The essential remit for use of the KSS funding was in that it should be used to address barriers that were recognised to be hindering local participation in NIHR portfolio studies. The approach taken in NTW was to canvas opinion on what these barriers are and determine the costs to address them. These costed proposals were then assessed by the Executive and commitments agreed against a budget of £415k. This is higher than the indicative allocation of £371k for KSS identified in the UKCRN funding letter but the Executive believed that the security afforded by the two year commitment was important in securing engagement of key services, many of whom were struggling to remain engaged with research..

The priorities for use of KSS funds were determined through discussions with TRN Clinical Leads and managers and through consultation with the SpG leads. Recurrent themes highlighted include pharmacy provision and RM&G manpower issues. Where these have not been explicitly addressed in the spending plans submitted by the Member Organisations, KSS funding was made available.

Three major new initiatives are being established through this funding stream. They are:

- Recruitment of Primary Care practices (£80k *per annum*)
- Employment of a CLRN consultant pharmacist, a new post with a CLRN-wide remit (£80k *per annum*)
- Employment of two community psychiatric nurses to enhance recruitment to MHRN and DeNDRoN studies (£80k *per annum*)

All three address specific and repeatedly cited local barriers which are hindering participation in NIHR portfolio studies.

9.3 Funding devolved to Member Organisations

The majority of the 2008-9 NTW CLRN funding will be devolved to Member Organisations. This strategy and the relative allocations have been agreed at Board level.

This will enable Member Organisations to manage and prioritise funding locally in the early stages of transition to an activity based model. In particular, lack of insight into



actual or expected NHS Support Costs meant that the only practical approach to delivering funding to services and personnel supporting research was through the local knowledge of the Member Organisation R&D departments.

2008-9 allocations to each Member Organisation

Member organisation	% split	Allocation for 2008-9
City Hospitals Sunderland NHS Foundation Trust	11.82%	£193,485
Gateshead Health NHS Foundation Trust	6.90%	£112,866
Newcastle upon Tyne Hospitals NHS Foundation Trust	49.26%	£806,186
Northumberland T&W NHS Trust	9.85%	£161,237
Northumbria Health Care Foundation Trust	9.85%	£161,237
North of Tyne PC Consortium	7.39%	£120,928
South of Tyne PC Consortium	0.49%	£8,062
South Tyneside NHS Foundation Trust	2.96%	£48,371
NTW Ambulance Trust	1.48%	£24,186
Totals	100.00%	£1,636,558

Guidance was given to local R&D departments as they prepared proposals on their local OuRs. Member Organisations were advised on eligibility of costs, on the prioritisation of barriers as perceived by the TRNs and on the expected proportions of spend within the major categories (*viz* consultant sessions, NHS Support costs and Management). Each Member Organisation returned an OuR based on predicted expenditure on:

- Research nurses and other staff involved in recruitment
- Research support services (eg imaging and pharmacy)
- RM&G staff time
- Essential running costs (meetings/training/PPI)

The former two categories are returned in the overall OuR as Service Support, the latter two as management costs.

Note: We appreciate that salaries of research nurses, pharmacists, pathologists and radiologists could be included as sessional commitments. We have made this distinction to emphasise that sessional support relates to time spent recruiting. As the activity picture becomes clearer in relation to duties and definitions, salaries can be moved between categories.



9.4 Summary of Outline use of Resources

Details of the types of staff and support infrastructure to be funded within each member organisation are set out within the OuR spreadsheet. As far as possible, each line is linked to a specific priority area.

9.4.1 Funding staff to create a Network

The majority of the funding allocated (both by the Executive and the member Organisations) is for specific posts. This is central to the management of these investments.

Specific people will be funded through the CLRN and they will be responsible for delivery of NIHR portfolio work.

- For physicians, nurses and midwives this will include direct interaction with patients;
- For lab-based scientists, radiographers, pathologists or pharmacists this will entail the effective service delivery and reporting;
- For R&D managers this will entail the effective facilitation of studies through the system.

Whilst there will be different management arrangements and performance targets for each of these groups the key principle for all will be that ***their absolute priority is participation in NIHR portfolio research.*** Performance management of this activity will undertaken by both the CLRN and the respective member organisation

9.4.2 Staffing plan

Following collation of the schedule 1 bids submitted by the Member Organisations, we have calculated the following approximate split in resource for delivery (ie excludes Core Team funding)

Headline funding figures compared to UKCRN guidelines

Funding area	% of delivery funding	UKCRN guidelines
Clinical Staff	28%	50-60%
Service Support	56%	30-40%
Research Management	16%	~10%

The service support commitment appears high (at the expense of Clinical Staff). However, research nurses and other allied professions, who might otherwise have been classed as clinical staff, have been included as service support as they are not necessarily directly involved recruitment. Moving the Nurse/Midwife costs into the Clinical Staff category changes the proportion to approximately equal funding of Clinical Staff and Service Support (at ~42% each).



Whilst management costs are high in this first year we expect this figure to fall in subsequent years as administrative processes are rationalised and front-line activities are prioritised. A breakdown of how service support will be targeted and delivered is presented below.

Service support provided and funding committed for 2008-9

Category	FTE funded	Funding committed	% of total Service Support
Staff			
Nurses and Midwives	10.55	£440,860	29%
Data / Admin	7.35	£264,451	17%
Technicians	9.15	£245,677	16%
Scientists	4.2	£230,000	15%
PAMs	2.7	£110,511	7%
“Non-staff”			
Reporting	NA	£110,500	7%
Tests	NA	£143,599	9%

The Staff vs Non-Staff distinction more closely reflects the way the costs are described within the organisations rather than the reality of the cost incurred. For example, the reporting of scans is cited as a non-staff cost by most Member Organisations yet the only component of the costing process was staff time.

The distinction between staff and non-staff in this analysis is that staff costs are attached to a named individual.

The single biggest area of investment in NTW is in pharmacy where a total of over £250k is being invested this year secure posts and expand capacity for portfolio activity. The Executive are being advised on this by the local NTW chief pharmacists, the Member Organisations and the LRNs.

Staff vs Non-staff costs

Category	FTE funded	Funding committed	% of total Service Support
Staff costs	33.94	£1,291,499	84%
Non-staff costs	NA	£254,099	16%
Total		£1,545,598	

The total service support committed is £415k from KSS and £1,230k from devolved allocations (totalling £1,645k). The NTW Board have requested that £100k contingency is held centrally to allow unexpected, project specific costs to be met.



9.5 Management challenges arising from the devolved model

Any model for the management of resource will have challenges associated with it. Centralised models risk being unresponsive and divorced from local need. Conversely, devolved models need to guard against losing accountability and strategic focus.

