Department of Health

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 Details of the aims and purpose of the NIHR Clinical Research Network can be found at: http://www.nihr.ac.uk/files/pdfs/Briefing%20documents/4.1%20Clinical%20Research%20Network.pdf

The NIHR Clinical Research Network is the English component of the UK Clinical Research Network.

1.3 The main role of the NIHR CRN is to provide infrastructure support for the initiation and delivery of high quality research which benefits patients and the NHS, including relevant research in public health and social care. This includes randomised controlled clinical trials of interventions (e.g. prevention, diagnosis, treatment and care studies) and other well-designed research. The NIHR CRN provides this support through:

- The NIHR CRN Study Support Service- a standard national framework for supporting the planning, set-up and delivery of high quality clinical research in England (Reference 1)
- NHS Support as defined by AcoRD (Reference 2)
- AcoRD Part B Research activities, where relevant, as defined by AcoRD (Reference 3)
- The equivalent of NHS Support in non-NHS settings (Reference 4) (e.g. research carried out in social care, care homes, hospices, or public health settings).

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[1] https://www.nihr.ac.uk/funding-and-support/study-support-service/

[2] https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

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

[4] This is a change in policy which enables the NIHR CRN to extend support to public health and social care research in non-NHS settings. Implementation will be phased to allow the financial and resource impact on the NIHR CRN to be monitored over a 12 month period culminating in a review in 2018. In this period, only social care research studies supported by the NIHR School for Social Care Research will be considered for NIHR CRN support. There are no restrictions on application for NIHR CRN support for public health research and other clinical research taking place in non-NHS settings.

1.4 The NIHR also provides research infrastructure in the NHS through a number of dedicated NIHR centres and facilities which support early translational (experimental medicine) research and clinical and applied health research (i.e. Biomedical Research Centres, Clinical Research Facilities for Experimental Medicine, Experimental Cancer Medicine Centres, Collaborations for Leadership in Applied Health Research and Care, Patient Safety Translational Research Centres, Healthcare Technology Cooperatives and Diagnostic Evidence Cooperatives and the successor Medtech and In Vitro Diagnostic Cooperatives (Reference 5).

1.5 The NHS is responsible for meeting the Treatment Costs of research via the normal arrangements for commissioning patient care (Reference 6).

2. Definition of 'research study'

2.1 Research can be defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods (Reference 7).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:

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[5] A full list of NIHR infrastructure can be found here: https://www.nihr.ac.uk/about-us/how-we-are-managed/our-structure/infrastructure/

[6] http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353

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

[7] http://beta.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

i. meet the definition of research as defined in section 2.1 above; and

ii. have appropriate ethical approval (e.g. NHS, Social Care REC, or Ministry of Defence REC); and Health Research Authority (HRA) Approval where required; and

iii. have full research funding (i.e. funding to meet all Research Costs in compliance with the AcoRD guidance) (Reference 8).

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.

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 consideration for NIHR CRN support provided they 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, 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

[8] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_133882

Partners, which is updated regularly, is available on the NIHR website http://www.nihr.ac.uk

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 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 funded by potentially eligible funding streams (see 3.11) 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 extended review process. The NIHR CRN manages the non-commercial extended review 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 3.15).

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 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 Co-ordinating 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 will be considered for NIHR CRN support via the non-commercial extended review process.

3.15 Non-commercial studies funded by overseas charities will be considered for NIHR CRN support via the non-commercial extended review process.

3.17 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

3.18 The aims of the NIHR CRN include facilitating high quality studies of benefit to patients that are supported by the life-sciences industry, strengthening research collaboration with industry and ensuring that the NHS, public health and social care, 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 must have appropriate ethical approval (e.g. NHS, Social Care REC); and HRA Approval where required, 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 will not be 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. Funding of study related activities require full cost recovery from industry as outlined in AcoRD.

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

3.22 The NIHR has other funding schemes which provide research infrastructure 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, Collaborations for Leadership in Applied Health Research and Care, Patient Safety Translational Research Centres, Healthcare Technology Cooperatives and Diagnostic Evidence Cooperatives and the successor Medtech and In Vitro Diagnostics Cooperatives).

3.23 Studies which are fully funded by this NIHR Research Infrastructure, and within the contracted NHS/ University partnership and formal partners, will not require additional support from the NIHR CRN.

3.24 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.

3.25 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 (for example Efficacy and Mechanism (EME), Invention for Innovation (i4i) etc)), NIHR's non-commercial Partners (i.e. medical research charities which meet the criteria in section 3.5), Research Councils (e.g. the Medical Research Council) or other areas of central government.

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.

4.2 Timely reporting of recruitment data to the NIHR CRN Co-ordinating Centre by the Chief Investigator or their team, and acknowledgement of NIHR CRN support in relevant publications, are conditions of accessing NIHR CRN support.

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.

High priority studies

5.2 Studies that have a high priority for NIHR CRN support are those eligible studies that 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 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 studies that are:

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

Low priority studies

5.4 Studies that have a low priority for NIHR CRN support are those eligible studies that 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.

Effective from 1st January 2018

Authored by NIHR Clinical Research Network

Policy approved by Department of Health Science, Research & Evidence Directorate

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.

Open competition

2. 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.

High quality peer review

3. Peer review must be independent, expert, and proportionate:

i. 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.
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.

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