

Eligibility Criteria for NIHR Clinical Research Network Support

Introduction

- 1.1 The purpose of this paper is to set out the criteria governing the eligibility of studies for NIHR Clinical Research Network (NIHR CRN) support. It therefore relates only to England.
- 1.2 Details of the aims and purpose of the NIHR Clinical Research Network can be found at:
<http://www.nihr.ac.uk/files/pdfs/Briefing%20documents/4.1%20Clinical%20Research%20Network.pdf>
The NIHR Clinical Research Network is the English component of the UK Clinical Research Network (UKCRN).
- 1.3 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 the NIHR or its Partners but conducted in the NHS outside these centres will have the necessary NHS Support provided by the NIHR CRN.
- 1.4 The NHS is responsible for meeting the Treatment Costs of research via the normal arrangements for commissioning patient care¹.

2 Definition of 'research study'

- 2.1 Research can be defined as the attempt to derive generalisable (i.e. of value to others in a similar situation) new knowledge by addressing clearly defined questions with systematic and rigorous methods². This excludes: audit; needs assessments; quality improvement and other local service evaluations. It also excludes routine banking of biological samples or data except where this activity is integral to a self-contained research project designed to test a clear hypothesis. NHS Research Ethics Committee approval and NHS permission are prerequisites for research to be supported via the NIHR CRN.
- 2.2 The Study Sponsor (as defined by the *Research Governance Framework for Health and Social Care*) has the formal responsibility for confirming that

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http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcircul ars/Healthserviceguidelines/DH_4018353

² Research Governance Framework for Health and Social Care. Second edition, 2005
(http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/AtoZ/Researchgovernance/DH_4002112)

a study is 'research'.

- 2.3 The definition of a research study as set out above applies to all studies for which NIHR Clinical Research Network support is sought regardless of the research funder.

3. Eligibility for NIHR CRN support

- 3.1 All studies must already have full research funding (i.e. funding to meet all research costs as defined in HSG (97)32) before they can be considered for NIHR CRN support.
- 3.2 The source of research funding is the principal determinant of eligibility for NIHR CRN support.

Automatically eligible studies

- 3.3 Studies that are automatically eligible for consideration for NIHR CRN support are studies that are funded by the NIHR, other areas of central Government, and NIHR non-commercial Partners.
- 3.4 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 (definitions are set out in Appendix I); and
 - ii) Fund research that is of clear value to the NHS; and
 - iii) Take appropriate account of the priorities, needs and realities of the NHS in making decisions about the research that they fund.
- 3.5 NIHR non-commercial Partner status is confirmed via a self-declaration process. NIHR non-commercial Partners are required to sign a self-declaration that they meet the criteria set out in 3.4, and to confirm the funding streams that are applicable. Non-commercial funding organisations that self-declare as NIHR non-commercial Partners may be audited to ensure that they meet the criteria. The list of NIHR non-commercial Partners, which is regularly updated, is available on the NIHR CRN Co-ordinating Centre website <http://www.crncc.nihr.ac.uk/>
- 3.6 Individual studies funded as part of programme or centre grants, or as part of research training awards, will be required to have undergone protocol peer review before they can be considered for NIHR CRN support (see Appendix I for the definition of high quality peer review). The study Sponsor should provide confirmation of appropriate peer review.
- 3.7 A non-commercial study supported by multiple funders is automatically eligible for NIHR CRN support if one of the funders is the NIHR, other areas

of central Government or an NIHR non-commercial Partner.

- 3.8 Studies where the funder providing the research costs is different from the funder managing the funding competition, including the peer review process, will have their eligibility determined by the funder responsible for managing the funding competition.

Potentially eligible studies

- 3.9 'Potentially eligible' studies require formal consideration via the Adoption Process. The NIHR CRN manages the Adoption Process for both commercial and non-commercial studies on behalf of the Department of Health.

- 3.10 Five types of studies require adoption:

- Commercial contract research (industry-funded, industry-sponsored studies)
- Investigator-initiated, commercial-collaborative studies (Industry-funded, non-industry sponsored studies)
- Non-commercial studies funded by overseas governments
- Non-commercial studies funded by overseas charities
- Certain other high quality studies (see 3.15)

- 3.11 **Commercial contract research.** 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 was developed by the UKCRC Industry Road Map Group to enable these studies to access NIHR CRN support³. Studies that are eligible for NIHR CRN support require full cost recovery from industry i.e. recovery of the cost of activities that are additional to treatment outside the context of the study including NHS Support Costs.

- 3.12 **Investigator-initiated, commercial collaborative studies** are 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

³ It is recognised that this process has been developed primarily with pharmaceutical and biotechnology studies in mind. Work is ongoing via the NIHR CRN Process Testing Group to assess the fitness for purpose of this process for a range of medical devices studies.

for NIHR CRN support (and for the NHS to meet the Treatment Costs, including Excess Treatment Costs, of the study), the potential field of researchers who could be awarded the funding must not have been restricted to specific Universities or NHS Trusts within England. Funders of investigator-initiated, commercial collaborative studies are required to provide the NIHR CRN Co-ordinating Centre with written confirmation that the funding opportunity was open to all qualified researchers in England.