For example, the devolved model for RM&G management adopted by NTW CLRN relies on Member Organisations providing operational management of CLRN-funded staff. While these staff are employed, hosted and operationally managed by the Member Organisation for whom they primarily work, they make up the CLRN Team and are accountable for CLRN and portfolio performance.

Similarly, the allocations to the Member Organisations have been devolved with clear guidance as to its use. The expected proportions to be used for Management, Clinical Sessions and Service Support have been communicated and it has been made clear that future funding allocations will be based on accrual figures.

The exact mechanism by which the model for delivery will evolve has not yet been established. As more information becomes available, both locally and nationally, a basis for activity based funding will be implemented in NTW CLRN. There are already areas becoming apparent where there is CLRN-wide need and scope for rationalising provision. One of these areas is in provision of Consultant Pharmacist expertise, an issue addressed through our Key Service Support following discussions between CLRN senior management and the Regional Chief Pharmacists' Group.

10 Other core activities

10.1 Supporting commercial research

A work programme will be established by the Executive in summer 2008 with the aim of establishing the current volume of industry-sponsored research in Member Organisations. The review will identify areas requiring support and areas, particularly within the SpGs where there is potential for rapid expansion in Pharma activity.

The appointment of the Industry Manager to the CLRN team will be key to supporting the commercial research initiative. The post-holder will assist companies and investigators through the feasibility, set-up and delivery of studies, ensuring consistency across the CLRN, quick turnaround and delivery to recruitment targets.

Feasibility assessments will be an important element of this. The Industry Manager will lead on collecting information on patient populations and delivery on past studies to establish realistic estimates for future research and set achievable targets.

'Time to first patient recruited' will be monitored along with regular reviews of accrual and we will maintain contact with the research teams to ensure targets are met. Regular contact with the Sponsor staff will provide opportunities to feed back information on recruitment issues or to find better ways of working. The Industry Manager as a consistent point of contact will, we believe, be attractive to industry and will forge strong relationships for future research.

The use of the costing template will be implemented by the Industry Manager, with advice given to companies, researchers and R&D departments on how to cost studies, with a strong push to use the model agreements to speed up contracting.



Newcastle upon Tyne Hospitals FT, our large Teaching Hospital has a strong background of commercial research, now managed largely through their Clinical Research Centre, an umbrella organisation of several research platforms. The Industry Liaison Officer will work closely with the Centre, being imbedded in the facility and with the industry leads within the TCRNs.

10.2 Patient and public involvement

The NTW CLRN stakeholders are already well served by groups with expertise in facilitating involvement of patients and the public in clinical research. We will establish a work programme in this area over the coming year but we are still at the scoping stage.

The University of Newcastle Policy, Ethics and Life Sciences Research Centre (PEALS) is based close to the CLRN offices and regularly hosts events to engage with the public, an example being the monthly Cafés Scientifique. We are also very fortunate to be hosted by the International Centre for Life (ICfL) arguably one of the most effective life sciences-focused education and public engagement organisations in the UK. In our public engagement efforts we intend to make good use of the established analytical and delivery mechanisms available to us.

Along with advice from INVOLVE and the UKCRN PPI Lead, we intend to work with current patient groups within the TCRNs and Member Organisations, with input from PEALS and the Centre for Life outreach and Education teams. We have a wide remit and there are particular challenges in delivering meaningful PPI in a generic setting. We are determined that our efforts are not tokenistic and will be led by the experts in this field on the appropriate committees to include patient and public representatives and what their role will be.

10.3 Training and workforce development

We have carried out an initial assessment of this area and will work up a formal work programme to be lead by Justine Smith the Lead RM&G manager. The evidence thus far is that we have varied training initiatives across the Member Organisations, all of which help inform researchers of the regulatory environment and R&D process. There is enthusiasm from R&D staff to spend time promoting research to clinical teams and providing training in governance areas. Current methods are:

- One-to-one training of researchers as go through process of study set-up and implementation
- Slide shows and supportive documentation on intranet sites
- Leaflets including easy to follow processes
- Presentations
- Access to UKCRN training sessions and online courses
- On-site training provided by external consultants

The work programme will include

- Collation of details of all courses available to local staff and promoting them, enabling staff to attend relevant courses provided by the UKCRN.



- Assessing quality and fitness for purpose of local training
- Assessing access to current GCP training provision (provided by Member Organisations, TCRNs and UKCRN)
- Deciding on requirement for all researchers to be trained in GCP, the level of training they require to perform their role effectively and update requirements – standardising across CLRN (taking different roles and responsibilities into account)
- Finding gaps in training needs and providing one-off or bespoke training sessions as needed
- Discussing training needs with UKCRN staff
- Collating training material across Member Organisations and providing standardised formats, building on current information
- Ensuring training logs kept current for all portfolio staff
- Arranging mentoring of new staff and staff taking on a new role for the CLRN
- Arranging forums for promoting research
- Providing updates to researchers in most effective way

We will also initiate and commission training when required. The first bespoke training session hosted by NTW CLRN is a Mental Capacity Act training day, led by local legal experts and focusing on research issues. This is being provided for all staff in the North East and promoted within neighbouring CLRNs.

The aim is to provide clear training plans for each research role, with appropriate access to training, ensuring the quality of research across the CLRN and empowering researchers. The varied and high quality local resources will be used to their full potential to create a highly motivated and competent research workforce.

10.4 Information systems

We do not intend to set up a separate work programme for IS. It is however integral to all the other WPs as information systems are key in the delivery of all CLRN functions.

The Information Manager will contribute to all areas of CLRN work, liaising with all operational staff to assess needs and propose solutions. An important part of the role will be collaborating with the UKCRN and other Information Managers to assess needs and best practice across all CLRNs, operationalise new IT systems locally, tailor current software and provide novel solutions to immediate and long term needs. Providing intelligent reports to CLRN core staff will be a major part of the role, enabling data to be presented to all partners in the CLRN in a meaningful way and allowing key targets to be monitored.

A training role will also be important, especially when bringing in new functionality and systems, spending time with local researcher and research groups to ensure accurate and timely reporting of accrual into the portfolio database.

