Department of Health & Social Care

NIHR | National Institute for Health and Care Research

DHSC Terms and Conditions for NIHR Research Delivery Network support

Updated December 2025

Contents

1. Introduction

1.1. This document sets out the Department of Health and Social Care's (DHSC) terms and conditions applicable to studies accepted onto the NIHR Research Delivery Network (NIHR RDN) Portfolio. It therefore relates only to NIHR RDN support for studies in England.

1.2. The expectations and requirements set out in these terms and conditions enable the NIHR RDN to monitor and manage a national portfolio of health and care research across England on behalf of the Department of Health and Social Care. They represent good portfolio management practice and enable effective allocation of resources to ensure as many studies as possible can be delivered and provide evidence to improve care and outcomes for UK citizens.

1.3. Studies accepted onto the portfolio should acknowledge RDN support in publication, ensuring that NIHR Visual Identity policy is followed.

1.4. Studies are required to meet the Department of Health and Social Care Eligibility Criteria for NIHR RDN support to be accepted onto the Portfolio and throughout the duration of its delivery. Details of the criteria can be found at https://www.nihr.ac.uk/eligibility-nihr-research-delivery-network-support

2. Responsible individuals and organisations

2.1. The UK Policy Framework for Health and Social Care Research[1] sets out principles of good practice in the management and conduct of health and social care research in the UK. The Framework details the responsibilities of specific individuals and organisations including chief investigators and research teams, funders, sponsors, Contract Research Organisations (CROs), research sites and principal investigators.

2.2. Acceptance of a study onto the NIHR RDN Portfolio, and provision of RDN support, as described in the DHSC Eligibility Criteria for NIHR RDN support, is intended to support individuals and organisations with responsibility for health and social care studies in conducting them effectively in the NHS and wider health and care system. Responsibility for the conduct and delivery of a study remains with the individuals and organisations that are legally accountable for them.

[1] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

2.3. The study sponsor has overall responsibility for compliance with these terms and conditions. Sponsors may delegate the actions necessary to comply with them to suitably qualified parties but retain overall responsibility for all aspects of the study and its delivery.

2.4. Details of the aims and purpose of the NIHR Research Delivery Network can be found at: https://www.nihr.ac.uk/support-and-services/support-for-delivering-research/research-delivery-network.

3. Terms and Conditions

3.1. Study Management Contact

3.1.1. To enable effective and ongoing communication regarding studies included in the NIHR RDN Portfolio, the sponsor is responsible for ensuring the NIHR RDN is provided with contact details of the appropriate study management contact (where sponsor has delegated activities) and that the information is maintained during the study lifecycle.

3.1.2. The NIHR RDN will endeavour to use IRAS information, as well as information provided within the non-commercial portfolio application or commercial submission, where possible to obtain sponsor and study management contacts.

3.1.3. Where the sponsor contact is different from IRAS submission, non-commercial portfolio application or commercial submission, the sponsor is responsible for providing an updated contact. It is important to note that ongoing inclusion of your study in the Portfolio may be affected if we do not hold appropriate contact details.

3.2. Contracting, costing and attribution

3.2.1. Sponsors are responsible for putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management in accordance with the UK Policy Framework.

3.2.2. Sponsors must ensure that the required templates and tools for contracting, costing and attribution are used, where relevant, for research studies applying for, or already included in, the NIHR RDN Portfolio as follows:

3.2.2.1. Commercial studies are required to use the online UK Interactive Costing Tool (iCT) which facilitates the UK National Contract Value Review (NCVR) process for transparent and streamlined costing and contracting. This is underpinned in England by the NHS standard contract and the National directive on commercial research studies with equivalent Devolved Administrations requirements in place for the rest of the UK and in accordance with UK AcoRD guidance.

3.2.2.2. Non-commercial studies are required to use the online UK Schedule of Events Cost Attribution Tool (SoECAT) process. The applicant must ensure that the SoECAT reflects the most recent version of the protocol for accurate cost attribution of the research project activities in accordance with UK AcoRD guidance.

