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## 1. Executive Summary

This document aims to provide the background information and methodologies that informed the funding required for the NIHR CRN for the financial year 2010/11. It sets out a detailed presentation of the modelling for the Comprehensive CRN funding requirement undertaken within the Activity Based Funding (ABF) project, and then includes this in the total requirement for the whole of the NIHR CRN.

The final funding requirement is set out in the table below:

**Table 1: CRN Budget Requirements 2010/11**

	2009/10 Allocation	2010/11 Allocation
TCRN LRNS	£36,439,366	£36,439,366
PCRN LRNS	£2,439,968	£2,439,968
CCRN	£222,975,021*	£236,669,486
National Contingency	Included in 2009/10 CCRN figure above	£9,051,180
<b>Total</b>	<b>£261,854,355</b>	<b>£284,600,000</b>

### Notes

\* This CCRN total figure for 2009/10 is the figure agreed by DH to be used for comparative purposes, and which does not take into account national contingency payments which were made for one year only.

ABF allocations continued to be driven by the directive that 'funding follows activity' and Table 2 below outlines the overall year on year increase in recruitment recorded in each of the allocated bands.

**Table 2: Recruitment Increase from 2009/10 ABF reporting period to 2010/11 for CCRN**

2010/2011	
Band 1 Study Tariff	£110
Observational Study Tariff	£358
Interventional Study Tariff	£1,509

	2009/10		2010/11		% variance	
	Recruitment	Cost	Recruitment	Cost	Recruitment	Cost
Band 1 (Inc. Band 1a £9.445m)	160,743	£13,108,040	116,174	£12,871,525	-27.73%	-1.80%
Observational	67,224	£16,427,102	144,681	£52,603,156	115.22%	220.22%
Interventional	53,321	£84,424,535	80,771	£123,709,042	51.48%	46.53%
Historic and CLRN Contingency	–	£16,269,771	–	–	–	–
National Contingency Allocations	–	£26,207,248	–	–	–	–
<b>Total</b>	<b>281,287</b>	<b>£156,436,696</b>	<b>341,626</b>	<b>£189,183,723</b>	<b>21.45%</b>	<b>20.93%</b>

### Notes

2010/11 based on information correct as at 5 November 2009 (1 October 2008 - 30 September 2009 Actual Recruitment excluding Industry Studies) Band 1 in 2009/10 combines Band 1a and Band 1b data.

The total of £156,436,696 for 2009/10 also includes two payments from the national contingency, i.e. NIHR CRN CC and CCLG which are not included in the CLRN allocations.

## 2. Description of ABF Modelling 2010/11

The information outlined here presents the 2010/11 funding requirement identified through the CRN Activity Based Funding (ABF) project. ABF was introduced into the NIHR CRN to inform the budgets for the Comprehensive CRN in 2009/10. In developing the 2010/11 model, the ABF project strived to develop, refine and move forward the 2009/10 model. The information represented in this paper achieves a collective response to the challenge of achieving a balance between the stable investment in infrastructure and activity based reimbursement. It summarises the work of the Project Team and the

significant input and active involvement from many different stakeholders through representation on the ABF Strategic Direction Team and the ABF National Reference Group.

Due to the large amounts of funding involved for the Activity Based Funding element of the Clinical Research Network budget, it was imperative throughout that explicit and transparent Project Governance was adhered to. The process is outlined below.

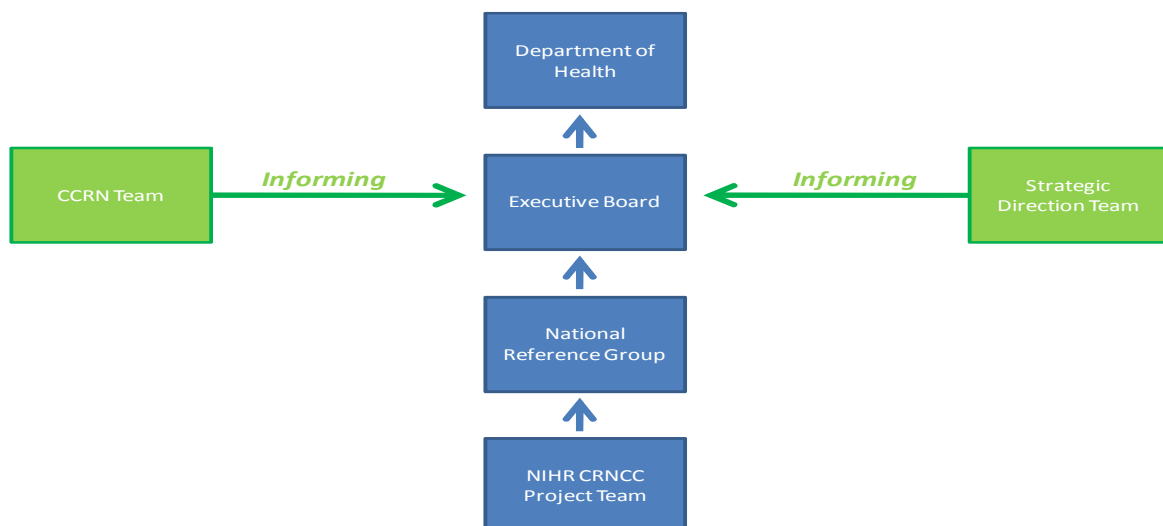
The Project Team report regularly on their work and progress to the ABF National Reference Group, who provide rigorous consideration and critical appraisal of the work undertaken, with subsequent recommendations for future work and activities. This review process is imperative to ensure methodologies are correct, consistent and that any proposals are appropriately scrutinised.

The conclusion of work undertaken by the Project Team, once approved by the ABF National Reference Group, is then submitted to the NIHR CRN CC Executive Board so that all senior colleagues are kept informed of ongoing developments and progress, whilst at the same time being able to direct and steer the Project Team to ensure the needs of the Department of Health are addressed in a coordinated implementation plan. The CRN CC Executive Board receive monthly reports on the project's activity and areas of work.

The Strategic Direction Team's role is to provide the vision, direction and goals for Activity Based Funding for 2010/11 onwards. This group of senior colleagues draws its membership from the ABF National Reference Group, the NIHR CRN CC Executive Board and senior clinical colleagues from the Clinical Research Networks.

