



## **National Institute for Health Research**

### **CLINICAL RESEARCH NETWORK**

#### **Introduction**

The vision of the National Institute for Health Research (NIHR) is to improve the health and wealth of the nation through research.

This document sets out how the NIHR Clinical Research Network is contributing to this vision. Information about other elements of the NIHR clinical research infrastructure can be found in companion documents.

#### **Overview**

The purpose of the NIHR Clinical Research Network is to provide a world-class health service infrastructure to support clinical research in the NHS in England. It comprises a Coordinating Centre, six topic specific research networks, a primary care research network and a comprehensive research network enabling research to be conducted across the full spectrum of disease and clinical need.

It allocates and manages funding to meet NHS Service Support (e.g. additional nursing time; pathology sessions; lab costs; imaging; additional out-patients costs) for eligible studies. These comprise randomised controlled clinical trials of interventions (including prevention, diagnosis, treatment and care) and other well designed studies for commercial and non-commercial sponsors. The criteria governing eligibility of studies for Network support can be found at [www.crncc.nihr.ac.uk](http://www.crncc.nihr.ac.uk). Industry-sponsored contract research is conducted on a cost recovery basis as stipulated in the NHS Finance Manual.

The NIHR CRN is the English component of the UK Clinical Research Network (UKCRN), developed under the auspices of the UK Clinical Research Collaboration ([www.ukcrc.org](http://www.ukcrc.org))

#### **Aim**

The Clinical Research Network aims to:

- Ensure that patients and healthcare professionals from all parts of England, and from all areas of healthcare, are able to participate in and benefit from clinical research.
- Improve the quality, speed and co-ordination of clinical research by removing the barriers to research in the NHS.
- Streamline and performance manage NHS Support for eligible studies to ensure that the NHS Service Support Costs of these studies are met in a

timely and efficient manner.

- Unify and streamline administrative procedures associated with regulation, governance, reporting, and approvals.
- Strengthen research collaboration with life sciences industries and ensure that the NHS can meet the health research needs of industry.
- Further integrate health research and patient care.

## Structure

The NIHR CRN comprises six topic specific Clinical Research Networks:

- NIHR Cancer Research Network (NCRN) ([www.ncrn.org.uk](http://www.ncrn.org.uk))
- Dementias and Neurodegenerative Diseases (DeNDRoN) ([www.dendron.org.uk](http://www.dendron.org.uk))
- Diabetes Research Network (DRN) ([www.ukdrn.org/](http://www.ukdrn.org/))
- Medicines for Children Research Network (MCRN) ([www.mcrn.org.uk](http://www.mcrn.org.uk))
- Mental Health Research Network (MHRN) ([www.ukmhrn.info](http://www.ukmhrn.info))
- Stroke Research Network (SRN) ([www.uksrn.ac.uk](http://www.uksrn.ac.uk))

NCRN provides national coverage. The other topic specific networks comprise six to eight Local Research Networks each.

In addition to the above topic specific Networks two other networks cover all of England:

- The Primary Care Research Network, comprising eight local Research Networks. It focuses on health areas for which primary care has particular responsibility, including disease prevention, health promotion, screening, early diagnosis and clinical management of long term conditions ([www.crncc.nihr.ac.uk/about\\_us/pcrn](http://www.crncc.nihr.ac.uk/about_us/pcrn)).
- The Comprehensive Clinical Research Network (CCRN), comprising 25 Local Research Networks covering England. These address all disease/need areas other than those covered by the topic specific CRNs. In addition, the CCRN collaborates with the topic specific CRNs to provide national coverage for their respective areas ([www.crncc.nihr.ac.uk/about\\_us/ccrn](http://www.crncc.nihr.ac.uk/about_us/ccrn)).

The work of all the Clinical Research Networks is coordinated by the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) ([www.crncc.nihr.ac.uk](http://www.crncc.nihr.ac.uk))

The six Topic Specific Networks each have a separate coordinating centre. The Primary Care and Comprehensive Networks are managed directly by the NIHR CRN Coordinating Centre. Coordinating centres and topic specific Local Research Networks were selected on the basis of open competition.

## Functions and activities

The core activities of the **Clinical Research Network Coordinating Centre** are:

- Providing leadership, coordination and performance management of the CRN in consultation with the Department of Health.

- Providing Co-ordinating Centre functions for the PCRN and CCRN.
- Supporting the NIHR and Department of Health in developing all Co-ordinating Centres and, through them, the Topic Specific Research Networks.
- Providing support to all Co-ordinating Centres and networks on issues and operating systems that are common to all NIHR Clinical Research Networks.
- Strengthening existing research interactions between the NHS and the life sciences industries.
- Promoting the active involvement of patients and the public in research.
- Managing internal and external relationships.
- Working closely with all NIHR and UKCRC partners - Government, research charities, industry and the public - to assist the NIHR and UKCRC in achieving their wider aims regarding the organisation and development of research infrastructure, research activity, research workforce, and regulation.

