

# Eligibility for inclusion of studies in the NIHR Clinical Research Network Portfolio

## Introduction

- 1.1 The purpose of this paper is to set out the criteria governing the eligibility of studies for inclusion in the NIHR Clinical Research Network Portfolio (the Portfolio). It therefore relates only to England.
- 1.2 The aims and purpose of the NIHR Clinical Research Network (NIHR CRN) are set out in *Best Research for Best Health* Implementation Plans 5.1 and 5.1a ([www.dh.gov.uk/research](http://www.dh.gov.uk/research)). The NIHR Clinical Research Network is the English component of the UK Clinical Research Network (UKCRN)
- 1.3 It is important to note that in future the NIHR CRN will be the only route for access to NHS Service Support Costs in England (together with more targeted support for specific infrastructure awards including Experimental Medicine Facilities, Biomedical Research Centres and Units, and Technology Platforms) – ‘NHS Support for Science Funding’ allocations to organisations providing NHS services will no longer exist. Studies that are accepted for inclusion in the Portfolio will therefore have automatic access to NHS Service Support Costs via the NIHR CRN, and access to Treatment Costs via the normal arrangements for commissioning patient care. Studies that are not in the Portfolio will not have automatic access to Service Support Costs and will not have automatic access to the resources, including active research management, of the UKCRN.
- 1.4 Arrangements for the provision of the Treatment Costs of research are not changing and remain the responsibility of the NHS as exercised by Primary Care Trusts performance managed by Strategic Health Authorities<sup>1</sup>.
- 1.5 It is expected that all high quality research that involves NHS patients and/or resources, and that is funded by the NIHR and its Partners, will be included in the Portfolio.

## 2 Definition of ‘study’

- 2.1 A research study is a structured activity which is intended to provide new knowledge which is generalisable (i.e. of value to others in a similar situation) and intended for wider dissemination<sup>1</sup>. This includes research funded by the NIHR that requires NHS Service Support, but it excludes

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<sup>1</sup> HSG(97)32 Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS

audit, needs assessments, quality improvement and other local service based work. Research involving NHS patients requires review by a Research Ethics Committee.

- 2.2 The main role of the NIHR CRN is to support later-phase clinical trials and other well-designed studies. The NIHR supports Experimental Medicine studies primarily through Clinical Research Facilities, Experimental Cancer Medicine Centres, and Biomedical Research Centres and Units. However, those Experimental Medicine studies funded by our Partners but conducted in the NHS outside these centres will have the necessary NHS Service Support provided by the NIHR CRN.

### **3. Eligibility and priority of studies**

All studies must already have full research funding before they can be included in the Portfolio. Research Costs cannot be provided by the UKCRN.

The resources needed to carry out research, both NHS service support and patient availability, are finite. To enable the Government to meet its commitment to provide the necessary NHS Service Support Costs of its own and its Partners' research, whilst also allowing other important research to be undertaken within the Network, this document lays out the method for determining eligibility for inclusion in the NIHR CRN portfolio and then prioritising eligible studies. The principal determinant of priority will be the source of research funding.

It is possible that there may be times when the portfolio becomes relatively full. At such times, it will be important that NIHR CRN effort on studies with the highest priority is not diminished. Studies with a lower priority can still receive NIHR CRN support but patient accrual may take a little longer

#### **3.1 Studies that have a high priority**

- a) Studies that are automatically eligible and that have a high priority for NIHR CRN support are studies that have the majority of their research funding provided by the NIHR, other areas of Government, and NIHR non-commercial Partners, including cancer studies agreed by CTAAC. NIHR non-commercial Partners are those organisations that:
- i) award research funds as a result of open competition across England with high quality peer review; and
  - ii) fund research that is of clear value to the NHS; and

- iii) take account of DH and NHS priorities and needs in their research funding strategies

The Government is committed to providing the necessary NHS Service Support Costs of its Partners' research. Therefore there should be no need for there to be any prioritisation of NIHR Partner's studies on the basis of the necessary costs of support.

Individual studies funded as part of programme grants, or as part of research training awards, will need to have their research protocols properly peer reviewed before they can be included in the Portfolio.

- b) One of the aims of the NIHR CRN is to facilitate studies of benefit to patients that are sponsored by industry. A specific adoption process has therefore been developed by the UKCRC Industry Road Map Group to enable these studies to be part of the Portfolio<sup>2</sup>. Studies that are accepted into the Portfolio in this way involve full cost recovery from industry.

### 3.2 Studies that have a medium priority

These studies require formal consideration prior to acceptance on the NIHR CRN Portfolio. The eligibility criteria are as set out in 3.1a. Two types of studies will be given a medium priority:

- a) Studies funded by overseas governments (e.g. US NIH, EU Framework Programmes).
- b) Studies that are initiated by non-commercial investigators (e.g. University or NHS staff) with the majority of the research funding being provided by a commercial organisation (e.g. a pharmaceutical, biotechnology or devices company) specifically to support that study. Contracts for such studies should include provision for the investigator to take responsibility for analysis, interpretation and publication of findings. This investigator-initiated commercial collaborative research includes pilot studies and nested exploratory studies. It is recognised that commercial organisations do not usually award this funding by means of a structured competition. Nevertheless, to be eligible for inclusion in the Portfolio, the potential field of researchers who could be awarded the funding must not have been restricted to specific Universities or NHS Trusts within England. In other words the funding must be open to all qualified researchers in England to apply for. It is also essential that all investigator-initiated commercial collaborative studies must have been subjected to high quality peer review before they can be included in the Portfolio. Peer review should be commensurate with the size and complexity of the study. Small local studies

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<sup>2</sup> It is recognised that this process has been developed primarily with pharmaceutical and biotechnology studies in mind. Work is ongoing assess the fitness for purpose of this process for the full range of medical devices studies.

will generally be offered methodological review by NIHR Research Design Services and priority review by a relevant AMRC member. Large multicentre studies may be reviewed by the NIHR HTA Programme.

### 3.3 Studies that have a lower priority

These studies require formal consideration prior to acceptance on the NIHR CRN Portfolio.

Certain other high quality studies may merit NHS Service Support (e.g. EORTC studies). The research funders of such studies will be considered formally in relation to the criteria set out in 3.1a. NIHR Local Research Networks that are performing well in supporting high priority studies may support these studies if sufficient capacity is available.

## 4 **Adoption Process**

A formal Adoption Process, the same as that used for industry sponsored studies (see 3.1 b), will be established to consider the eligibility of studies under 3.2 and 3.3 for inclusion in the Portfolio and the capacity of individual local research networks to undertake these studies. The UKCRN will manage the Adoption Process on behalf of the Department of Health. The Adoption Process, together with other rigorous checks leading to a single sign-off, will enable the NHS and others to know that a study has been approved on behalf of the Secretary of State for the various kinds of support that the NIHR provides.

**Department of Health  
January 2008**