The Comprehensive CRN Coordinating Team provide a consultative role to inform the management of the National Contingency and contribute to the refinement and development of the ABF model for 2010/11 onwards, based on their network experience, and intimate knowledge of the CLRNs and their past and present Outline Use of Resources and Business Plans.

**Figure 1: ABF Project Governance**



## 2.1 ABF Methodology

The recruitment reporting period to inform the CRN Budget 2010/11 of **1 October 2008 to 30 September 2009** was selected to:

- Minimise overlap in the reporting period used in ABF 2009/10 (April to October 2008)
- Reflect four full quarters
- Take into account the real need to notify CLRNs of their indicative budgets as early as possible

All figures used for the ABF Model 2010/11 are based on the above reporting period. The deadline for the reporting of this data was 16 October 2009.

Funding for the NIHR Comprehensive CRN Budget is provided by the Department of Health and modelled by the NIHR CRN CC to ensure that allocations to each of the respective networks provide the NHS with excellent clinical research infrastructure to support the service support requirements of the portfolio of clinical research studies, and to thereby facilitate the increased patient participation into those studies to meet the requirements of the National Ambition as defined in the NHS Operating Framework 2009. All of the work outlined is based on the following:

- Funding directly follows activity
- CLRN allocations are based on average tariffs across three bands (by type of study)
- These respective tariffs are applied on a per participant basis.

As a result the activity based element of CLRN budgets is targeted to clearly identified output. This is a refinement on the previous model which allocated funds to CLRNs on a proportional basis of their activity, and clearly demonstrates a direction of travel away from previous NHS Research and Development Support Funding, with a now transparent and accountable method of providing comprehensive detail of where and how funds have been distributed across England.

The 2009/10 model incorporated several adjustments to address the limitations associated with the available activity information. For ABF 2010/11, there are no adjustments in the activity based funding element of the CLRN budgets for pipeline study or unreported study activity during that period. The historic adjustment (£9.99m) and the CLRN locally held contingency (£6.7m) payments that were included in 2009/10, are **not included** in the modelling work for 2010/11. The matter of confidence with the Portfolio Database has continued to be raised as an issue, but close monitoring and significant efforts by all networks and the NIHR CRN CC has significantly reduced CCRN pipeline studies (now less than 5% of the total number of portfolio studies), and the level of portfolio recruitment data completeness at the time of the reporting deadline was for all networks in excess of 90%. This active management of recruitment reporting over the past year has seen the most noticeable increase in Mental Health studies, with 90% of the portfolio studies reporting recruitment by the 16 October 2009, in comparison to less than 50% in November 2008.

One of the main developments for ABF 2010/11 was the extensive work carried out regarding study costings. The 2009/10 arrangements were informed by a set of study costings from approximately 113 studies, of which 85 were unique. The 2010/11 model draws on data available from 566 study costings of which 370 are unique. This sample was not only larger in size but comparative work was undertaken to ensure that appropriate representation was drawn from all Topic areas. N.B. Mental Health did stand out as being an area under-represented in the sample versus its Portfolio presence, which was followed up with the Mental Health Research Network Coordinating Centre who were unable to submit further costs within the timelines provided, thus this area remains slightly under-represented in the modelling process.

Subsequently, ABF 2010/11 provides development of the model but not radical changes, which in itself ensures a level of stability and consistency for the CLRNs, as changing the model would have been a potential cause of instability. It is also anticipated that the outcomes of any changes to annual budgets that are derived from changes in study activity are much more acceptable than changes to the model itself, which is considered crucial in developing relationships between CLRNs and Member Organisations.

All CLRN allocations continue to be based on retrospective data therefore intelligent local management of all components of the CLRN annual budget will continue to be a key priority for CLRNs as they address the needs for all studies prospectively.

In 2009/10 the three London CLRNs included a London Weighting factor at 7%, which was applied only to the core management team. This has been extended in 2010/11 to all components of the London CLRN budget, including the per capita and the activity based elements.

In the light of restricted budgets the inflationary uplift for 2010/11 will need to be met by network efficiencies, therefore no uplift will be applied to budgets. The CRN CC note that this restriction may be a particular challenge for the P/TCRN LRNs as they have fixed committed budgets and will be tied into paying inflationary costs and salary increments.

### **Other issues which have been considered but not quantified explicitly within the 2010/11 proposed allocations:**

- Recruitment costs, have been considered as an economy of scale issue and a judgement made as to whether there is sufficient balance within the CLRN budget, for example, that those studies which are easy to recruit to are counterbalanced by those which are difficult, and this equilibrium is addressed through the average tariffs awarded to each of the bands. This management of diversity is one of the crucial factors in a CLRNs success.
- Follow up costs are included in these proposed allocations as the calculation of service support costs are based on the full duration of the study.
- The issue of Patient Identification Centres (PICs) and Cross Referral of Patients is recognised not as a single issue but more of a complex multifaceted area. It was agreed at the ABF National Reference Group that more work is required in this area to identify the studies which involve PICs, and to scope their recruitment patterns and scale of impact. For the financial year 2010/11 there is no recommendation that any additional payments should be made for this activity but that this should be managed locally.

## **2.2 ABF 2010/11 Band Definitions**

*Please note: the definitions offered for each of the ABF bands, is an attempt to clarify the 'band allocations' for the purposes of Activity Based Funding. It is important to recognise and acknowledge that Interventional studies in particular can vary widely in their complexity: phase I studies may involve just one centre and a few participants but can be quite intensive in terms of data collection and monitoring of participants; phase III studies involve many sites and tens of participants at any given site. The definitions are therefore not intended to narrowly define the study but recognise that within each of the bands there is a wide range of diversity which is addressed through the agreed 'average' tariff.*

### **Band 1 – Large Sample Studies**

A study where the total UK planned sample size (throughout the lifetime of the study), is equal to, or greater than 10,000 participants. This can be an observational or interventional study, but the key factor to determine the band is the **total planned sample (participant) size of the study** as provided by the Chief Investigator on the portfolio database.

The CLRN allocation for each of these studies is based on the actual recruitment to each of those studies.