Areas to be prioritised by the Information Manager:

- Ensuring IT systems are in place to support smooth implementation of CSP



- Creating a contact database
- Provision of a database to manage HRCs and Passports
- Tool to collect and report finance data for CLRN and individual studies
- Assessing current plans for trial management tools in UKCRN and external products available
- Providing short term and where necessary long term solutions to trial management needs, including linking different databases to reduce duplication of effort and increase consistency
- Transferring data from current systems into new solutions
- Uploading accrual data onto portfolio database where required
- Setting up SharePoint and managing content
- Managing website content
- Providing regular reports and ad hoc reports in formats required by CLRN staff

The integration of current systems and new solutions will result in a strong infrastructure across the CLRN, enabling the most efficient use of time, ensuring high quality output and increasing capacity.



11 Summary

The Board and Executive of NTW CLRN are seeking to make the Northumberland, Tyne and Wear area a destination of choice for studies seeking to recruit NHS patients into NIHR Portfolio studies. We have set out in this plan our approach to establishing a network of people and infrastructure capable of delivering this vision. We are mindful of the pace and extent of the change we are undertaking and we are seeking stable sustainable growth in partnership with our stakeholders.

11.1 *Securing the baseline*

- Identified studies that should be added to the portfolio and others for which accrual figures can be contributed.
- 64.5 consultant sessions awarded across all organisations and Networks to individuals and teams already active in recruiting to NIHR portfolio trials. These sessions are to be built into job planning processes over the next year and represent a significant step in the process of cultural change being undertaken. (£750k).
- CLRN funding providing stability in Member Organisations for R&D and RM&G staff with a commitment to reforming the RM&G processes for portfolio studies (£460k)
- Hospital service departments consulted on requirements for NHS support for portfolio, almost £1m invested to secure activity in the transitional period and begin to grow capacity.

11.2 *Building the platform*

- Establishing the CLRN initiative and building productive, mutually beneficial working relationships with Member Organisations
- Primary Care Practices (£80k)
- Specialty Groups driving recruitment to portfolio trials
- CLRN Consultant Pharmacist (£80k)
- CPNs funded in Mental Health Trust (£80k)
- Strategic investment by Member Organisations designed to pump-prime activity. Examples include: Clinical session support within NTW Mental Health Trust (£76k); Research Midwife time secured in South Tyneside to recruit to established portfolio studies under the guidance of the Reproductive Health SpG (£12k); The Ambulance Trust establishing a research facilitation post to scope possibility of contribution to portfolio studies (£25k, matched by Durham, Tees Valley)



Appendix 1 : Board Membership, Stakeholder Representation and Meeting Dates

Board Management		
UKCRN	Professor Sir George Alberti	Chair
UKCRN	Professor Tim Goodship	Clinical Director
UKCRN	Dr Séamus O'Neill	CLRN Senior Manager
UKCRN	Dr Jonathan Gower	UKCRN Observer
Member organisations and Consortia		
City Hospitals Sunderland NHS Foundation Trust	Professor Chris Gray	R&D Director
Gateshead Health NHS Foundation Trust	Dr Alan Thomas	R&D Lead
Northumberland Care Trust	Professor Vivien Hollyoak	NoT PC Consortium Representative
Newcastle PCT		
North Tyneside PCT		
North East Ambulance Service NHS Trust	Dr Colin Cessford	Dir. Of Strategy & Clinical Standards
Northumberland, Tyne and Wear NHS Trust	Dr Andrew Fairbairn	Medical Director
Northumbria Health Care NHS Foundation Trust	Dr Richard Walker	Clinical Director for R&D
South Tyneside NHS Foundation Trust	Mr David Shilton	Executive Director – Nursing & Clinical Governance
Gateshead PCT	Dr David Hambleton	SoT PC Consortium Representative
South Tyneside PCT		
Sunderland Teaching PCT		
The Newcastle-upon-Tyne Hospitals NHS Foundation Trust	Mr Brian Steven	Finance Director



HEI Representation		
Newcastle University	Professor Alastair Burt	Dean of Clinical Medicine
Sunderland University	Professor Greg Rubin	Prof. of Pimary Care
Northumbria University	Professor Charlotte Clarke	Director of Community, Health and Education Studies Research Centre
LRNs		
Northern and Yorkshire Primary Care Research Network	Professor Greg Rubin	Clinical Lead
Northern Cancer Research Network	Dr Philip Atherton	Clinical Lead
North East Dementias and Neurodegenerative Diseases Research Network	Professor John O'Brien	Clinical Lead
North East Mental Health Research Hub	Professor Nicol Ferrier	Clinical Lead
North East Stroke Research Network	Professor Chris Gray	Clinical Lead
North East and Cumbria Diabetes Research Network	Professor Mark Walker	Clinical Lead
Other Key Stakeholders		
Strategic Health Authority	Dr Eugene Milne	Deputy Medical Director
PPI Rep	Vacant	
PPI Rep	Vacant	



	Board	Executive
July 07	<i>8th June</i>	
November 07	<i>23rd November</i>	
December 07		<i>20th December</i>
January 08		<i>17th January</i>
February 08		<i>7th February</i>
March 08		<i>4th March</i>
April 08		<i>1st April</i>
May 08	<i>16th May</i>	<i>1st May, 22nd May</i>
June 08		12 th June
July 08		3 rd July, 24 th July
August 08		14 th August
September 08	12 th Sept	4 th Sept, 25 th Sept
October 08		16 th October
November 08		6 th Nov, 27 th Nov
December 08		18 th December
January 09	30 th January	TBA
February 09		TBA
March 09		TBA
April 09	TBA	TBA



Appendix 2 : A pilot scheme for Local Enhanced Service (LES) for clinical research in Primary Care

NTW CLRN Primary Care Working Group

The Board and Executive of the NTW CLRN have identified a pressing need for effective engagement with Primary Care as a key requirement for improving both the number and reach of NIHR portfolio studies within the CLRN.

We are committed to seeing the Primary Care arena within NTW CLRN becoming a destination of choice for clinical studies. However we recognise that there is a great deal of work to do to build the sort of infrastructure and experience that would allow this goal to be realised.

Dr Scott Wilkes is the Primary care representative on the Executive and has been instrumental in setting up a Primary Care Working Group (PCWG) which reports to the Executive. Scott's primary objective was to establish a CLRN initiative to promote engagement with Primary Care practices. This was to be carried out in collaboration with the local PCRN and the two Primary care consortia in the CLRN which cover North of Tyne (NoT) and South of Tyne (SoT) respectively .

