



Department  
of Health &  
Social Care

# Eligibility Criteria for NIHR Research Delivery Network Support

Published October 2024

# Contents

1. Introduction .....	3
2. Definition of 'research study' .....	4
3. Eligibility for NIHR RDN support .....	4
Non-commercial studies funded by automatically eligible funding streams ...	5
Non-commercial studies funded by potentially eligible funding streams .....	5
Commercial contract research .....	6
Studies supported by other NIHR infrastructure .....	7
4. Assessing need for NIHR RDN support .....	8
5. Prioritisation of NIHR RDN support .....	8
Appendix 1 .....	9
Definitions for non-commercial studies seeking NIHR RDN support, which includes support to meet NHS Support Costs (or equivalent in non-NHS settings) .....	9

# 1. Introduction

- 1.1. The purpose of this paper is to set out the criteria governing the eligibility of studies for National Institute for Health and Care Research (NIHR) Research Delivery Network (RDN) support. It, therefore, relates only to England.
- 1.2. The NIHR RDN Portfolio of studies consists of research studies that are eligible for support from the NIHR RDN in England. Studies are required to meet these eligibility criteria to be accepted onto the NIHR RDN Portfolio and throughout the duration of their delivery.
- 1.3. Studies are also required to comply with the Terms and Conditions for NIHR RDN<sup>1</sup> and acknowledge NIHR RDN support in relevant publications.
- 1.4. Details of the aims and purpose of the NIHR RDN can be found at <https://rdn.nihr.ac.uk/about-us>
- 1.5. The main role of the NIHR RDN is to provide support for the planning and delivery of high-quality research, which benefits patients and the NHS, including relevant research carried out in non-NHS community, primary and residential settings. This includes clinical trials (e.g. prevention, diagnosis, treatment, and care studies), and other well-designed health and social care research studies. The NIHR RDN provides this support through:
  - The NIHR RDN Study Support Service<sup>2</sup> – a standard national framework for supporting the planning and delivery of high-quality research in England
  - Providing NHS organisations with funding to meet NHS Support Costs as defined by the Attributing the costs of health and social care research (AcoRD) framework<sup>3</sup>
  - Providing NHS organisations with funding to meet Part B Research Costs, where relevant, as defined by AcoRD<sup>3</sup>
  - Providing health and care delivery organisations with funding to meet the equivalent of NHS Support in non-NHS settings (e.g. 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 AcoRD<sup>3</sup> where Integrated Care Systems (ICSs) are the responsible commissioner
  - Access to relevant research delivery training<sup>4</sup>, including Good Clinical Practice training

---

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

2 <https://www.nihr.ac.uk/support-and-services/support-for-delivering-research/clinical-research-network/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/career-development>

- ISRCTN registration<sup>5</sup> via the Central Portfolio Management System<sup>6</sup>. The Department of Health and Social Care fund registration of non-commercial studies with an interventional component.

1.6. Note: The NHS is responsible for meeting the Treatment Costs of research, as defined by AcoRD<sup>3</sup>, 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 Research<sup>7</sup> 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 RDN support is sought regardless of the study type or research funder.

## 3. Eligibility for NIHR RDN support

3.1. For a study to be considered for NIHR RDN support it must:

- i. Meet the definition of research as defined in section 2.1 above; and
- ii. Have appropriate ethical approval (e.g. NHS Research Ethics Committee (REC), Social Care REC, or Ministry of Defence REC); and
- iii. Have Health Research Authority (HRA) Approval where required; and
- iv. Have either:
  - Full Research Cost funding for non-commercial studies in compliance with AcoRD<sup>3</sup> guidance, or
  - Full funding for all costs for commercial contract studies in compliance with AcoRD<sup>3</sup> guidance.

3.2. NIHR RDN 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

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

<sup>6</sup> <https://www.nihr.ac.uk/integrated-research-intelligence-system-including-cpms-lpms>

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

RDN support must also meet the requirements detailed below.

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

### **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 RDN Non-commercial Partners, are automatically eligible for NIHR RDN support provided they meet the conditions set out in section 3.1.

3.5. NIHR RDN 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 RDN Non-commercial Partner status is confirmed via a self-declaration process. NIHR RDN 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 RDN Non-commercial Partners may be audited to ensure that they meet the criteria. The list of NIHR RDN Non-commercial Partners, which is updated regularly, is available on the NIHR website<sup>8</sup>.

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 RDN 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 RDN support if one of the funding streams is the NIHR, other areas of central Government or an NIHR RDN 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.

---

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

## **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 RDN Non-commercial Partner are potentially eligible to access NIHR RDN support following additional eligibility checks via the non-commercial extended review process. The NIHR RDN manages the non-commercial extended review process on behalf of the Department of Health and Social Care.
- 3.11. The following types of non-commercial studies are considered potentially eligible for NIHR RDN 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 (e.g. University or NHS staff) with research funding 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.
- 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 RDN 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 RDN 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 RDN 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 RDN 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 RDN support via the non-commercial extended review process.

### **Commercial contract research**

- 3.17. The NIHR RDN aims to help the life sciences industry plan 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 RDN 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 delivery organisations.
- 3.19. If the study is deemed eligible and one or more delivery organisation/s within the health and care system in England confirms it has the required capacity and capability to participate, it will continue to receive NIHR RDN support providing it complies with the Terms and Conditions for NIHR RDN support<sup>1</sup>
- 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 RDN support.
- 3.21. Industry-sponsored studies that are eligible for NIHR RDN support are able to access NIHR RDN Support and Services.
- 3.22. As set out in AcoRD<sup>3</sup> and in 3.1 above, study related activities require full cost recovery from industry, in line with NHS England's National Directive for Commercial Contract Research where relevant.

### **Studies supported by other NIHR infrastructure**

- 3.23. The NIHR has other funding schemes, which provide research infrastructure<sup>9</sup> 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, Experimental Cancer Medicine Centres, Applied Research Collaborations, Translational Research Collaborations, Patient Safety Research Collaborations, and HealthTech Research Centres).<sup>10</sup>
- 3.24. Studies 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 RDN except as set out in section 3.25 and 3.26 below.
- 3.25. NIHR RDN 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

---

<sup>9</sup> <https://www.nihr.ac.uk/about-us/what-we-do/infrastructure>

<sup>10</sup> Commercial Research Delivery Centres will be in operation from 1 April 2025. These centres will provide additional capacity for the delivery of commercial clinical research.

formal partners) is involved and requires support.

- 3.26. NIHR RDN 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 RDN's Non-commercial Partners, UK Research and Innovation or other areas of central government.

## 4. Assessing need for NIHR RDN support

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

## 5. Prioritisation of NIHR RDN support

- 5.1. The resources needed to support research, both NIHR RDN 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 RDN, there is a need to prioritise eligible studies. When resources are stretched, it is important that NIHR RDN effort on studies with the highest priority is not diminished. Studies with a lower priority can still receive NIHR RDN 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 RDN 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 RDN Non-commercial Partners' research. Therefore, there should be no need for there to be any prioritisation of NIHR RDN Non-commercial Partner studies based on 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 RDN support, which includes support to meet NHS Support Costs (or equivalent in non-NHS settings)**

## **1. NIHR RDN 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 interest<sup>11</sup>, 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.

---

<sup>11</sup> <https://www.nihr.ac.uk/nihr-conflicts-interest-policy-funding-and-awards>

© Crown copyright 2024

[www.gov.uk/dhsc](http://www.gov.uk/dhsc)

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit [nationalarchives.gov.uk/doc/open-government-licence/version/3](http://nationalarchives.gov.uk/doc/open-government-licence/version/3).

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

