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 [NIHR Clinical Research Network](https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm) (Cited 15 Mar 2023).

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 its 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 requirements for research to be supported via the NIHR CRN.

2.2 The Study Sponsor (as defined by the UK Policy Framework for Health and Social Care Research) has the formal responsibility for confirming that 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 and in compliance with the AcoRD guidance) before they can be considered for NIHR CRN support3.

3.2 NIHR CRN support for non-commercial studies includes meeting the NHS Support Costs of these studies. As these are funded via the public purse, non-commercial studies seeking NIHR CRN support must also meet the requirements detailed in Appendix 1.

3.3 The source of research funding is the principal determinant of eligibility for NIHR CRN support.

***Automatically eligible non-commercial studies***

3.4 Studies that are automatically eligible for consideration for NIHR CRN support are those that are funded by the NIHR, other areas of central Government and NIHR non-commercial Partners, which meet the definition of ‘research’ as defined in 2.1.

3.5 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 1); 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.

3.6 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 for NIHR CRN support, which includes NHS Support Costs (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.

3.7 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.

3.8 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.

3.9 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 non-commercial studies***

3.10 ‘Potentially eligible’ non-commercial studies undergo additional eligibility checks to ensure the study meets the criteria described in section 2.1 and 3.5 (definitions in Appendix 1) via the non-commercial adoption process. The NIHR CRN manages the non-commercial adoption process on behalf of the Department of Health

3.11 The following types of non-commercial studies are considered potentially eligible:

• 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 3.14) 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 for NIHR CRN support, which includes NHS Support Costs (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 non-commercial Adoption Process.

3.14 **Non-commercial studies funded by overseas charities** will be considered for NIHR CRN support via the non-commercial 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 3.5 will be considered for NIHR CRN support via the non-commercial Adoption Process.

***Potentially eligible commercial contract research***

3.16 The aims of the NIHR CRN include facilitating high quality studies of benefit to patients that are funded and sponsored by the life-sciences industry, strengthening research collaboration with industry and ensuring that the NHS can meet the health research needs of industry. This includes meeting regulatory requirements. In order to be eligible for NIHR CRN support, the study must meet the definition of ‘research’ as defined in section 2.1 and the study must receive NHS Research Ethics Committee approval and NHS permission prior to initiation at individual sites. If the study is eligible, the NIHR CRN will work with the study sponsor to determine feasibility within England. This will focus on site interest, capability to deliver and recruitment targets. If the study is both eligible and feasible within England, it will receive NIHR CRN support. NIHR CRN manages the Eligibility Review process for commercial contract research on behalf of the Department of Health.

3.17 Pharmacovigilance studies and other post authorization safety studies required by regulatory authorities that meet these criteria are in scope. This is in keeping with NIHR's mission to improve the health and wealth of the nation (growth) through research. Studies whose primary objective is to support product marketing will not be eligible for the NIHR CRN portfolio.

3.18 Studies that are eligible for NIHR CRN support require full funding from industry i.e. funding of the activities that are additional to treatment outside the context of the study, including funding for all Research Costs and NHS Support Costs.

**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 Main 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 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 eligible and feasible studies that are:

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

b) 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 non-commercial 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 eligible and feasible 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 eligible and feasible 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 3.5

**Department of Health**

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More information on [Department of Health and Social Care Eligibility Criteria](https://www.nihr.ac.uk/documents/researchers/collaborations-services-and-support-for-your-research/run-your-study/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support.pdf) (Cited 15 Mar 2023)

**APPENDIX 1**

**Definitions for non-commercial studies seeking NIHR CRN support, which includes support to meet NHS Support Costs**

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 review5.

**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.