Where a UK planned sample size was not available (e.g. classed as an International Multi-Centre), this list was referred back to the Portfolio Team for further investigation. All but one of these referrals has now been clarified with an appropriate UK planned sample size and included in the finalised list. The final study (study ID 6404 FCLL) has also been included in the calculations. In 2009/10, there were a total of 32 Band 1a and 1b studies (14 Band 1a, 18 Band 1b). For ABF 2010/11, there are a total of 41 studies in this category and these are outlined in Table 3.

This is the band of studies where a more evident variation of reporting has been tracked across the time period of ABF 2009/10 and 2010/11. In 2009/10, this band was split into high recruiting Band 1b and very high recruiting, (anticipated) low cost Band 1a. The work undertaken to review the Band 1a studies that were submitted for a separate individual study by study costing exercise, resulted in an average cost being applied (£132) that could in hindsight have been set at the same time as the other bands. The proposal here is for a continuation of the Band 1 philosophy, with high recruiting studies (as suggested with a UK planned sample size of greater than or equal to 10,000 participants) to be separated into their own band.

**Table 3: Band 1 Studies 2010/11: UK Planned Sample Size of at least 10,000 Participants**

Study ID	Study Acronym	UK Planned Sample Size	Design
2057	MAVARIC	100,000	Observational
7129	COSMOS -International cohort study of mobile phone use and health	100,000	Observational
7454	Airwave Health Monitoring Study	70,000	Observational
5837	ProMPT	66,000	Observational
3795	The Million Women Study: Disease Susceptibility in Women	60,000	Observational
7083	Fungal Infection Risk Evaluation (FIRE)	60,000	Observational
4051	Birthplace: National prospective cohort study	57,000	Observational
4179	UK CHIC	36,500	Observational
1390	SEARCH	36,000	Observational
5150	LOLIPOP	28,500	Observational
1620	BBC-NCRN cohort	25,000	Observational
4563	Impact of the General Practitioner contract on health improvement and inequalities in cardiovascular	25,000	Observational
869	UK Genetic Prostate Cancer Study	21,000	Observational
1269	NSCCG	20,000	Observational
2501	Q-CHAT	20,000	Both
4134	PULSEOX	20,000	Interventional
7302	Toxicity from biologic therapy (BSRBR)	17,100	Observational
3815	DRN082 (DARE)	17,000	Observational
2421	DESCARTE	16,000	Observational
4773	DAVROS	16,000	Observational
5123	PRIMIT	16,000	Interventional
1346	LLP	15,000	Observational
6352	Cost efficient service provision in neurorehabilitation	12,500	Observational
3508	SMOotH Study	12,296	Both
5695	Extended genome wide association study in coeliac disease	12,000	Observational
2490	SCOOP	11,580	Interventional
4641	Evaluation: THF Co-Creating Health Initiative, v1	11,172	Observational
4496	OPPTIMUM	10,400	Interventional
6637	MANCAS2	10,254	Observational
2202	DRN 055 FENLAND (LRN East)	10,000	Observational
2219	EPIC - Norfolk Third Health Check	10,000	Observational
2257	DRN 023 ASCEND	10,000	Interventional
2809	DRN 059 NDCCS (LRN Eastern)	10,000	Observational
3544	The genetic analysis of multiple sclerosis	10,000	Observational
4505	Born in Bradford	10,000	Observational

Study ID	Study Acronym	UK Planned Sample Size	Design
4719	ALDDDES: Improving the detection of alcohol-related liver disease	10,000	Observational
5094	Lym1	10,000	Observational
6404	FCLL	10,000	Observational
6542	FBCS	10,000	Observational
6727	HiLo	10,000	Both
7229	The national programme for enhanced pneumococcal surveillance	10,000	Observational

*Data correct at 27 October 2009*

### **Band 1 Tariff 2010/11**

The calculation of the Band 1 tariff was derived from 13 of the studies in Table 3. As part of the study costings exercise we received 47 different costs for those 13 studies, and an average was calculated based on those available costs, i.e. £110. For ABF 2010/11, the tariff of £110 is then applied to the participants recruited to the study on an annual basis.

As this band of studies includes both Interventional and Observational studies, the basket of study costings was also used to calculate separately the average service supports costs for the Interventional and Observational studies within Band 1. The average cost for the Interventional studies which were submitted was £126, and the average cost for the Observational studies was £96.

The Band 1 category also includes a wide range of service support costs across the sample, for example the Interventional study, 'SCOOP' produced an average cost of £130, whilst 'MAVARIC', a high recruiting Observational study, produced an average cost of £25.

### **Band 2 Observational**

A study in which the participants' lifestyle or care pathway is not affected by being part of the study (e.g. the investigator does not determine whether or not participants receive or do not receive a particular treatment). For an observational study, the investigator observes the outcome of participants following their exposure (or non-exposure) to a particular intervention or lifestyle. Interventions observed may include disease screening processes, surgical procedures, lifestyle factors (e.g. smoking) and may be studied prospectively or retrospectively. Classic type of observational studies are: cohort studies and case control studies. In observational studies, the intervention is usually being given as part of the standard care pathway and in this respect the clinical element of the study protocols tend to be simpler.

### **Band 2 Tariff 2010/11**

As a result of the study costings exercise the task to re-calculate the existing bands was undertaken based on this enhanced information, and for Observational studies resulted in a 47% increase in the tariff allocation to £358, as outlined in Table 4 on page 9.

### **Band 3 Interventional**

A study where the participants' exposure to a particular intervention (e.g. care pathway or lifestyle) is influenced by participating in the study (e.g. whether or not a participant receives a particular treatment will be determined by the research protocol). Interventions observed may include disease screening processes, surgical procedures, lifestyle factors (e.g. exercise). These studies are prospective. Clinical trials are the most common type of interventional study. Clinical trials of drug interventions are usually categorised by phase (Phase I, II, III, IV). This categorisation does not generally extend to types of intervention such as radiotherapy, surgery, medical devices. 'Before and after studies' are another type of interventional study as they assess participants before and after introducing a particular intervention (i.e. the participants' exposure to the intervention is again influenced by the research protocol).

### Band 3 Tariff 2010/11

The study costings for this category of study was more extensive this year and significant efforts were made by colleagues from across the Clinical Research Networks to ensure that there was appropriate representation in the sample from a wide range of Interventional studies. However as outlined in Table 4 below, based on the actual tariff allocation for 2009/10 (£1,583), there has been a 5% decrease in the 2010/11 tariff allocation to £1,509.

