



ALLOCATION OF SESSIONAL SUPPORT FOR CLINICIANS OF ALL PROFESSIONS CONTRIBUTING TO NIHR PORTFOLIO STUDIES

GUIDANCE FOR CLRN CLINICAL DIRECTORS

1 Introduction and background

NIHR Comprehensive Local Research Networks (CLRN)s¹ have funding to meet the relevant costs of clinicians of all professions² who are engaged in UKCRN Portfolio research³ alongside their other clinical duties. The typical duties of these clinicians include: identifying patients eligible to participate in UKCRN Portfolio studies; explaining studies to patients; obtaining informed consent; the management of patients through the research process and research-related follow-up; local study management including adverse event reporting; communication and liaison with the study Chief Investigator and/or Clinical Trials Unit.

Accountability for the use and distribution of this funding lies with the Clinical Directors of the CLRNs. The intention is that the distribution of this funding within CLRNs should be related to research activity. The level of activity required to accrue patients to a study will clearly vary with the complexity of a study; for example, simple studies might involve taking consent, a blood test, and some simple data collection, whereas more complex studies might involve specialised psychosocial evaluations, or randomisation to novel therapies. Furthermore methods to fund clinician time within NHS organisations must reflect their diversity and varying needs.

For information, a model estimating the total time clinicians spend in delivering a study, including recruitment and follow up, for different types of studies, has been developed by Piers Kotting (DeNDRoN) for UKCRN (Annex 1). Piers' work identified two key domains for the classification of studies: patient characteristics and study design.

¹ <http://www.ukcrn.org.uk/index/networks/comprehensive.html>

² This stream of funding is available for clinicians of all professions acting to accrue and follow up patients in NIHR CRN Portfolio studies.

³ http://www.ukcrn.org.uk/index/clinical/portfolio_new/P_eligibility.html

Patient characteristics

Category A: Adults with no difficulties in relation to capacity, mental health, or communication

Category B: Adults with difficulties in relation to capacity, mental health, or communication, or children

Study design

Category 1: Surveys, sample collections, epidemiological studies

Category 2: Simple observational studies

Category 3: Complex observational and simple interventional studies

Category 4: Complex, high-risk or hyperacute interventional studies

This model produced estimates for the numbers of patients per annum that, on average, might be expected to be recruited by a clinician in one 4-hour session per week, for a 40 week (working) year, in each of these categories. These estimates are presented in the table below.

	Study Category 1	Study Category 2	Study Category 3	Study Category 4
Patient category A	120	80	40	20
Patient category B	60	40	20	10

(It can be noted that this work – amongst other data – informed the planning for the NIHR CCRN 2008/09 budget, to the extent that it used a modelling assumption that the ‘average capacity’ of one clinician 4-hour session per week is to recruit 50 new patients per year and follow up existing patients).

2 Issues to consider in allocating this funding stream

Historically there have no clear and consistent arrangements for the distribution of funding to support clinicians to recruit patients in to trials and to follow them up.

A range of options exist for the allocation of this new funding stream for sessional support to ensure the delivery of NIHR portfolio studies across UKCRN. It is recognised that there will have to be flexibility and a clear link will have to be maintained between the allocation of these resources and research performance. Allocations must be made by CLRN Clinical Directors on the basis of local knowledge and with the involvement of NHS organisations and TCRN/PCRN local research networks.

The primary purpose is to reimburse the NHS, i.e. a clinician’s employing trust/organisation, for the additional time taken (above standard patient care) to participate in NIHR portfolio studies, for example:

- To discuss, consent, and perform trial related procedures at trial enrolment
- For study follow up activities
- For additional interventions
- Study-related administration
- GCP training sessions
- Trial specific meetings, launch, follow on, site set up.

3 Potential models of allocation

A number of potential models of funding allocation are described below, which provide a range of options in providing support for these activities. It would be expected that CLRNs would adopt whichever model was most appropriate on a case-by-case basis, and therefore that a diversity of models would be used within an individual CLRN.

3.1 Research active teams

Recent evidence from the Upper GI MDT in Bristol from Stephen Falk analysing recruitment into OE05 trial for adenocarcinoma of the oesophagus shows that from the first discussion at the MDT 70% of patients may be identified as eligible for this trial and that clinical nurse specialists, surgeons, endoscopists, and other members of the MDT, therefore mention the study to patients and encourage participation in advance of the clinic appointment to discuss treatment and trial entry. Stephen concluded that is possible that by implementing a system of individual reimbursement that the team effort to enter patients into trials will be jeopardised.

An allocation may be made to a research team for which the entire team is accountable and the use of resources is explicit. Such funding may be broadened to a clinical department of directorate, or to an entire NHS organisation, if linked clearly and transparently to research performance. The model of funding sessions to a group may be most relevant for large NHS trusts, or for stable or high recruiting areas within the portfolio, or where research is embedded in the culture of routine practice, e.g. NCRN.

Similarly, an allocation may be made to a primary care organisation such as a general practice. Where appropriate, such allocations should reflect the use of hub and spoke models where spoke practices refer into studies being conducted in the hub. Spoke practices will need to be funded to carry out the activities that occur at that site, such as searches of clinical records, initial contact with potential participants, and any contingent follow-up.

3.2 Research active individuals

The provision of an allocation to support the activities of a specific individual(s), as opposed to a group of individuals may be the most appropriate approach in many situations. This may include providing support to:

- Research active individuals recruiting into NIHR portfolio studies within organisations that have low levels of research activity.
- Individuals who have particular expertise and are performing highly specialised research.
- NHS organisations or individuals that participate in research only on an occasional basis, or only for a specific study.

4 NIHR Flexibility and Sustainability Funding

Network-related NIHR Flexibility and Sustainability Funding (FSF) can be used as an additional source of funding to support clinicians participating in, or intending to participate in, UKCRN Portfolio research. NIHR FSF is intended to support flexibility and sustainability in the network workforce. It should not be used as the long-term, primary source of funding for any individual, and therefore NIHR FSF should be attached to an individual for a

specified period of time (usually no more than 1 year). Further guidance on the use of NIHR FSF can be found at http://www.ukcrn.org.uk/index/networks/comprehensive/resource_library/misc.htm

5. Examples of different systems

We shall be collating examples of different systems of allocation of sessional support from CLRNs as these are developed and implemented, and will include them in a revised version of this paper. One such paper, from the Northumberland, Tyne and Wear CLRN, is attached as Annex 1. We would be interested in receiving further examples, and any general comments on this work-in-progress.

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