The membership of the PCWG is

- Dr Scott Wilkes (Executive representative for Primary Care, NTW CLRN)
- Dr Séamus O'Neill (Senior Manager, NTW CLRN)
- Mrs Terri Harding (NYREN)
- Dr Shona Haining (R&D Manager, North of Tyne Primary Care Consortium)
- TBA (South of Tyne Primary Care Consortium)

The proposal

The NTW CLRN is establishing a pilot scheme to recruit a first wave of 'enhanced' Primary Care clinical research services. The pilot scheme seeks to demonstrate potential value in:

- Increasing the participation of local primary care services in NIHR portfolio studies
- Creating a quality and performance driven environment for developing primary care clinical research sites.
- Increasing the recognition of the local primary care contribution to the national and local NHS agenda amongst service commissioning teams (with a view to improving opportunities for rapid application of research into local commissioning cycles).

A clear requirement was identified by the PCWG to enable these goals to be achieved. It was necessary to address barriers locally to involvement of Primary Care in high quality research studies. An analysis of these barriers was carried out and the group decided that the most effective way forward was to identify local champions and work with them to develop and extend their involvement. In particular the vision was for these Primary Care champions to work closely with the CLRN Specialty Groups and Topic Network CSGs.



The PCWG sought to develop a process which would identify Primary Care practitioners who would be in a position to act as champions for NIHR portfolio research.

Rolled out in NTW CLRN from June 2008, the scheme offers 2 years of substantial practical and financial support from the CLRN. Using the Key Service Support funding stream, £8,000 per annum has been offered to practices as research infrastructure pump-priming to encourage engagement with the CLRN agenda.

The assistance provided by the CLRN would include

- Core funding rising to a maximum £8,000 dependant upon successful recruitment.
- Provision of (and guidance on) standard policies and procedures associated with research to ensure compliance with relevant legislation and Health Care Standards;
- Access to free of charge training via the UKCRN training schemes;
- Practical help and advice from NTW CLRN and the PCRN N&Y with achieving 'research-ready' accreditation, setting up adopted studies and obtaining relevant approvals to establish the Practice as a research site;
- Assistance to the Practice in the development of its own research site portfolio describing research interests, track record, expertise, population profile, capacity to recruit and local costs.

Crucially, the PCWG will also provide advice to Practices on the NIHR portfolio and how to get involved in established studies.

For the infrastructural funding awarded to the Practices, the PCWG decided against being prescriptive in how the recipient practices use the funding they receive, rather a variety of possible models have been rehearsed which have been cited by research active practices as being successful, such as:

- Funding for Nurse time (or other practice based roles)
- Contribution towards the practitioner costs of reviewing studies for feasibility
- Costs to set up basic administrative systems

Expected activity

Rather than micro-manage the expenditure against the £8,000 service support infrastructure (a relatively modest sum per practice) the PCWG will assess the return on this investment against the following explicit criteria:

1. Feasibility review: Practices are expected to demonstrate that they have reviewed feasibility of 6 portfolio trials per annum and will be asked to provide their rationale for adopting or rejecting them. An estimate of the time spent reviewing the trials for the process of adoption will be required annually.
2. Recruitment: Practices will be expected to recruit to a minimum of 2 portfolio trials per annum and to report 6 monthly, the number of portfolio trials that are ongoing. The format of the 6 monthly report has not been finalised yet but it is intended that it will not be onerous. However, it will need to contain the number of recruits and an estimate of the time taken on each recruit.

Milestones expected of participating practices



By the end of year 1, it is anticipated that participating Practices would have:

- A clear understanding of the opportunities afforded by the NIHR portfolio as demonstrated by having taken on studies to which they are recruiting or will recruit.
- Engaged with the requirements for effective and sustainable participation in clinical research. Evidence of this will be apparent in how the Practices go about making their service compliant with the Research Governance framework.
- Contribute to Specialty Group and Topic Network planning of studies with a Primary Care requirement.
- It is also anticipated that participating Practices would complete their clinical research site profiling which would give them a competitive edge when approached by Pharma and other research sponsors.

In year 2 of the scheme, Practices will:

- Maintain their commitment to the high quality clinical research agenda as evidenced by further moves towards research readiness accreditation
- Continue to carry out feasibility reviews and ongoing recruitment and adoption of further portfolio studies.
- Act in a mentoring capacity to the next wave of practices seeking to participate in the scheme

For this they will continue to be funded by the CLRN, via the appropriate PCT.

Criteria for selection

In order to qualify for the LES support package the Practice is expected to demonstrate the following:

- Timely submission of Expression of Interest; form attached
- The desire and capacity to take part in the scheme
- Explicit expressed commitment to setting up the structures necessary to enable participation in high quality clinical research
- Explicit commitment to taking on at least two studies from the NIHR portfolio and to begin recruiting in the first year
- A willingness to undergo a 'research-ready' style accreditation
- Preparedness to effectively liaise with a nominated LES delivery coordinator throughout the pilot
- A commitment to participate in quarterly meetings of the LES Practices with to build the network and develop the primary care research culture.

Process for recruitment of LES Practices

Expressions of interest (EoI) have been requested through circulation of the attached letter of invitation and form for submission of EoI. Through PCRN N&Y, all GP Practices north and south of Tyne have been contacted and invited to apply. Many have since called to discuss the detail of the arrangement. All returned EoIs will be reviewed by the PCWG in early June 2008 and the successful applicants will be notified and funds released as soon as possible thereafter.

It is anticipated that this call for EoIs will generate a competition. It is hoped that 10 awards can be made and that a second tier of practices, not successful for full funding in the pilot can be encouraged to work towards a renewed application in 2009-10. In the intervening year the CLRN and PCRN teams will work closely with the second tier



practices to develop the research awareness and culture. Access to UKCRN training, for example, will be made available and practice representatives will be made informed of events and communications relating to Primary Care research within the Network.

Review of the process and performance

The performance of practices against the stated metrics will be assessed every 6 months and decisions taken on continuation of funding will be made after 2 years.

Funding will be withdrawn if practices are not meeting the minimum criteria specified

The second tier practices will automatically be included in the process for subsequent rounds of awards but there will also be another call for EoIs.

One issue that the PCWG consider to be fundamental to this process is an evaluation of the efficacy of this intervention. The assumption, network-wide, which is as yet unproven is that this sort of intervention improves quality and output in terms of portfolio research. We intend to evaluate the outcomes both quantitatively (in terms of the feasibility and accrual metrics) and also qualitatively in terms of the perceptions and experience of those involved. Funding for this on a local basis may be available through the CLRN, but the team are looking, with interested academic partners into potential funding sources for a national evaluation. As we, in UKCRN, are in the business of testing the efficacy of interventions, we should seek to lead on evidence based practice. It seems prudent, therefore, to ensure that our own interventions are tested with the same degree of rigour that we would expect of the projects we adopt.