### 3. Proposals for ABF 2010/11

As a result of the study costings exercise the task to re-calculate the existing bands was undertaken based on this enhanced information.

**Table 4: Summary of Band Tariff Allocations; Approximate vs. Actual Tariff for 2009/10; proposed Actual Tariff for 2010/11**

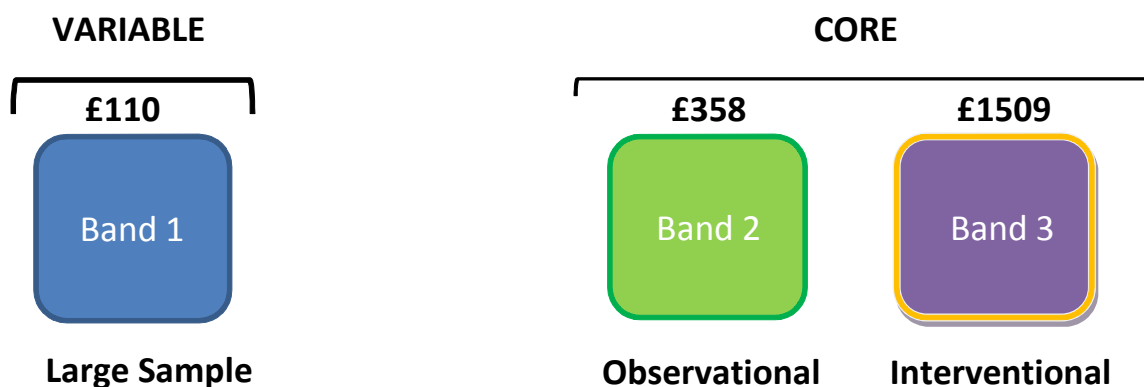
Band and Type of Study	Approximate tariff allocation per band for 2009/10	Actual tariff allocation per band for 2009/10	Actual tariff allocation per band for 2010/11
Band 1 (tariff relates to Band 1b for 2009/10)	£100	£100	£110
Band 2 Observational	£260	£244	£358
Band 3 Interventional	£1,135	£1,583	£1,509

For the 2009/10 model, the budget was allocated based on the proportional activity of the networks rather than on each individual recruitment (based on concerns at the time of the incomplete nature of the portfolio database, and the need to include a % uplift for pipeline studies etc). The table above summarises the initial proposal for 2009/10, the actual basis of the 2009/10 CLRN budgets, and the actual band tariffs for 2010/11.

As clearly outlined, the main difference for 2010/11 is the increased tariff for the Observational category which based on the actual allocation for 2009/10 (£244), has seen a 47% increase in tariff for allocation in 2010/11 to £358.

The statistical work that was undertaken to calculate the revised tariffs for 2010/11 is available upon request from the ABF Project Team.

Therefore to clarify, the ABF Model 2010/11 is based on **3 bands**:



#### **4. Proposed Comprehensive CRN Funding 2010/11**

The model above has then been applied to the recruitment data for each of the three bands, and the total for each of the CLRN bands, and their overall activity based element of the budget is outlined overleaf in Table 5. Whilst the activity based element is only one component of the CLRN budget it was considered important to investigate the reasons for any significant variances in the activity pattern and these are summarised in the table. It was also important to note that this information triangulated with the information collated in the first six months of 2009/10 through the ABF Tracker Budget, and concurred with the evidence that we had gathered regarding the relative stability for most of the CLRN bands in the Observational and Interventional category and more noticeable variance in the high recruiting studies.

Table 5: Proposed Total Activity Based Funding Element by CLRN 2010/11

BAND 1 (a study where the total planned sample size (throughout the lifetime of the study) is equal to or greater than 10,000 participants)

2010/2011	
Band 1 Tariff	£110
Observational Tariff	£358
Interventional Tariff	£1,509

CLRN	Band 1		Observational		Interventional		2010/11	2010/11	2009/10	% Year on Year £ Allocation Variance	Explanation
	Recruitment	Cost	Recruitment	Cost	Recruitment	Cost	Total Recruitment	Total Allocation	Total Allocation		
B'ham & Black Country	5,586	£614,460	10,904	£3,903,632	4,720	£7,122,480	21,210	£11,640,572	£8,822,205	31.95%	Overall decrease in Recruitment, increase in Interventional
Central & East London	4,180	£491,986	16,625	£6,368,373	7,942	£12,823,391	28,747	£19,683,750	£16,119,351	22.11%	Overall increase in Recruitment, mainly Interventional
Cheshire & Merseyside	4,751	£522,610	4,454	£1,594,532	3,079	£4,646,211	12,284	£6,763,353	£7,146,880	-5.37%	
Co Durham & Tees Valley	1,291	£142,010	925	£331,150	1,352	£2,040,168	3,568	£2,513,328	£2,452,770	2.47%	
Cumbria & Lancashire	1,082	£119,020	1,394	£499,052	1,212	£1,828,908	3,688	£2,446,980	£2,502,915	-2.23%	
Essex & Hertfordshire	3,356	£369,160	1,455	£520,890	1,888	£2,848,992	6,699	£3,739,042	£3,208,675	16.53%	Overall increase in Recruitment
Greater Manchester	16,431	£1,807,410	7,776	£2,783,808	4,754	£7,173,786	28,961	£11,765,004	£7,858,900	49.70%	Change in model relating to Band 1
Hampshire & Isle of Wight	5,714	£628,540	5,783	£2,070,314	3,277	£4,944,993	14,774	£7,643,847	£6,587,045	16.04%	Overall decrease in Recruitment with large study closing, however increase in Interventional
Kent & Medway	567	£62,370	2,430	£869,940	738	£1,113,642	3,735	£2,045,952	£1,250,195	63.65%	Overall increase in Recruitment, mainly Interventional
Leics, Northants & Rutland	1,020	£112,200	2,658	£951,564	2,783	£4,199,547	6,461	£5,263,311	£3,929,480	33.94%	Overall decrease in Band 1 Recruitment, increase in Interventional and Observational
London (NW)	3,677	£432,783	7,835	£3,001,275	3,290	£5,312,133	14,802	£8,746,191	£8,543,070	2.38%	Overall decrease in Band 1 Recruitment, increase in Interventional and Observational

