



Department
of Health &
Social Care

Eligibility Criteria for NIHR Clinical Research Network Support

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1. 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. The NIHR CRN Portfolio of studies consists of research studies that are eligible for support from the NIHR CRN in England. Studies are required to meet these eligibility criteria to be accepted onto the portfolio and throughout the duration of their delivery.
- 1.3. Studies are also required to comply with the Terms and Conditions for NIHR Clinical Research Network Support¹ and acknowledge NIHR CRN support in relevant publications.
- 1.4. Details of the aims and purpose of the NIHR Clinical Research Network can be found at: <https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm>
- 1.5. The main role of the NIHR CRN is to provide support for the initiation and delivery of high-quality research which benefits patients and the NHS, including relevant research carried out in social care, care homes, hospices, or public health settings. This includes randomised controlled clinical trials of interventions (eg. prevention, diagnosis, treatment and care studies) and other well-designed research. The NIHR CRN provides this support through:
 - The NIHR CRN Study Support Service² – a standard national framework for supporting the planning, set-up and delivery of high-quality research in England
 - Providing NHS organisations with funding to meet NHS Support Costs as defined by AcoRD³
 - Providing NHS organisations with funding to meet Part B Research Costs, where relevant, as defined by AcoRD³
 - Providing health and care delivery organisations with funding to meet the equivalent of NHS Support in non-NHS settings (eg. research carried out in social care, care homes, hospices, or public health settings)
 - Providing a mechanism for NHS organisations to access Excess Treatment Costs as defined by AcoRD³ where Integrated Care Systems (ICSs) are the responsible commissioner
 - Access to relevant research delivery training⁴, including Good Clinical Practice training

¹ <https://www.nihr.ac.uk/documents/eligibility-for-nihr-clinical-research-network-support/23746>

² <https://www.nihr.ac.uk/researchers/i-need-help-to-deliver-my-research/study-support-service>

³ <https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>

⁴ <https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/>

- ISRCTN registration⁵ via the Central Portfolio Management System⁶. Registration of non-commercial studies with an interventional component is funded by the Department of Health and Social Care (DHSC).

1.6. Note: The NHS is responsible for meeting the Treatment Costs of research, as defined by AcoRD³, via the normal arrangements for commissioning patient care.

2. Definition of ‘research study’

- 2.1. Research is defined in the UK Policy Framework for Health and Social Care Research⁷ as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. 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.
- 2.2. 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 study type or research funder.

3. Eligibility for NIHR CRN support

- 3.1. For a study to be considered for NIHR CRN support it must:
- meet the definition of research as defined in section 2.1 above; and
 - have appropriate ethical approval (eg. NHS REC, Social Care REC, or Ministry of Defence REC); and
 - have Health Research Authority (HRA) Approval where required; and
 - have either
 - full Research Cost funding for non-commercial studies in compliance with AcoRD³ guidance, or
 - full funding for all costs for commercial contract studies in compliance with AcoRD³ guidance.
- 3.2. NIHR CRN support for non-commercial studies includes meeting the NHS Support Costs (or equivalent in non-NHS settings) of these studies. As these costs are funded via the public purse, non-commercial studies seeking NIHR CRN support must also meet the requirements detailed below.
- 3.3. The source of research funding is the principal determinant of eligibility for NIHR CRN support.

⁵ <https://www.nihr.ac.uk/documents/isrctn-registration/11585>

⁶ <https://www.nihr.ac.uk/documents/integrated-research-intelligence-system/11634>

⁷ <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

Non-commercial studies funded by automatically eligible funding streams

- 3.4. Studies that are funded by the NIHR and/or other areas of central Government, and those which are funded by NIHR Non-commercial Partners, are automatically eligible for NIHR CRN support provided they meet the conditions set out in section 3.1.
- 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, social care or public health; and
 - iii. Take appropriate account of the priorities, needs and realities of the NHS, social care or public health, 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 3.5, 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 updated regularly, is available on the NIHR website⁸.
- 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 1 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 considered automatically eligible for NIHR CRN support if one of the funding streams 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.

Non-commercial studies funded by potentially eligible funding streams

- 3.10. Non-commercial studies which meet the conditions set out in sections 3.1 and 3.5 but are not funded by the NIHR, other areas of central Government, or an NIHR Non-commercial partner are potentially eligible to access NIHR CRN support following additional eligibility checks (definitions in Appendix 1) via the non-commercial extended review process. The NIHR CRN manages the non-commercial extended review process on behalf of the Department of Health and Social Care.

⁸ <https://www.nihr.ac.uk/documents/nihr-non-commercial-partner-list/11458>

- 3.11. The following types of non-commercial studies are considered potentially eligible for NIHR CRN support:
- 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 3.16).
- 3.12. Investigator-initiated, commercial collaborative studies are studies that are initiated by non-commercial investigators (eg. University or NHS staff) with research funding provided by a commercial organisation (eg. 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.
- 3.13. 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 (or equivalent in non-NHS settings); 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 Coordinating Centre with written confirmation that the funding opportunity was open to all qualified researchers in England.
- 3.14. It is also essential that all investigator initiated commercial collaborative studies must have been subjected to high quality peer review (definitions are set out in Appendix 1) 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.
- 3.15. Non-commercial studies funded by overseas governments and charities will be considered for NIHR CRN support via the non-commercial extended review process.
- 3.16. Certain other high-quality studies funded by any source of funding not mentioned above, but which meet the criteria set out in 3.5 will be considered for NIHR CRN support via the non-commercial extended review process.