Circulation: Northumberland Tyne and Wear General Practices

Copied to: Northumberland CT
 North Tyneside PCT
 Newcastle PCT
 Gateshead PCT
 South Tyneside PCT
 Sunderland PCT
 Northern Faculty of the RCGP
 Northern and Yorkshire (NYReN) PCRN



Appendix 3 : Network Building - Dates of meetings with Trust and LRN Managers

Meetings scheduled	First Tuesday Meetings		LRN Managers Meetings
	Trust R&D Managers	Trust-based RM&G managers	
May 08		6 th May	20 th May
June 08	3 rd June		
July 08		1 st July	22 nd July
August 08		5 th August	
September 08	2 nd September		23 rd September
October 08		7 th October	
November 08		5 th November	18 th November
December 08	2 nd December		
January 09		6 th January	20 th January
February 09		3 rd February	
March 09	3 rd March		
April 09		7 th April	



Appendix 4 : Studies reported as active in 2007 by member organisation

<i>Northumberland, Tyne and Wear NHS Trust</i>	25	NESRN	2
DeNDRoN	6	DRN	1
MHRN	4	Gateshead Health NHS Foundation Trust	39
DOH/NHS/NIHR	3	NCRN	28
MRC	4	DeNDRON	6
ESRC	1	DRN	1
BUPA Foundation	2	NESRN	3
Sir Jules Thorn Charitable Trust	1	DRN	1
Stanley Foundation	1	City Hospitals Sunderland NHS Foundation Trust	123
Commercial studies	3	NCRN	26
Northumbria Health Care Foundation Trust	32	DeNDRON	3
NCRN	20	NESRN	5
DeNDRoN	3	DRN	3
MHRN	1	Children Research Fund	2
NESRN	6	Parkinson Disease Society	2
DRN	2	PPP Healthcare Foundation	3
Newcastle upon Tyne Hospitals NHS Foundation Trust	433	British Heart Foundation	3
NCRN	76	Various	3
DeNDRoN	1	Arthritis Research Campaign	1
MHRN	1	British Geriatric Society	1
NESRN	6	British Orthodontic Society	1
DRN	10	Stroke Association	1
Action Research	2	Welcome Trust	2
Alzheimer's Society	2	British Society for Rheumatology	1
ARC	19	MRC	6
BBSRC	5	Diabetes UK	1
Birth Defects	2	EORTC	1
BHF	15	Applied Neurodiagnostic	1
Diabetes UK	1	Gov/DH/NHS	27
DOH/NHS/NIHR	30	ESSRC	1
EORTC	4	Commercial Trials	29
ESRC	3	Primary Care Trusts	37
EU	10	MHRN	2
Foods Standards Agency	3	DRN	1
Kidney Research UK	2	PCN	4
MRC	33	BHF	1
Muscular Dystrophy Campaign	3	ESRC	2
Parkinson's Disease Society	3	ARC	3
Royal Colleges	6	Home Office	1
Wellcome Trust	26	DOH, NIHR, NHS	9
Commercial studies	170	MRC/Wellcome	6
South Tyneside NHS Foundation Trust	22	BHF	1
NCRN	19	EU	1
		Commercial	6



Appendix 5 : The NTW portfolio and guidance for PIs and CIs

List of non-TLRN studies which have accrual associated with a site within NTW CLRN since April 2007

StudyID	Acronym	Title	ActiveStatus	Randomised	SampleSize	Topic	Investigator	SiteName	Total
2231	BOOST II UK	Which oxygen saturation level should we use for very premature infants? A randomised controlled trial	Open	Randomised	1200	Meds for Children	M Abu_Harb	Sunderland Royal Hospital	6
2312	ADEPT	Abnormal Doppler Enteral Prescription Trial	Open	Randomised	400	Meds for Children	Nick Embleton	Royal Victoria Infirmary	9
2442	DILIGEN	Pharmacogenetics of antimicrobial drug-induced liver injury.	Open	Non-randomised	1000	Oral and Gastrointestinal	Jill Henderson	Newcastle General Hospital	2
								Sunderland Royal Hospital	1
								Freeman Hospital	5
								Newcastle University	3
								Fenham Hall Medical Group Newcastle	19
								Biddlestone Health Group Newcastle	10
3813	The EQUIP Study	Enhancing the Quality of Information-sharing in Primary care for children with respiratory tract infections.	Open	Randomised	600	PCRN	Nick Francis	Guide Post Medical Group	6
4304	TracMan	Tracheostomy Management in Critical Care	Open	Randomised	1692	Respiratory	J Cosgrove	Freeman Hospital	1
2470	VIDEO	A randomised, double blind, placebo-controlled trial of Vitamin D supplementation in the management of symptomatic knee osteoarthritis (the VIDEO Study)	Open	Randomised	600	PCRN (co-adopted by Musculoskeletal)	Fraser Birrell	Royal Victoria Infirmary	51
2508	TRISH-UK	U.K. Trial of Radioiodine Intervention for Subclinical Hyperthyroidism	Open	Randomised	780	PCRN	Simon Pearce	Royal Victoria Infirmary	2



2261	NESGAS	A randomized, multicentre, multinational trial to evaluate the safety and efficacy of Growth Hormone treatment at varying doses in short children, born small for gestational age (SGA)	Open	Randomised	303	Meds for Children	Timothy Cheetham	Royal Victoria Infirmary	3
2478	LIFELAX	LIFELAX: Diet and Lifestyle vs laxatives in the management of chronic constipation in older people	Closed						5
3460	TOPS	A randomised preference trial of medical versus surgical termination of pregnancies less than 14 weeks' gestation (TOPS)	Open	Randomised	2232	Reproductive Health	S Robson	Royal Victoria Infirmary	679
3776	NEST	Neonatal ECMO Study of Temperature	Open	Randomised	118	Meds for Children	Jane Cassidy	Freeman Hospital	2
Grand Total									804



List of non-TLRN studies which have been adopted into the NIHR portfolio in May 2008 with an NTW CI