CLRN	Band 1		Observational		Interventional		2010/11	2010/11	2009/10	Year on Year £ Allocation Variance	Explanation
	Recruitment	Cost	Recruitment	Cost	Recruitment	Cost	Total Recruitment	Total Allocation	Total Allocation		
London (S)	4,141	£487,396	7,757	£2,971,396	6,051	£9,770,126	17,949	£13,228,918	£16,186,600	-18.27%	£5.7m National Contingency payment to Royal Marsden
Norfolk and Suffolk	6,302	£693,220	1,501	£537,358	1,564	£2,360,076	9,367	£3,590,654	£3,684,395	-2.54%	
N & E Yorks & N Lincs	2,260	£248,600	5,411	£1,937,138	1,553	£2,343,477	9,224	£4,529,215	£3,864,520	17.20%	Overall increase in Recruitment
N'land, Tyne & Wear	1,704	£187,440	8,378	£2,999,324	3,497	£5,276,973	13,579	£8,463,737	£6,427,705	31.68%	Overall increase in Recruitment, mainly Interventional
Peninsula	4,753	£522,830	5,618	£2,011,244	2,061	£3,110,049	12,432	£5,644,123	£5,290,045	6.69%	
South Yorkshire	6,293	£692,230	2,677	£958,366	1,351	£2,038,659	10,321	£3,689,255	£4,618,640	-20.12%	Overall increase in recruitment, but decrease in interventional recruitment
Surrey & Sussex	3,064	£337,040	4,060	£1,453,480	1,634	£2,465,706	8,758	£4,256,226	£2,906,005	46.46%	Overall increase in Recruitment
Thames Valley	3,425	£376,750	8,935	£3,198,730	2,880	£4,345,920	15,240	£7,921,400	£6,360,675	24.54%	Overall increase in Recruitment
Trent	2,431	£267,410	7,290	£2,609,820	3,074	£4,638,666	12,795	£7,515,896	£5,497,005	36.73%	Overall increase in Recruitment
West Anglia	6,321	£695,310	6,353	£2,274,374	5,089	£7,679,301	17,763	£10,648,985	£5,546,655	91.99%	Overall increase in Recruitment, also one study moving from Band 1 to Interventional
West Midlands (N)	6,737	£741,070	5,115	£1,831,170	1,543	£2,328,387	13,395	£4,900,627	£5,884,580	-16.72%	Overall decrease in Recruitment (two large studies closing NorSTOP and KNEPP)
West Midlands (S)	4,480	£492,800	1,843	£659,794	2,173	£3,279,057	8,496	£4,431,651	£3,666,020	20.88%	Overall increase in Recruitment
West Yorkshire	6,656	£732,160	8,399	£3,006,842	6,920	£10,442,280	21,975	£14,181,282	£7,603,505	86.51%	Overall increase in Recruitment, also large study moving from band 1b to Interventional
Western	9,952	£1,094,720	9,105	£3,259,590	6,346	£9,576,114	25,403	£13,930,424	£10,478,860	32.94%	Overall increase in Recruitment
<b>Grand Total</b>	<b>116,174</b>	<b>£12,871,525</b>	<b>144,681</b>	<b>£52,603,156</b>	<b>80,771</b>	<b>£123,709,042</b>	<b>341,626</b>	<b>£189,183,723</b>	<b>£156,436,696</b>	<b>20.93%</b>	

## Notes

This table represents the total proposed allocations by band, with the appropriate recruitment as the surrogate for this figure.

In summary, Table 6 outlines the overall increase in recruitment recorded in each of the allocated bands, and the subsequent budget implications:

**Table 6: Year on Year Variance - Recruitment and Cost**

	2009/10		2010/11		% variance	
	Recruitment	Cost	Recruitment	Cost	Recruitment	Cost
<b>Band 1 (Inc. Band 1a £9.445m)</b>	160,743	£13,108,040	116,174	£12,871,525	-27.73%	-1.80%
Observational	67,224	£16,427,102	144,681	£52,603,156	115.22%	220.22%
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*Notes*

2010/11 based on information correct as at 5 November 2009 (1 October 2008 - 30 September 2009 Actual Recruitment excluding Industry Studies) Band 1 in 2009/10 combines Band 1a and Band 1b data.

The total of £156,436,696 for 2009/10 also includes two payments from the national contingency, i.e. NIHR CRN CC and CCLG which are not included in the CLRN allocations.

The next step of the modelling was to add the activity based element to each of the CLRNs core management costs and per capita allocations, and these figures combined present the proposed CLRN annual budgets as summarised in Table 7.

Table 7: Proposed CLRN Budget 2010/11 (Excluding National Contingency)

