

A guide to NIHR Clinical Research Network Funding at UCLH

Some background

UCLH has a strong track record in leading and hosting clinical research studies on the national portfolio. UCLH/UCL clinical research staff also have a strong track record in recruiting patients and other research subjects to these studies. UCLH accounted for the 33% (10.5k) of the total 31.8 k sector recruitment. UCLH has continued in 2012-13 to be the lead, accounting for 36% of portfolio.

The accessibility of the national portfolio to patients and the opportunity for all to take part in research are key components of the Government's strategy for the life sciences. It is essential that UCLH utilises the funding it receives for its national portfolio activity in a way that incentivises and supports our clinical investigators to efficiently maximise recruitment of patients to their studies and enables the Trust's divisions and departments to cover their costs of supporting the activity. .

The NIHR Clinical Research Network allocates funding to NHS Trusts, via Comprehensive Local Research Networks (CLRNs), to help Trusts meet the NHS Support costs of clinical research studies that are adopted onto a national portfolio.

UCLH is a member of the Central and East London CLRN and therefore receives its allocation of infrastructure funding to support its portfolio activities from there. The CEL CLRN has recently changed its method of allocating funding for NHS Support costs. Under the new system a greater proportion of the funds will be allocated directly to NHS Trusts in CEL for them to allocate to clinical divisions, service support departments and clinical researchers to support portfolio activity.

How much funding is UCLH getting from CEL CLRN this year?

UCLH has this year been awarded a total of £4.2m for the period April 2012 to March 2013. The funding allocation is made up of the following sums:

- £1.2m for **Activity based** studies. These are studies that were adopted onto the national portfolio before 1st April 2009.
- £2m for studies which were funded through the **CEL CLRN's contingency funding mechanism** in prior years. This includes studies funded through the Medicines for Children Research Network and the North London Cancer Research Network.
- £0.377m for the UCLH **Research Management & Governance Team**, consisting of Coordinators and administrators employed in the JRO, who support the research management processes of UCLH and a network of 5 other Trusts.
- A balance of £0.518m to be used for **UCLH Principal Investigator**-led new NIHR adopted studies, which will be going through the R&D approval system in the 2012-13 financial year.

What is the funding used for?

The total allocation must be used to cover the NHS Support costs of all ongoing and new NIHR portfolio studies running at UCLH. Specifically, the funding is used to cover NHS Support Costs.

1. What are NHS Support costs?

NHS Support costs are the additional patient care costs associated with research, which would end once the research activity in question had stopped, even if the same patient care continued to be provided. This might cover such things as extra blood tests, additional scans, nursing input.

What costs are not eligible for this funding?

- a. **Research Costs:** These are the core costs of the research itself and are met by the research funding organisation, typically a medical research charity, a research council or one of the NIHR's programme grant schemes. Research costs typically include the costs of staff who are specifically employed to carry out the research, such as Clinical Research Fellows and Research Nurses. In practice, it is helpful to think about these costs as being essential for the delivery of a research project.
- b. **Treatment Costs:** Like NHS Support Costs these are patient care costs in that they contribute to the care of the patient, but unlike NHS Support costs they are integral to the provision of the treatment or diagnostics regime. Treatment costs continue to be incurred if the patient care service in question continued to be provided after the research activity had stopped

2. Boundary between NHS costs & research costs

For most types of cost, the distinction is relatively straightforward. There are, however, some greyer areas. Nursing input to a study can, for example, exist as a research cost, NHS Support cost or even a treatment cost. Funding for staff who are integral to the delivery of the study (eg the Research Fellow or the Research Nurse) should come from the grant funding body. Funding for other posts that support the smooth running of the study and the efficient identification of patients could potentially come from CLRN research funding allocations.

Allocation of NHS Support Costs under the new system

1. Support for existing studies

For Studies which were adopted onto the portfolio prior to April 2009, funding has been allocated to the UCLH clinical division where the PI is based. (Appendix 1). The PI and the clinical division will agree on how the funds can be used to meet NHS support costs for NIHR adopted studies.