StudyID	Acronym	Title	ActiveStatus	Randomised	SampleSize	Topic	Investigator	SiteName
3974		Integrating impairment and social models of healthcare: Treating sentence level difficulties in aphasia and making a difference	Open	Non-randomised	20	Generic Health Relevancee	Dr Anne Whitworth	NUTH
3907		A needs-based education package for patients with ankylosing spondylitis	Open	Non-randomised	48	Musculoskeletal	Dr Lesley Kay	NUTH
4630	IOXT	Improving Outcomes in Intermittent Exotropia study	Closed	Non-randomised	465	Ophthalmology	Mr M P Clarke	NUTH
4588	CBT	Training a Speech and Language Therapist in Cognitive Behavioural Therapy to treat Functional Dysphonia - A Randomised Controlled Trial	Open	Randomised	62	Nervous system disorders	Mr Vincent Deary	NUTH
2623	CHANGE	The CHANGE Study - Congenital Hearts: a National Gene/Environment Study	Open	Non-randomised	2000	Cardiovascular	Professor Judith Goodship	NUTH
4622	HCV Lipid Study	A randomised, controlled, factorial pilot study investigating Omacor and/or Fluvastatin in patients with chronic hepatitis C who have not responded to standard combination anti-viral therapy	Open	Randomised	72	Metabolic and Endocrine	Professor M F Bassending	NUTH
4616	Azithromycin trial	A randomised, double blind, placebo controlled study to assess the effect of antibiotic therapy on chronic rejection in human lung transplantation	Open	Randomised	64	Respiratory	Professor Paul Corris	NUTH
2866		The Production and Evaluation of a video-based exercise program for patients with shoulder pain	Open	Non-randomised	30	Musculoskeletal	Dr David Wright	Sunderland
3672		Atrial repolarisation: New measures for non-invasive assessment of heart disease	Open		400	Cardiovascular	Dr P Langley	NUTH
4625		A pilot controlled clinical trial of Salvia officinalis (sage) for cognitive impairment in Parkinson's disease	Open	Randomised	40	Nervous system disorders	Professor D Burn	NUTH



List of non-TLRN studies where a complete dataset has been submitted in May 2008 and adoption is expected

StudyID	Acronym	Title	ActiveStatus	Randomised	SampleSize	Topic	Investigator	SiteName
	The MEDE study	Development of metabolomics as novel approach to biological indicators which characterise and quantify dietary exposure	Open	Non-randomised	48	Generic Health Relevance	Professor J Mathers	NUTH
	Kidney MRI and Type 1 diabetes	Development of High Field Magnetic Resonance Techniques for the Non-Invasive Investigation of Kidney Disease	In set-up	Non-randomised	36	Diabetes	Professor S Marshall	NUTH
	FAST-CHD	Genetic factors predisposing to congenital heart disease	Open	Non-randomised	600	Cardiovascular	Professor Bernard Keavney	NUTH
	The GrainMark study	Biomarkers of whole-grain intake; contribution of alkylresorcinols and mammalian lignans to the metabolome	Open	Randomised	54	Metabolic and endocrine	Dr C Seal	NUTH
	INTOPT	Interventions to optimise the practice of transfusion ('INTOPT') - Understanding transfusion prescribing behaviour in two clinical areas	Open	Non-randomised	620	Blood	Professor M Eccles	NUTH
		Using genotype to predict coronary heart disease: assessing impact upon medication adherence	Open	Non-randomised	500	Cardiovascular	Dr D Neely	NUTH

List of non-TLRN studies on the portfolio where there is an NTW PI but no record of accrual

StudyID	Acronym	Title	ActiveStatus	Randomised	SampleSize	Topic	Investigator	SiteName	Total
4628	arcOGEN	The arcOGEN study: A genome wide association study of osteoarthritis	Open	Non-randomised	8000	Musculoskeletal	Professor A McCaskie	NUTH	
4076	TRACE RA	Trial of Atorvastatin for the primary prevention of Cardiovascular Events in Rheumatoid Arthritis	Open	Randomised	3808	Cardiovascular	Dr D Walker	NUTH	



Northumberland, Tyne and Wear CLRN – Guide to getting accrual started for NIHR portfolio studies

Submitting accrual data via the UKCRN Web Portal

Accrual for NIHR portfolio studies can only be entered online by the named accrual contact. The UKCN portfolio and accrual system is accessed by the UKCRN Web Portal. The accrual contact will need to activate his/her user account. To do this, go to <http://www.ukcrn.org.uk/index.html> and click on login at the top right hand corner. This will open a new window (<https://portal.ukcrn.org.uk/login/>). If you then click on sign up you will be asked to put in your e-mail address. This MUST be the same e-mail address that was submitted for you as the accrual contact. You can then choose a password and activate your account. Chief investigators and study coordinators will also have an account which is activated in the same way. This account will allow them to change the details of the study BUT NOT submit accrual data unless they are also the accrual contact.

Further information is provided in the file “UKCRN Web Portal User Guide”

Standard accrual data format

Accrual data has to be submitted in a standard format. This is the excel file called UKCRN Accrual data template.xls. There is a user guide called “UKCRN Portfolio and Accrual System Standard Accrual Data Format”. I would suggest that initially that you submit only the mandatory field plus the Site ID. There is an excel spreadsheet (UKCRN Accrual sites codes.xls) which gives the Site ID for all NHS organisations. You can just search on the name. Remember that accrual data is only needed from 1st April 2007. However, if patients have entered the study before that date then the running total should reflect this. For instance, if the first patient entered in April 2007 was your 100th patient then the figure in the running total should be 100.

Accrual Upload

The process for accrual upload is described in the “UKCRN Accrual Upload System User Guide”. It looks pretty straightforward! Remember that you only need to keep one accrual file to which you add data and upload every month. You could start by uploading the accrual data that you have up to the end of April 2008.