CLRN	% of England Population	2009/10			2010/11			CLRN Budget 2009/10 £m	Proposed CLRN Budget 2010/11 £m	% Variance	Final CLRN Budget 2010/11 £m
		CLRN Core Team £m	Per capita allocation £m	Activity based allocation 09/10 £m	CLRN Core Team £m	Per capita allocation £m	Activity based allocation 10/11 £m				
B'ham & Black Country	4.10%	0.430	2.262	8.822	0.439	2.229	11.641	11.515	14.309	24.3%	12.897
Central & East London	5.50%	0.462	3.068	16.119	0.470	3.235	19.684	19.650	23.388	19.0%	21.025
Cheshire & Merseyside	4.70%	0.430	2.623	7.147	0.439	2.584	6.763	10.200	9.786	-4.1%	9.786
Co Durham & Tees Valley	2.30%	0.430	1.277	2.453	0.439	1.258	2.513	4.160	4.210	1.2%	4.210
Cumbria & Lancashire	3.90%	0.430	2.147	2.503	0.439	2.115	2.447	5.080	5.001	-1.6%	5.001
Essex & Hertfordshire	5.30%	0.430	2.975	3.209	0.439	2.931	3.739	6.614	7.109	7.5%	6.945
Greater Manchester	5.10%	0.430	2.858	7.859	0.439	2.816	11.765	11.148	15.020	34.7%	13.377
Hampshire & Isle of Wight	3.60%	0.430	2.003	6.587	0.439	1.973	7.644	9.020	10.056	11.5%	9.651
Kent & Medway	3.20%	0.430	1.789	1.250	0.439	1.763	2.046	3.470	4.248	22.4%	3.886
Leics, Northants & Rutland	3.20%	0.430	1.770	3.929	0.439	1.744	5.263	6.130	7.446	21.5%	6.866
London (NW)	3.70%	0.460	2.039	8.543	0.468	2.150	8.746	11.042	11.364	2.9%	11.364
London (S)	5.70%	0.461	3.153	16.187	0.469	3.323	13.229	19.800	17.021	-14.0%	18.100
Norfolk & Suffolk	2.70%	0.430	1.505	3.684	0.439	1.483	3.591	5.620	5.513	-1.9%	5.513
N & E Yorks & N Lincs	3.30%	0.430	1.835	3.865	0.439	1.808	4.529	6.130	6.776	10.5%	6.559
N'land, Tyne & Wear	2.80%	0.430	1.552	6.428	0.439	1.529	8.464	8.410	10.432	24.0%	9.419
Peninsula	3.20%	0.430	1.800	5.290	0.439	1.773	5.644	7.520	7.856	4.5%	7.856
South Yorkshire	2.60%	0.430	1.421	4.619	0.439	1.400	3.689	6.470	5.528	-14.6%	5.823
Surrey & Sussex	5.10%	0.430	2.851	2.906	0.439	2.809	4.256	6.188	7.504	21.3%	6.930
Thames Valley	4.20%	0.430	2.366	6.361	0.439	2.331	7.921	9.157	10.691	16.8%	9.798
Trent	5.30%	0.430	2.953	5.497	0.439	2.909	7.516	8.880	10.864	22.3%	9.946
West Anglia	2.90%	0.430	1.623	5.547	0.439	1.599	10.649	7.600	12.687	66.9%	9.120
West Midlands (N)	3.50%	0.430	1.933	5.885	0.439	1.904	4.901	8.248	7.244	-12.2%	7.423
West Midlands (S)	3.10%	0.430	1.734	3.666	0.439	1.708	4.432	5.830	6.579	12.8%	6.238
West Yorkshire	4.20%	0.430	2.344	7.604	0.439	2.309	14.181	10.378	16.929	63.1%	12.453
Western	6.80%	0.430	3.808	10.479	0.439	3.752	13.930	14.718	18.121	23.1%	16.484
<b>TOTAL</b>		<b>10.850</b>	<b>55.688</b>	<b>156.437</b>	<b>11.065</b>	<b>55.435</b>	<b>189.184</b>	<b>222.975</b>	<b>255.683</b>	<b>14.7%</b>	<b>236.669</b>

## Notes

Table 7 (on page 14) represents the total proposed allocations by band, with the appropriate recruitment as the surrogate for this figure.

KEY	
> 0%	
0% < -5%	
-5% <	

## 5. Application of Transitional Payments

The issue of stability for CLRN annual budgets was discussed on several occasions at the ABF National Reference Group and with the Strategic Direction Team. It is also an issue which the ABF Project Team has received feedback on from CLRN Senior Managers and colleagues across the NIHR CRN CC. Therefore as outlined in Table 7 each CLRN was RAG rated depending on the downward variance between their allocated budget in 2009/10 and that proposed in 2010/11.

There were 2 important considerations at this point of the ABF modelling process:

1. The general principle of ABF is that resource should follow activity and this will subsequently mean that CLRN budgets may go up and down. This principle provides the CLRN with many challenges and does introduce an element of risk, particularly when the CLRN (and Member Organisations) may find that their portfolio activity is decreasing. In practice, for individual staff members, the usual NHS re-deployment processes would need to be applied if staff could no longer be funded via CLRN. Staff-turnover and the shortage of staff for some specialist posts, for example, in pharmacy may provide the means of reducing this risk further. The creation of a flexible (redeployable) CLRN staffing pool to support portfolio studies, also helps to mitigate this risk.
2. The shared concern of the networks, of the prospect of significant changes in their allocations for 2010/11, leading to serious financial instability, and a consequent disincentive for their Member Organisations to support CLRN funded posts, or indeed CLRN funded activity. This would be especially unwelcome at this stage of the CLRN development, particularly as there are widespread and encouraging signs of progress being made by the network teams. Many CLRNs have invested in pools of research nurses and other disciplines to develop delivery capacity. The impact of that investment is still to be realised and could not realistically be evident within this initial phase. A significant number of NHS Trusts already need persuading to recruit to CLRN funded posts (perceived as short term and high risk) therefore to build on and develop NHS Engagement we need to take action to ensure their fears do not become a reality. The impact on P/TCRN LRN also needs to be considered as many rely on CLRN allocations for the provision of vital resource.

### 5.1 Capping of CLRN Annual Allocations

The CLRN budgets have been calculated on the basis of the ABF Project work, and the framework that stakeholders across the Clinical Research Networks have contributed to and accepted as a fair and transparent way forward. The implementation of a cap at a -5% maximum decrease (as outlined in the CRN Budget Proposal December 2009) was discussed at some length as part of the project governance arrangements, however given the restrictions on the budget for 2010/11 this has been amended following debate at the NIHR CRN CC Executive Board to -10%. There were only 3 CLRNs which generated a budget for 2010/11 at less than -10%, these were London South, South Yorkshire and West Midlands North.

The most significant change is the introduction of a +% cap to limit the annual increase of any one CLRN in the financial year 2010/11.