It is also essential that all investigator-initiated commercial collaborative studies must have been subjected to high quality peer review before they can be considered for NIHR CRN support. Peer review should be commensurate with the size and complexity of the study. The study Sponsor should provide confirmation of appropriate peer review.

- 3.13 **Non-commercial studies funded by overseas governments** will be considered for NIHR CRN support via the Adoption Process.
- 3.14 **Non-commercial studies funded by overseas charities** will be considered for NIHR CRN support via the Adoption Process.
- 3.15 **Certain other high quality studies** funded by any source of funding not mentioned above, but which appear to meet the criteria set out in 3.4 will be considered for NIHR CRN support via the Adoption Process.

4 Assessing need for NIHR CRN support

- 4.1 It is the responsibility of the relevant Local Research Network (Comprehensive, Topic Specific or Primary Care) to consider a study's requirement for NIHR CRN support at each site. This process will be co-ordinated by the Lead Network⁴ on behalf of the Chief Investigator. This assessment will be made only for studies that have been accepted as eligible for NIHR CRN support by the NIHR CRN Co-ordinating Centre (as set out in sections 2 and 3). For multi-centre studies the NIHR CRN support required may vary across Local Research Networks and sites.
- 4.2 Timely reporting of recruitment data to the NIHR CRN Co-ordinating Centre by the Chief Investigator or their team, and acknowledgement of Network support in relevant publications, are conditions of accessing NIHR CRN support.

5 Prioritisation of NIHR CRN support

- 5.1 The resources needed in the NHS to support research, both NHS Support and availability of suitable/appropriate patients, are finite. To enable the

⁴ A description of the Lead Network is available via http://www.crnc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Networks/CCRN/Documents/guidance_lead_network_service_may2010.pdf

Government to meet its commitment to provide the necessary NHS Support for its own and its Partners' research, whilst also allowing other important research to be undertaken within the Network, there is a need to prioritise eligible studies. When resources are stretched it is 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 recruitment may take a little longer.

High priority studies

5.2 Studies that have a high priority for NIHR CRN support are those studies that are:

- a) Funded by the NIHR, other areas of central Government or an NIHR non-commercial Partner or
- b) Adopted commercial contract research

The Government is committed to providing the necessary NHS Support for its non-commercial Partners' research therefore there should be no need for there to be any prioritisation of NIHR Partner studies on the basis of the costs of support.

Medium priority studies

5.3 Studies that have a medium priority for NIHR CRN support are those studies that are:

- a) Funded by overseas governments; or
- b) Investigator-initiated commercial collaborative studies

Low priority studies

5.4 Studies that have a low priority for NIHR CRN support are those studies that are:

- a) Funded by overseas charities; or
- b) Funded by any source of funding not mentioned above, but which meet the criteria set out in 3.4

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Definitions of the criteria for ‘NIHR non-commercial Partner’

1. 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 appropriate account of the priorities, needs and realities of the NHS in making decisions about the research that they fund.

Open competition

2. Open competition ensures that the best range of researchers is able to apply for the funding. Open competition is defined by:
 - a) The competition being open to all appropriately qualified individuals, and
 - b) Knowledge of the competition being available to all appropriately qualified individuals, and
 - c) The research funder being completely independent of the recipient organisation.

High quality peer review

3. Peer review must be independent, expert, and proportionate:
 - a) **Independent:** At least two individual experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators’ host institution and not involved in the study in any way. Reviewers do not need to be anonymous.
 - b) **Expert:** Reviewers should have knowledge of the relevant discipline to consider the clinical and/or service based aspects of the protocol, and/or have the expertise to assess the methodological and statistical aspects of the study.
 - c) **Proportionate:** Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher level (more reviewers with broader expertise and often independent review committee or board), and potentially international peer review. Small single-centre studies and investigator-initiated commercial collaborative studies still require expert and independent peer review but this might be arranged through the institutions R&D office (as required by the NHS Research Governance Framework for England and Wales). If the R&D office is unable to undertake the review, the NIHR CRN Co-ordinating Centre will arrange a review via the NIHR Health Technology Assessment Programme or the NIHR Research Design Service, dependant on the size of the study.

Clear value to the NHS

4. This requirement is specified in the ‘Statement of partnership on non-commercial R&D in the NHS in England’ (Annex B of ‘Responsibilities for meeting the Patient care Costs associated with Research and Development in the NHS’, HSG(97)32). As part of the self-declaration as an NIHR non-commercial Partner, funding organisations are required to confirm that the research they fund is of clear value to the NHS.