Commercial contract research

- 3.17. The NIHR CRN aims to help the life sciences industry plan, set-up and deliver research in both the NHS and across the wider health and social care environment in England.

- 3.18. To be eligible for NIHR CRN support, the study must meet the definition of 'research' as defined in section 2.1 and meet the conditions set out in section 3.1 prior to initiation at individual sites.
- 3.19. If the study is deemed eligible, the NIHR CRN will determine feasibility across England via its NIHR CRN Study Support Service to confirm site interest and/or initiate an assessment of site capacity and capability to participate. If the study is both eligible and feasible within England, it will continue to receive NIHR CRN support.
- 3.20. 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 are not eligible for NIHR CRN support.
- 3.21. Industry-sponsored studies that are eligible for NIHR CRN support are able to access the NIHR CRN Study Support Service free of charge.
- 3.22. As set out in AcoRD³ and in 3.1 above, study related activities require full cost recovery from industry.

Studies supported by other NIHR Infrastructure (eg. Biomedical Research Centres)

- 3.23. The NIHR has other funding schemes which provide research infrastructure⁹ in the NHS and the associated NHS Support Costs for their early translational (experimental medicine), clinical research and applied health research (i.e. Biomedical Research Centres, Clinical Research Facilities for Experimental Medicine, Experimental Cancer Medicine Centres, Applied Research Collaborations, Translational Research Collaborations, Patient Safety Research Collaborations, and MedTech and In Vitro Diagnostics Cooperatives).
- 3.24. Studies which are fully funded by this NIHR Research Infrastructure, and within the contracted NHS/ University partnership and formal partners, will not receive additional funding support from the NIHR CRN except as set out in section 3.25 and 3.26 below.
- 3.25. NIHR CRN support may be required for multi-centre, non-commercial research, funded and supported by the NIHR Research Infrastructure, when an additional collaborating site/s (i.e. not the contracted NHS/ University partnership and formal partners) is involved and requires support.
- 3.26. NIHR CRN support will be available for eligible research studies funded and supported by NIHR Research Infrastructure when additional funding is awarded from NIHR research programmes, NIHR's Non-commercial Partners, UK Research and Innovation or other areas of central government.

⁹ <https://www.nihr.ac.uk/explore-nihr/support/research-infrastructure.htm>

4. Assessing need for NIHR CRN support

- 4.1. It is the responsibility of the relevant Local Clinical Research Network to consider a study's requirement for NIHR CRN support at each site. This will be initiated by deliverability assessments at the earliest opportunity in line with NIHR CRN Study Support Service. It is expected that a study is optimised for delivery i.e. both eligible and deliverable/feasible before support commences. For multi-centre studies the NIHR CRN support required and provided may vary across Local Clinical Research Networks and research sites, based upon need.

5. Prioritisation of NIHR CRN support

- 5.1. The resources needed to support research, both NIHR CRN support and the availability of suitable/appropriate individuals, are finite. To enable the Government to meet its commitment to provide the necessary NHS Support (or equivalent in a non-NHS setting) for its own and its Partners' research, whilst also allowing other important research to be undertaken within the NIHR CRN, 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.

5.2. **High priority studies** are:

- i. Funded by the NIHR, other areas of central Government or an NIHR Non-commercial Partner; or
- ii. Commercial contract research.

The Government is committed to providing the necessary NHS Support (or equivalent in a non-NHS setting) for its NIHR 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.

5.3. **Medium priority studies** are:

- i. Funded by overseas governments; or
- ii. Investigator-initiated commercial collaborative studies.

5.4. **Low priority studies** are:

- i. Funded by overseas charities; or
- ii. Funded by any source of funding not mentioned above, but which meet the criteria set out in 3.5.

Appendix 1

Definitions for non-commercial studies seeking NIHR CRN support, which includes support to meet NHS Support Costs (or equivalent in non-NHS settings)

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, social care, or public health; and
- iii. Take appropriate account of the priorities, needs and realities of the NHS, social care, or public health in making decisions about the research that they fund.

2. Open competition

Open competition ensures that the best range of researchers is able to apply for the funding. Open competition is defined by:

- i. The competition being open to all appropriately qualified individuals; and Knowledge of the competition being available to all appropriately qualified individuals; and
- ii. The research funder (organisation/ institution that awards the funds) being completely independent of the recipient (organisation/ institution that will receive the funds); and
- iii. The competition being open to all appropriate host organisations i.e. there is no geographical restriction on where, in England, the research can be undertaken, unless, the award is linked to a training post that is only available at a limited number of sites.

3. High quality peer review

Peer review must be independent, expert, and proportionate:

- i. Independent: At least two individual independent experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators' host institution, have no conflicts of interest¹⁰, and not involved in the study in any way. Reviewers do not need to be anonymous.
- ii. 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.
- iii. 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.

¹⁰ <https://www.nihr.ac.uk/documents/nihr-conflicts-of-interest-policy-funding-and-awards/25637>

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