Table 8: CLRN Budget for 2010/11 with Capping at -10% and a Staged + % (5%, 7%, 12% and 20%)

CLRN	Total CLRN Budget 2009/10 £m	Total Proposed CLRN Budget 2010/11 (Dec '09) * £m	% Variance (2009/10 vs 2010/11 Budget)	Final CLRN Budget 2010/11 with Capping (March '10) ** £m	Variance (2009/10 vs Final 2010/11 Budget) £m	% of Total Budget
B'ham & Black Country	£11.515	£14.309	24.3%	£12.897	£1.382	5.45%
Central & East London	£19.650	£23.388	19.0%	£21.025	£1.375	8.88%
Cheshire & Merseyside	£10.200	£9.786	-4.1%	£9.786	-£0.414	4.14%
Co Durham & Tees Valley	£4.160	£4.210	1.2%	£4.210	£0.050	1.78%
Cumbria & Lancashire	£5.080	£5.001	-1.6%	£5.001	-£0.079	2.11%
Essex & Hertfordshire	£6.614	£7.109	7.5%	£6.945	£0.331	2.93%
Greater Manchester	£11.148	£15.020	34.7%	£13.377	£2.230	5.65%
Hampshire & Isle of Wight	£9.020	£10.056	11.5%	£9.651	£0.631	4.08%
Kent & Medway	£3.470	£4.248	22.4%	£3.886	£0.416	1.64%
Leics, Northants & Rutland	£6.130	£7.446	21.5%	£6.866	£0.736	2.90%
London (NW)	£11.042	£11.364	2.9%	£11.364	£0.322	4.80%
London (S)	£19.800	£17.021	-14.0%	£18.100	-£1.700	7.65%
Norfolk & Suffolk	£5.620	£5.513	-1.9%	£5.513	-£0.107	2.33%
N & E Yorks & N Lincs	£6.130	£6.776	10.5%	£6.559	£0.429	2.77%
N'land, Tyne & Wear	£8.410	£10.432	24.0%	£9.419	£1.009	3.98%
Peninsula	£7.520	£7.856	4.5%	£7.856	£0.336	3.32%
South Yorkshire	£6.470	£5.528	-14.6%	£5.823	-£0.647	2.46%
Surrey & Sussex	£6.188	£7.504	21.3%	£6.930	£0.743	2.93%
Thames Valley	£9.157	£10.691	16.8%	£9.798	£0.641	4.14%
Trent	£8.880	£10.864	22.3%	£9.946	£1.066	4.20%
West Anglia	£7.600	£12.687	66.9%	£9.120	£1.520	3.85%
West Midlands (N)	£8.248	£7.244	-12.2%	£7.423	-£0.825	3.14%
West Midlands (S)	£5.830	£6.579	12.8%	£6.238	£0.408	2.64%
West Yorkshire	£10.378	£16.929	63.1%	£12.453	£2.076	5.26%
Western	£14.718	£18.121	23.1%	£16.484	£1.766	6.96%
<b>TOTAL</b>	<b>£222.975</b>	<b>£255.683</b>	<b>15%</b>	<b>£236.669</b>	<b>£13.694</b>	

## Notes

\* The Total Proposed CLRN Budget 2010/11 (Dec '09) is the initial proposal made to the Department of Health in December 2009, but now including the additional £15k per CLRN for additional host costs.

\*\* The Final CLRN Budget 2010/11 with Capping includes additional capping measures as outlined below:

## Key to Capping:

	reduction in budget - any budget reduction is limited to -10%
	0% to +10% variance equals 5% cap increase on Total Proposed Budget for 2010/11
	+10% to +20% variance equals 7% cap increase on Total Proposed Budget for 2010/11
	+20% to +30% variance equals 12% cap increase on Total Proposed Budget for 2010/11
	+30% and above variance equals 20% cap increase on Total Proposed Budget 2010/11

In addition to the sums outlined in the previous tables, an additional requirement for the CRN Budget requirements for 2010/11 was a review of the national contingency allocation.

## 6. National Contingency Allocation

### 6.1 Report on National Contingency 2009/10

For the financial year 2009/10 the national contingency was originally agreed at £34,401,475. This subsequently increased to £35,320,173 as outlined in Table 9.

This was to address the following costs:

- a. **Band 1a studies:** (studies with a recruitment pattern two standard deviations above the mean) which were to be costed on an individual basis and funded from the national contingency.
- b. **Band 4 studies:** (studies defined in 2009/10 as considered to be exceptionally complex or to have an exceptionally high associated cost). As with Band 1a studies a commitment was made to consider these on a case by case basis in response to demonstrable need. Note: These studies had already been allocated funding based on their presence in the Band 2 or 3 categories, and so it was intended that only additional funding requirements would be addressed through the National Contingency.
- c. The remainder of the national contingency was intended to provide for any other NHS service support costs incurred by NHS organisations in supporting NIHR CRN Portfolio studies that could not be met from existing allocations. In particular this recognised the incomplete nature of the NIHR CRN Portfolio activity database at the time of the 2009/10 modelling. This issue has been addressed in year through the ABF Tracker Budget, where monthly variances on a CLRN-by-CLRN basis have been identified and shared with the Department of Health.

For the first six months of the 2009/10 financial year, the ABF tracker budget demonstrated that the majority of CLRNs activity was following a steady trajectory and no adjustment to the budget was required. However for those networks which demonstrated a consistent trend (increase in recruitment of more than 10% over at least 3 consecutive months), a more detailed analysis was undertaken to identify how activity may have changed, for example through the resolution of CCRN portfolio pipeline studies and the inclusion of additional recruitment information. This analysis was the basis of a recommendation to the Department of Health for two CLRNs, and which resulted in additional funds being made available to these CLRNs (see Table 9, reference 003 and 004).

At the 2009/10 mid-year point, (and following the ABF reporting deadline of 16 October 2009) there was a noticeable increase in the level of completeness of recruitment reporting across all networks. A final ABF Tracker Budget report was therefore generated on 26 October 2009, and this highlighted a significant increase in recruitment for the period covered by the 2009/10 allocations.

The results of the October ABF Tracker Budget report were triangulated with the CCRN detailed mid-year returns, and their plans for providing support to their Member Organisations for the remainder of the financial year 2009/10. This robust and active management of the networks was the basis of the additional recommendations outlined in Table 9 (n=8, see reference 017 to 024).

Table 9 overleaf outlines the balance sheet for the 2009/10 national contingency fund, and provides an overview of the payments that have been made and a brief indication of the nature of these payments.