3.2.2.3. All studies are required to use the model agreements as defined by the HRA/HRCW approval letter.

3.3. Minimum Data Set

3.3.1. To effectively monitor the national portfolio of studies, and achieve the aims set out in 1.2 above, a minimum data set is required at a study and site level as set out in Table 1 below. This minimum data set is required once a study has been deemed eligible to create a study record in the Central Portfolio Management System (CPMS) and include the study in the NIHR RDN Portfolio and must be maintained throughout the duration of the study.

3.3.2. Where available, NIHR RDN will utilise data provided via IRAS, NIHR RDN commercial submission or the NIHR RDN non-commercial portfolio application service. Where data is not available through these sources, or requires clarification, the NIHR RDN will contact the sponsor or delegated study management contact to confirm data points items following the eligibility decision.

3.3.3. The sponsor or their delegate is responsible for ensuring a response to requests for data items is provided within 30 days of the request being made. If requested data items are not

provided within the timeframe, the CPMS study record will not be made 'live' resulting in the study not being included in the NIHR RDN Portfolio.

Table 1: Minimum data set

IRAS ID	Study type (non-commercial, commercial, collaborative)[2]
Study acronym / short title	Study title
Study Sponsor organisation	Study funder(s)
Is the study managed by a CTU or CRO?	Study coordinator/ company representative/ research activity coordinator
Chief Investigator	If applicable, commercial study type (e.g. medical device, pharmaceutical, biotechnology, diagnostics, other)
Study geographical scope (e.g. single site, UK multisite, multinational)	Study lead administration (England/ Wales/ Scotland/ Northern Ireland)
Study phase(s)	Study design type (e.g. interventional, observational, both)
Study setting (e.g. primary care, secondary care, etc)	Study participant type
Study UK location (location of sites)	Open to new sites (yes/no)
UK planned opening date	UK planned closure date
UK actual opening date	UK actual closure date
Study inclusion criteria	Study exclusion criteria
If applicable, global recruitment sample size	UK sample size
Study status (e.g. open to recruitment, closed to recruitment, etc)	

3.4. Changes to minimum data set, including funding arrangements and key milestones

3.4.1. The sponsor or their delegate is required to inform NIHR RDN of any changes to funding, sponsor arrangements or key milestones. This includes but is not limited to study status, study recruitment target, planned open date, actual open to recruitment date, planned closure to recruitment date, actual closure to recruitment date and incorrect recruitment activity data. Sponsors must ensure that updated key milestones are provided within 90 days of the previous data point elapsing. If updated milestone data is not

[2] Commercial studies are funded by a private organisation, such as a pharmaceutical or life sciences company.
Non-commercial studies are funded by a not-for-profit organisation, such as an NIHR funding award, university, charity or NHS trust.
Collaborative studies are funded by both private and not-for-profit organisations.

provided within 90 days, the study will be withdrawn from the RDN Portfolio and will no longer be eligible for RDN support.

3.5. Recruitment data reporting and oversight

3.5.1. To ensure NIHR RDN can effectively monitor the national portfolio and achieve the aims set out above, we require reporting of data on recruitment via Local Portfolio Management Systems[3] (LPMSs). The NIHR RDN, on behalf of DHSC, will be moving to real time data monitoring and sites and sponsors are expected to maintain their datasets as close to real time as possible.

3.5.2. Sponsors or their delegates are required to oversee the recruitment data provided by sites and inform NIHR RDN of any inaccuracies via the Central Portfolio Management System[4]. Where sponsors delegate this responsibility to a CRO, this must be made clear in the delegated responsibility agreement.

3.5.3. Sponsors of global commercial contract studies must supply notification of a UK site achieving the first global or European recruit to the NIHR RDN within 30 days of recruitment.

3.5.4. Sites are expected to continue recruitment to the end of study on a national basis, even if this entails recruiting over their initially set target.

3.5.5. Accurate and up-to-date data informs site allocations for RDN financial support via the RDN funding model.

3.6. Studies that have met recruitment targets in England

3.6.1. Where the study recruitment target has been met for the UK, it is expected that the study will close to recruitment.

3.6.2. If the sponsor wishes to extend the recruitment target and ensure the study remains open to recruitment, they are required to inform the NIHR RDN of the updated recruitment target and revised planned closure dates.