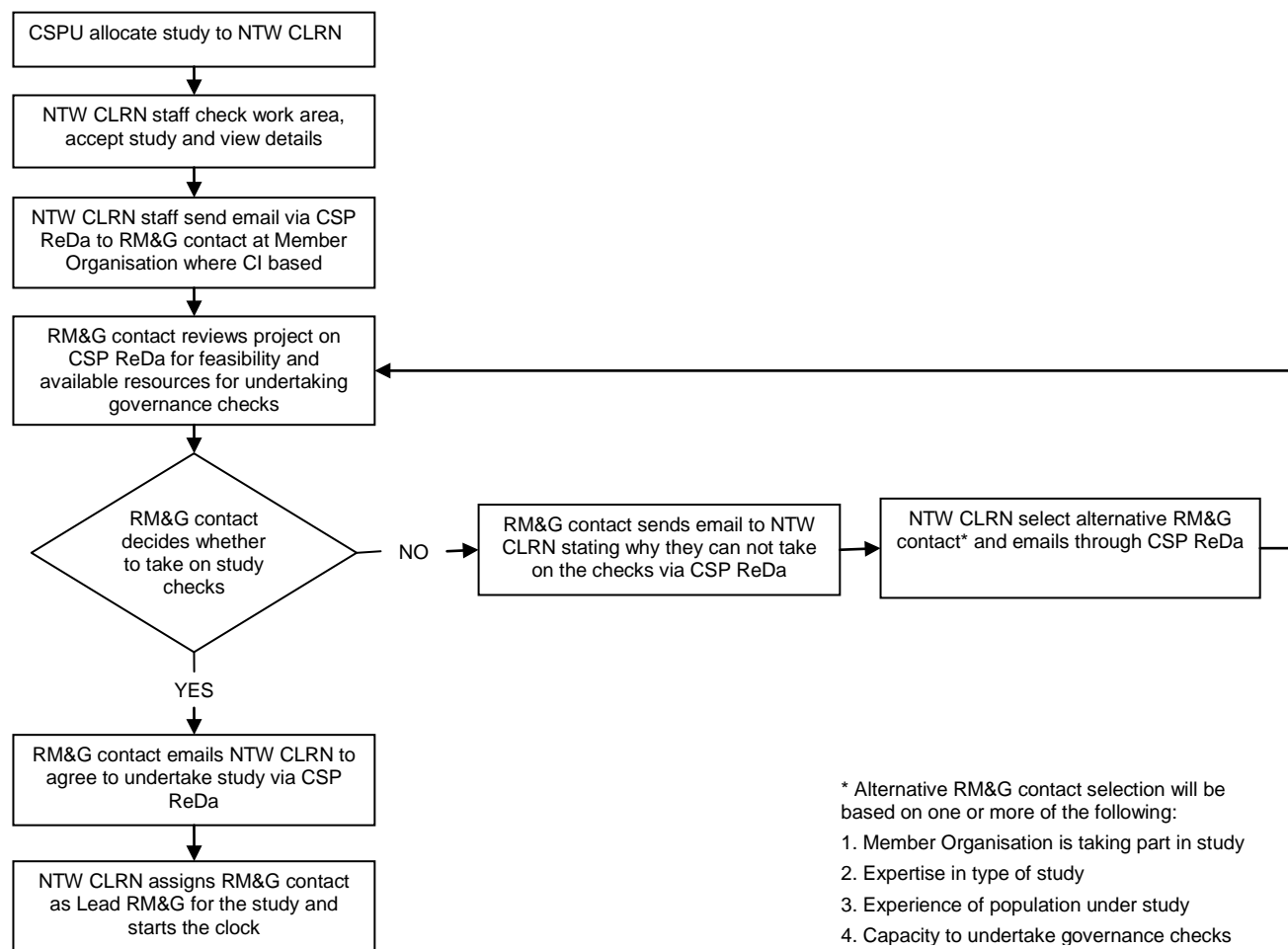


Appendix 6 : Programmes scored as Strong or Moderate in NHS R&D reports of Member Organisations

Northumberland, Tyne and Wear NHS Trust
Brain Ageing and Dementia
Change processes in cognitive behaviour therapy (CBT).
Child & Adolescent Developmental Research: Autism and Mental Health
Evaluating New Mental Health Services
Forensic and prison mental health services
Reducing alcohol and substance related harm
Treatment safety and effectiveness in severe mental illness.
Northumbria Health Care Foundation Trust
Childhood Disability
Luminal Gastroenterology and Nutrition
Parkinson's Disease
Stroke Research Programme
Newcastle upon Tyne Hospitals NHS Foundation Trust
Cancer
Cardiovascular Physics and Engineering Research
Child Health
Dental Health
Diabetes and Human Nutrition
Feto-Maternal and Women's Health
Genetic approaches to Disease
Immunobiology and Transplantation
Liver Diseases
Musculoskeletal
Neurosciences
Otolaryngology and Ophthalmology
Gateshead Health NHS Foundation Trust
Surgical Research
City Hospitals Sunderland NHS Foundation Trust (RLN)
RLN Ageing and Cerebrovascular Disease Programme
RLN Delivery of Care - Multidisciplinary Programme
RLN Ophthalmology Research programme
RLN Urology and Urology Cancer