**Table 9: Summary Balance Sheet of National Contingency 2009/10**

Ref. No.	Description	Allocations	NIHR CRN CC Feedback	Department of Health Feedback
001	Band 1a studies costed on an individual basis for 20 CLRNs	£9,455,068	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
002	Norfolk and Suffolk CLRN - additional payment in response to Application One	£173,351	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
003	London (North West) CLRN Tracker Adjustment based on July 2009 Tracker	£1,558,910	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
004	London (South) CLRN Tracker Adjustment based on July 2009 Tracker	£1,074,385	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
005	London (South) CLRN Royal Marsden Additional Allocation	£5,700,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
006	Greater Manchester CLRN SWIFT Study Application	£40,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
007	Thames Valley CLRN Oxvalve Study Application	£437,516	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
008	Swine Flu GCP Training, CLRN & TCRN Network Support	£34,187	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
009	Central & East London National Prion Monitoring Cohort Study	£185,613	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
010	CCLG Network, Funding for CCLG Centres	£373,194	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
011	London (North West) CLRN CHAMP Study Application	£120,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
012	West Midlands South Trust Based Appointments, Thames Valley DRN Expansion	£139,564	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
013	London (North West) CLRN Edwards Study Application	£41,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
014	Hampshire and Isle of White CLRN, service support costs for multiple interventional studies	£16,167	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
015	Norfolk and Suffolk, PCRN Study delivery coordinator	£47,706	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
016	Central & East London request for support of new and ongoing studies	£6,542,673	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
017	Greater Manchester CLRN Tracker Adjustment based on revised tracker as at 26 October 2009, following ABF deadline	£480,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
018	Hampshire and Isle of White CLRN Tracker Adjustment based on revised tracker as at 26 October 2009, following ABF deadline	£490,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
019	London (North West) CLRN Tracker Adjustment based on revised tracker as at 26 October 2009, following ABF deadline	£2,680,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
020	London (South) CLRN Tracker Adjustment based on revised tracker as at 26 October 2009, following ABF deadline	£1,240,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
021	North and East Yorkshire and North Lincolnshire CLRN Tracker Adjustment based on revised tracker as at 26 October 2009, following ABF deadline	£360,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
022	Surrey & Sussex CLRN Tracker Adjustment based on revised tracker as at 26 October 2009, following ABF deadline	£290,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
023	West Yorkshire CLRN Tracker Adjustment based on revised tracker as at 26 October 2009, following ABF deadline	£220,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
024	Western CLRN Tracker Adjustment based on revised tracker as at 26 October 2009, following ABF deadline	£610,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
025	Norfolk & Suffolk CLRN application on behalf of Critical Care Local Speciality Group	£25,697	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health

Ref. No.	Description	Allocations	NIHR CRN CC Feedback	Department of Health Feedback
031	West Anglia CLRN, CFAS II (re-submitted application on behalf of Trent CLRN)	£45,685	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
032	Pilot scheme, impact of nurse specialists on recruitment into Surgery trials (National initiative backed by Dame Sally Davis and Peter Selby)	£25,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
034	Essex & Hertfordshire CLRN, RTQA payment 2009/10	£76,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
035	London (North West) CLRN, RTQA payment 2009/10	£43,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
036	Thames Valley CLRN, RTQA payment 2009/10	£13,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
037	Central and East London, Flu Watch study	£377,979	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
038	National Speciality Group Chairs payment 20 x £30,000	£600,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
039	Central & East London CLRN December Tracker Adjustment	£270,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
040	Greater Manchester CLRN December Tracker Adjustment	£150,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
041	Hampshire & Isle of Wight CLRN December Tracker Adjustment	£10,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
042	North & East Yorkshire & North Lincolnshire CLRN December Tracker Adjustment	£10,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
043	Surrey & Sussex CLRN December Tracker Adjustment	£10,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
044	Trent CLRN December Tracker Adjustment	£60,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
045	Western CLRN December Tracker Adjustment	£100,000	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
047	West Anglia CLRN, CFAS II (On behalf of Northumberland, Tyne & Wear CLRN)	£45,829	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
048	West Anglia CLRN, CFAS II (On behalf of West Anglia CLRN)	£48,094	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
049	South Yorkshire CLRN, KICKOFF	£10,450	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
050	Essex & Hertfordshire, Mental Health Application	£48,123	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
051	West Yorkshire CLRN - to support the following areas; Musculoskeletal Disease, Cardiovascular, Clinical Genetics and Renal & Urogenital	£1,041,982	Agreed & signed off by NIHR CRN CC	Agreed & signed off by Department of Health
	<b>Total Allocations 2009/10</b>	<b>£35,320,173</b>		

## 6.2 Proposal for National Contingency 2010/11

The national contingency has been restricted to £9,051,180 for 2010/11 and was also to address the £5m for Mental Health exceptional payments, therefore leaving a working balance of £4,051,180 from which a number of initiatives will be confirmed in quarter one of the new financial year. The proposals include the hyper acute stroke initiative (confirmed by the SRN CC at £1,264,494), and National Radiotherapy Trials Quality Assurance Centre (£737,883) and support for CCLG (£373,194). Therefore the remainder will be in the region of £1.6m and will be limited to supporting unanticipated in year costs and emergencies.

## 7. Total CRN Budget Requirement 2010/11

Taking all the different components of the CRN budgets into consideration we have outlined below in Table 10 the financial implications of the:

- Re-costing of the average band tariff (and in particular the increase in the Observational tariff of 47% based on the more robust costings exercise)
- Application of these tariffs to the actual recruitment data recorded for a full one year period on a per participant basis
- Inclusion of a small national contingency fund to address additional cost pressures which may arise within the financial year 2010/11

The ABF calculations for 2009/10 (1 April – 31 Oct 2008 prorated for the full year)

= total recruitment of 281,287 participants;

The ABF calculations for 2010/11 (1 October 2008 – 30 September 2009)

= total recruitment of 341,626 participants,

In conclusion, the proposed Clinical Research Network budget requirements for 2010/11 are as outlined above **£284,600,000**

**Table 10: CRN Budget Requirements 2010/11**

	2009/10 Allocation	2010/11 Allocation
TCRN LRNS	£36,439,366	£36,439,366
PCRN LRNS	£2,439,968	£2,439,968
CCRN	£222,975,021*	£236,669,486
National Contingency	Included in 2009/10 CCRN figure above	£9,051,180
<b>Total</b>	<b>£261,854,355</b>	<b>£284,600,000</b>

### Notes

\* This CCRN total figure for 2009/10 is the figure agreed by DH to be used for comparative purposes, and which does not take into account national contingency payments which were made for one year only.

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