



Department
of Health &
Social Care

Terms and Conditions for NIHR Clinical Research Network Support

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1. Introduction

- 1.1. The purpose of this paper is to set out the terms and conditions applicable to studies accepted onto the NIHR Clinical Research Network (NIHR CRN) Portfolio. It, therefore, relates only to NIHR CRN support for studies in England.
- 1.2. The expectations and requirements set out in these terms and conditions enable the NIHR CRN 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. These terms and conditions apply to all studies accepted onto the NIHR CRN Portfolio regardless of the study type or research funder. They are applicable from the point of acceptance onto the Portfolio until the study closes to recruitment.
- 1.4. Studies are required to meet the Eligibility Criteria for NIHR CRN support to be accepted onto the Portfolio and throughout the duration of its delivery. Details of these criteria can be found at <https://www.nihr.ac.uk/documents/eligibility-for-nihr-clinical-research-network-support/23746>.

2. Responsible individuals and organisations

- 2.1. The UK Policy Framework for Health and Social Care Research¹ 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), and research sites and principal investigators.
- 2.2. Acceptance of a study onto the NIHR CRN Portfolio, and provision of CRN support as described in the Eligibility Criteria for NIHR CRN 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 Clinical Research Network can be found at: <https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm>

3. Terms and Conditions

3.1. Study Management Contact

- 3.1.1. To enable effective and ongoing communication regarding studies included in the NIHR CRN Portfolio, the sponsor is responsible for ensuring the NIHR CRN 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 CRN 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 receive responses to later requests.
- 3.1.4. Up to three requests will be made to request data and information related to a study. If responses to requests for information are not received within 90 days of the original request being made, the study will be removed from the NIHR CRN Portfolio.

3.2. Minimum Data Set

- 3.2.1. In order to effectively monitor the national portfolio of studies, and achieve the aims set out in 1.2 above, a minimum data set is required for each study as set out in Table 1 below. This minimum data set is required once a study has been deemed eligible in order to create a study record in the Central Portfolio Management System (CPMS) and include the study in the

NIHR CRN Portfolio and must be maintained throughout the duration of the study.

3.2.2. Where available, NIHR CRN will utilise data provided via IRAS, NIHR CRN commercial submission or the NIHR CRN Non-commercial Portfolio Application service. Where data is not available through these sources, or requires clarification, the NIHR CRN will contact the sponsor or delegated study management contact to confirm data points items following the eligibility decision.

3.2.3. The sponsor or their delegate are 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 CRN Portfolio.

Table 1: Minimum dataset

IRAS ID	
Study Acronym / Short Title	Study Title
Study Sponsor Organisation	Study Funder(s)
Study Is managed by CTU or CRO?	Study Coordinator/ Company Representative/ Research Activity Coordinator
Chief Investigator	If applicable, Commercial Study Type (eg, medical device, pharmaceutical, biotechnology, diagnostics, other)
Study Geographical Scope (eg, single site, UK multisite, multinational)	Study Lead Administration (England/Wales/Scotland/Northern Ireland)
Study Phase(s)	Study Design Type (eg, interventional, observational, both)
Study Setting (eg, primary care, secondary care, etc)	Study Participant Type

Study UK Location Id (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 (eg, open to recruitment, closed to recruitment, etc)	

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

- 3.3.1. The sponsor or their delegate is required to inform NIHR CRN 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.

3.4. Recruitment data reporting and oversight

- 3.4.1. To ensure NIHR CRN are able to effectively monitor the national portfolio and achieve the aims set out in 2.1 above, we require monthly reporting of data on recruitment via Local Portfolio Management Systems² (LPMSs). The NIHR CRN works with sites to encourage and enable them to provide the data, however, responsibility for reporting of these data to NIHR CRN remains with the sponsor or their delegate.
- 3.4.2. Sponsors or their delegates are required to oversee the recruitment data provided by sites and inform NIHR CRN of any inaccuracies via the Central Portfolio Management System³.

² In exceptional cases (as approved by NIHR CRN before study initiation), the sponsor may need to provide monthly recruitment updates.

³ <https://www.nihr.ac.uk/documents/integrated-research-intelligence-system/11634>

- 3.4.3. Sponsors of global commercial contract studies must supply notification of a UK site achieving the first global or European recruit via email within 30 days of validation of recruitment via: crncc.support@nihr.ac.uk.
- 3.4.4. 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. Studies that have met recruitment targets in England

- 3.5.1. Where the study recruitment target has been met for the UK, it is expected that the study will close to recruitment.
- 3.5.2. If the sponsor wishes to extend the recruitment target and ensure the study remains open to recruitment they are required to inform the NIHR CRN of the updated recruitment target and revised planned closure dates.
- 3.5.3. Sponsors of non-commercial studies or their delegates are also required to confirm that appropriate funding is in place to cover increased costs associated with higher recruitment, including Research Costs, in line with the NIHR CRN eligibility criteria.
- 3.5.4. If full funding for all study activities is not in place, NIHR CRN support will be withdrawn. Please be aware that studies withdrawn from the NIHR CRN portfolio will not be able to access support costs, and Excess Treatment Costs for studies where these are provided by integrated care boards (ICBs).

3.6. Monitoring progress and addressing issues affecting progress

- 3.6.1. NIHR CRN 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.
- 3.6.2. 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.
- 3.6.3. The NIHR CRN can provide additional support to identify ways in which the study may be able to more effectively progress through its Study Support Service⁴. However, responsibility for effective delivery of the study remains with the study sponsor and delivery sites.

⁴ <https://www.nihr.ac.uk/researchers/i-need-help-to-deliver-my-research/study-support-service>

Assessing progress of open studies

- 3.6.4. 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.
- 3.6.5. After three months, the NIHR CRN will assess the progress of studies against portfolio trends and identify studies that appear to be off track.
- 3.6.6. Sponsors or their delegates are required to provide their own assessment of study progress within 90 days of being notified a study is off track and, if required, every 90 days thereafter via the sponsor engagement tool. 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 CRN Portfolio.
- 3.6.7. Sponsors or their delegates are required to notify the NIHR CRN 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

- 3.6.8. The Eligibility Criteria for NIHR CRN 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 CRN Portfolio and CRN support will be withdrawn. This is independent of the study's originally intended scientific merit.
- 3.6.9. Where there has been no recruitment activity for a continuous six-month period, the NIHR CRN 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 eg. the rate of recruitment is expected to be lower than 1 over a 6 month period. Subsequent follow-ups will occur every 90 days to ensure NIHR CRN are appraised of the current situation and any planned action to address an ongoing lack of progress.

- 3.6.10. If no recruitment has been achieved within a continuous 12-month period, and no corrective action is planned, the study will be removed from the NIHR CRN Portfolio. NIHR CRN will also take other justifiable factors into consideration before further action, eg. rare disease studies. However, persistent lack of recruitment must be addressed by all studies.
- 3.6.11. 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 CRN Portfolio.
- 3.6.12. Please be aware that studies withdrawn from the NIHR CRN Portfolio will not be able to access support costs, and Excess Treatment Costs for studies where these are provided by integrated care boards (ICBs).
- 3.6.13. 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.

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