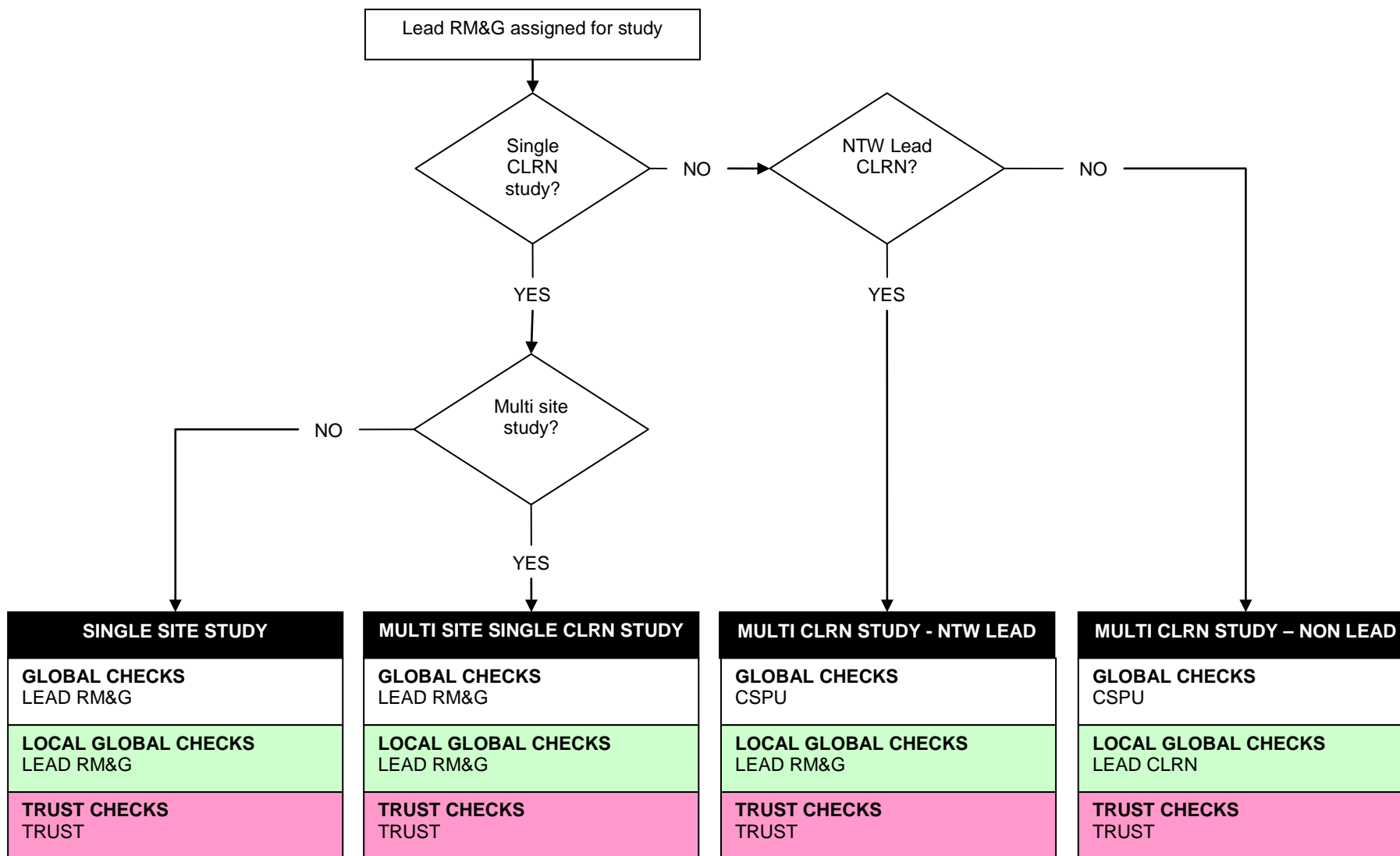


Appendix 7 : Delegation of governance checks within the CLRN





Governance check levels within CLRN





Appendix 8 : Award of consultant sessions

A number of principles underpinned the process, all of which had been endorsed by the Board and Executive, specifically that:

- The process should be open to staff of all professions, from all Member Organisations
- The process should be transparent and competitive
- The primary criterion for assessment of applications and performance management of the PAs allocated would be the benefit to recruitment into NIHR portfolio trials.

The guidance on the number of sessions to be allocated was initially to be limited to 50 but following discussions with UKCRN a revised maximum of 70 was agreed. The NTW CLRN Executive believed that this extra investment (and recognition) was warranted given the volume of high-quality research being undertaken and the need to secure research time for the many consultants who were central to both securing existing levels of activity and building capacity.

The award of sessions to University funded staff was an issue on which the Executive sought clarification from UKCRN. In the end, no distinction was made between applications made by Clinical Academics and full-time NHS personnel.

Many individual applications overlapped in relation to the studies cited. Similarly, group applications claimed responsibility for multiple studies but no formal attribution of activity or responsibility was made (or requested). The acceptance of an element of subjectivity around contribution to the portfolio and quality was an important part of the process.

The Process

The CLRN Executive agreed *a standard form* for applications. The sections of the form reflected the evidence that the Executive considered to be important in making a valid allocation of sessions and also for ensuring that the investment was likely to generate a return in terms of portfolio activity. This evidence gathering concentrated on current and future contribution to portfolio studies. The insight into portfolio activity provided by this self-reported return was imperfect as we did not have a mechanism for checking that the claims matched the portfolio.

Distribution of the forms

The form was *distributed* to R&D Leads within Member Organisations and a request was made that the document was disseminated widely amongst the professions. A one month deadline for return of the form to the CLRN Senior manager was imposed so that the funding arrangements could be put in place as soon as possible after the start of the 2008-09 financial year.

The R&D departments within the Member Organisations were asked to sign off all applications so that they were fully aware of the submissions going in. Similarly the clinical line manager for each applicant was required to sign off the form to ensure that they were aware of implications for service delivery and job-planning.



The forms were returned, collated and assessed by the 6 members of the Executive who then met to compare assessments and decide on allocations.

Assessing the applications

The mechanism of assessment was explicit. Two scores were given (both A, B or C) for:

- “Contribution to portfolio studies” and
- “Appropriateness of the number of sessions applied for”.

The range of assessments returned by the panel was recorded and a final decision noted. The results of the process are summarised as the minutes of the Executive for 1st April 2008.

Some applications were made on behalf of teams. The members of the team were named and the application was assessed as a unit by the same criteria as were applied to individual applications.

It is worth noting that there was a remarkable consensus of opinion between panel members in spite of potential differences across constituencies and Trust allegiances. The whole process took less than two hours.

A distinction between Support and Front-line Recruitment

The quality of the applications was high and many more sessions could have been awarded, particularly to individuals in support services such as Pathology, Radiology and Microbiology. However, a decision was taken to address requirements in these areas through other funding streams and concentrate the sessional support on front-line recruitment capacity. The strategic imperative was to provide support to those clinicians delivering current (baseline) activity and to secure this capacity by having it embedded in job planning. However, as a result of this approach, most of the unsuccessful applications were from staff in service disciplines.

A consequent risk arising is the potential alienation of services such as those mentioned above, without whom studies could not be undertaken. This risk is to be managed through a) dialogue with the Member Organisations to ensure that service departments are prioritised within the service support and sessional streams of the funding allocated to them and b) by explaining to those involved the rationale used.

Outcome and strategic fit

A total of 71 applications were made for 118 sessions. In all, 64.5 PA sessions were awarded to a total of 106 consultants. At the end of the process an assessment was made of the distribution across networks and Member Organisations. An analysis was also made of how the awards mapped to topic networks and specialty groups. All Member Organisations were found to be represented in the awards and all bar one of the awards were made in areas in which NTW has either a topic network or an established specialty group. The awards were not amended in light of either analysis.

Post-award management of the funding

Applicants (lead applicants where there were group applications) were notified by letter. The letters were copied to the R&D Director and the Medical Director of the applicant's employing organisation. Funding will follow to the Member Organisation as it arrives from UKCRN quarterly. To avoid the workload involved for management accounts in



each organisation in providing individual salary costings, a flat rate of £11,500 per session will be used to determine payment to Member Organisations.

An issue which arises from the award of sessions to HEI funded individuals is in ensuring that the funding awarded is used to support recruitment into portfolio studies and, moreover, that it is used in the cognate research areas to which it was awarded by virtue of the activity taking place. The Universities are not Member Organisations but do have representation at Board level. The imperative of using the funding to underpin recruitment to the areas for which the funding is intended will be managed through Board level dialogue with the HEIs. HEIs will be given a clear brief to report on use of the funding to support NIHR accrual. We believe that the Clinical Academics awarded sessions will lobby hard to ensure that this happens to best effect within their institutions.

Performance Management

The award letter set out the terms under which the sessions have been awarded. All sessions have been awarded for two years after which an assessment will be made as to whether (funding permitting) the award should be renewed. Successful applicants (and groups) have been informed that they will be required to provide a report at the end of the first year on the recruitment they have undertaken. The format of this report has still to be worked up but it will focus on the individual studies recruited to and the number of patients who went into each.

Discussions within the Executive (in consultation with the Board) will dictate whether we seek further applications in a year and how we deal with new-starters.



Appendix 9 : Outline use of Resources Spreadsheet