3.6.3. Sponsors of non-commercial studies or their delegates are responsible for ensuring that appropriate funding is in place to cover increased costs associated with higher recruitment,

[3] In exceptional cases (as approved by NIHR RDN before study initiation), the sponsor may need to provide monthly recruitment updates

[4] https://www.nihr.ac.uk/integrated-research-intelligence-system-including-cpms-lpms

including research costs, in line with the NIHR RDN eligibility criteria.

3.6.4. If full funding for all study activities is not in place, NIHR RDN support will be withdrawn. Please be aware that studies withdrawn from the NIHR RDN portfolio will not be able to access support costs, and Excess Treatment Costs for studies where these are provided by integrated care boards (ICBs). The infrastructure support provided by the NIHR RDN to sites such as pharmacy, radiology and pathology will also not be accessible to studies withdrawn from the portfolio.

3.7. Monitoring progress and addressing issues affecting progress

3.7.1. NIHR RDN assesses study progress through a combination of its own monitoring and sponsor assessment. This recognises that while studies may appear to be off track, the sponsor or their delegate is best placed to confirm the progress of a study against its planned milestones.

3.7.2. Where a study is off track, or is at risk of becoming off track, sponsors and their delegates are required to work with research sites to address any barriers to progress.

3.7.3. The NIHR RDN can provide additional support to identify ways in which the study may be able to more effectively progress through its Study Support Service[5]. However, responsibility for effective delivery of the study remains with the study sponsor and delivery sites.

Assessing progress of open studies

3.7.4. During the first three months after a study opens to recruitment, study progress is not actively monitored and reporting of sponsors assessment of progress is not required.

3.7.5. After three months, the NIHR RDN will assess the progress of studies and identify studies that appear to be off track.

3.7.6. Sponsors or their delegates are required to provide their own assessment of study progress within 90 days of a study appearing as off track and, if required, every 90 days thereafter

[5] https://www.nihr.ac.uk/support-and-services/support-for-delivering-research/clinical-research-network/study-support-service

via the sponsor engagement tool. If assessment is not provided within 90 days of becoming due, the study will be removed from the NIHR RDN Portfolio.

3.7.7. Sponsors or their delegates are required to notify the NIHR RDN when a study has a planned or expected period of no recruitment for more than 90 days, for example suspension while awaiting a substantial amendment or known staffing gaps, to enable effective portfolio monitoring. Sponsors or their delegates also should ensure planned restart dates are supplied and maintained.

Open studies with no recruitment for over 6 months

3.7.8. The eligibility criteria for NIHR RDN support specifies several requirements, including clear value to the NHS and taking account of the needs and realities of the NHS. Studies that are not progressing, and therefore do not meet these requirements, will no longer be eligible to be on the NIHR RDN Portfolio and RDN support will be withdrawn. This is independent of the study's originally intended scientific merit.

3.7.9. Where there has been no recruitment activity for a continuous 6 month period, the NIHR RDN will contact the sponsor or their delegate to request information about actions being taken to address the lack of progress. The exception to this is where this is in line with the study plan e.g. the rate of recruitment is expected to be lower than 1 over this period. Subsequent follow-ups will occur every 90 days to ensure NIHR RDN are appraised of the current situation and any planned action to address an ongoing lack of progress.

3.7.10. If no recruitment activity[6] has been achieved within a 12-month period from UK actual opening date, and no corrective action is planned, the study will be removed from the NIHR RDN Portfolio.

3.7.11. DHSC may instruct the RDN to withdraw support and remove commercial interventional studies from the portfolio if studies are not set up within timeframes and reasonable circumstances as set out by DHSC via the UK Clinical Research Delivery Programme.

3.7.12. NIHR RDN will also take other justifiable factors into consideration before this further action, e.g. rare disease

[6] As per Date of First Participant First Visit definition

studies, low-recruitment studies, and extension studies. However, persistent lack of recruitment must be addressed by all studies.

3.7.13. If responses to requests for information are not received within 90 days of a request being made, the study will be removed from the NIHR RDN Portfolio.

3.7.14. Please be aware that studies withdrawn from the NIHR RDN Portfolio will not be able to access support costs, and Excess Treatment Costs for studies where these are provided by integrated care boards (ICBs).

3.7.15. These actions represent good portfolio management practice and enable effective allocation of resources to ensure as many studies as possible can be delivered and provide evidence to improve care and outcomes for UK citizens.