NHS Support funding for studies that were adopted after 1st April 2009 was allocated through the contingency funding mechanism outlined above. These funding awards were made as grants to clinical investigators.

For those studies which received funding under this mechanism, and are on-going (and for which an extension was agreed with the CEL CLRN), the funding for 2012 has been set aside by the CLRN and will be invoiced for by the JRO on behalf of the Award holders. This funding includes £985k which was directly awarded by the CEL CLRN, £766k through the North London Cancer Network and £91k through the Medicines for Children Research Network.

2. Support for new studies

For all new studies that are adopted onto the portfolio from 1st April 2012, the JRO will continue to cost all new NIHR portfolio studies as part of the application process for R&D approval for NHS Support costs.

The source of funding support for these new studies depends on who is leading the study:

- a. For new studies where the Chief Investigator is at UCLH/UCL, the Trust through the Joint Research Office can approach the CLRN for additional funding. The JRO will provide assistance with costing and a supporting statement required for the application.
- b. Where the Principal Investigator is at UCLH/UCL, funding for NHS Support costs will be provided via the JRO. In addition infrastructure requirements, such as nursing and Investigator time will be provided through newly established research support hubs as detailed below.

Any further infrastructure requirements will be directed to the CLRN's newly launched funding stream for strategic development.

The NHS Support costs of the new clinical research study will be determined from the information supplied on the SSI and R&D form as the primary source. The JRO finance team will liaise with the PI and research team throughout the process and inform them of the NHS Support costs. The award will initially be on annual basis, with commitment to funding the subsequent years.

The PI shall inform the JRO finance team once the study has commenced for the income to be transferred to the Clinical Departments and service support departments where the study is based. Income will not be transferred before commencement of a study.

On a monthly basis Investigators should upload patient recruitment (accrual) to the NIHR portal as set out in the conditions for NIHR adoption. The JRO will receive monthly reports from the CLRN and will review the status of recruitment to each study quarterly. Continued funding of the hubs will be dependant upon meeting anticipated recruitment targets, amongst other factors.

3. Infrastructure Support

These are costs that cannot reasonably be attributed to a single research project, but instead relate to groups of related studies. These groups of studies could be led by a single investigator or groups of investigators working in the same clinical division, perhaps researching similar patient groups.

This funding will build upon the contingency funding system put in place previously by CEL CLRN by providing targeted support for groups of investigators and promoting greater coordination and sharing of infrastructure support between and within groups of investigators to achieve common goals.

The funding will be used to facilitate the establishment of **Research Support Hubs** by funding the basic infrastructure to facilitate support of both new and existing researchers.

Key characteristics of Research Support Hubs are as follows:

- Named lead investigator, or local “research delivery champion” who will be responsible for managing the resource and agreeing with colleagues and clinical division how the resource will be accessible on a wider scale.
- Usually based on the clinical division structure, and therefore providing resource for the division’s portfolio.
- Stated case from the lead, in conjunction with his/her clinical division, describing the business plan for delivery of clinical research studies in the hub.
- Typically it is envisaged that the resource will be allocated for the purpose of improving recruitment timelines to NIHR portfolio studies and thus enabling PIs to meet their time to target responsibilities.
- Inclusive of past and current Portfolio activity and the potential to successfully deliver a portfolio of projects.

The JRO anticipates supporting 6-7 Research Support Hubs in the most research active clinical divisions. We are also considering supplementing the CLRN funding with Research Capability Funding to boost the support available for this activity. The list of the Hubs with the Leads will be published shortly.

We also suggest that the JRO “buy” an allocation within the support services for each hub. This will allow researchers within a hub access to the services.

The key to the success of this system is likely to be a collective, coordinated approach. This will offer Hubs a means of remaining joined up, succeeding and measuring their success, and arguing a case for resources. The new system will offer great opportunities for clinicians to contribute to research at many levels, all of them important and critical to success.