The core activities of the **co-ordinating centres** for each topic specific network are:

- Providing leadership to the Topic Specific Network.
- Developing the Local Research Networks.
- Managing the Topic Specific Network on behalf of the NIHR.
- Co-ordinating network participation in NIHR Clinical Research Network Portfolio studies.
- Developing and quality assuring Local Research Networks.
- Promoting the active involvement of patients and the public in research.
- Managing internal and external relationships.
- Working with the NIHR Clinical Research Network Co-ordinating Centre to achieve the aims of the NIHR Clinical Research Network.

The core activities of each of the **Local Research Networks** of the topic specific networks are:

- Recruiting patients to participate in eligible studies in the topic area.
- Managing the progress of patients through the research process.
- Carrying out investigations, assessments and tests attributed as NHS Support activities using DH guidance on the attribution of non-commercial Research costs, Support costs and Treatment costs.
- Collecting, collating and submitting research performance management data.
- Promoting the active involvement of patients and the public in research.
- Working with the NIHR Clinical Research Network Co-ordinating Centre to achieve the aims of the Network as part of the NIHR Clinical Research Network.

- Local Research Networks are not funded to:
  - Carry out activities that are attributed to Research Costs or NHS Treatment Costs;
  - Support studies that are not eligible for NIHR Clinical Research Network support;
  - Undertake any training other than that required to fulfil their role as NIHR Associates e.g. GCP training is acceptable.

The core activities of the **Comprehensive Local Research Networks** (NIHR CLRNs) are:

- Allocating and managing funding to meet the NHS Service Support Costs of eligible studies.
- Managing the level of activity (e.g. recruitment) for each study in every research-active NHS organisation in the NIHR CLRN.
- Managing the level of network funding to be provided to each research-active NHS organisation in the NIHR CLRN, including the full spectrum of primary, secondary, and tertiary care services, to support the funded research activity.
- Managing, monitoring, and controlling the use of that funding within each NHS organisation in the NIHR CLRN.
- Collecting, collating and submitting research performance management data.
- Helping researchers to cost research proposals properly by identifying and quantifying Research Costs, Service Support Costs, and Treatment Costs (including Excess Treatment Costs).
- Liaising with commissioners and Trusts in planning the treatment costs of research.
- Supporting CLRN member organisations in their adoption of the NIHR Research Support Services framework.
- Providing a local advice service, linked to the national advice service provided by the NIHR Clinical Research Network Coordinating Centre, to provide consistent high quality first-line advice on working with regulations such as the EU clinical trials directive and other legislation affecting clinical research.
- Advising researchers on the processes for application for ethical review and other authorisations.
- Advising researchers on the processes associated with NIHR Coordinated System for gaining NHS Permission (NIHR CSP).
- Working with research employers (NHS and university) to implement and manage research passports that simplify honorary contracts and related checks.
- Working with the research ethics committee system and arranging site-specific assessments to support ethical review.
- Working with researchers and NHS data guardians to facilitate epidemiological and survey-based research.

- Liaising with University governance offices on sponsorship issues.
- Managing the planned NIHR Information System locally.
- Improving user satisfaction with NHS R&D.
- Signposting investigators towards support in carrying out research that has been approved and funded.
- Signposting investigators towards support in developing high quality research proposals, e.g. the NIHR Research Design Service.
- Providing controls and assurances by providing a system of research management checks for care organisations and ethical review as part of proper research governance. Many individual checks will be swept up into a continuous process of assessment and sample checking, wherever that will reduce the potential for delaying individual studies. For some of the research management checks the NIHR CLRN will be acting for NHS organisations that remain legally responsible for the outcome. A standard form of agreement (Membership Agreement) has been developed to set out these delegated functions.
- Supporting MHRA inspectors, the Healthcare Commission and Strategic Health Authorities in identifying and correcting organisational failures.
- Working with the UK Panel for Biomedical Research Integrity to help employers of researchers improve the conduct of research and handle cases of suspected misconduct effectively.

NIHR CLRNs provide clinical research support staff to carry out NIHR Clinical Research Network Portfolio studies. Activities include:

- Recruiting patients to participate in eligible studies.
- Managing the progress of patients through the research process.
- Carrying out investigations, assessments and tests attributed as NHS Support activities using DH guidance on the attribution of non-commercial Research costs, Support costs and Treatment costs
- Collecting, collating and submitting research performance management data
- Promoting the active involvement of patients and public in research.
- Working with the NIHR Clinical Research Network Co-ordinating Centre to achieve the aims of the NIHR Comprehensive Clinical Research Network as part of the NIHR Clinical Research Network.
- NIHR CLRNs are not funded to:
  - Carry out activities that are attributed to Research Costs or NHS Treatment Costs;
  - Support studies that are not eligible for NIHR Clinical Research Network support;
  - Undertake any training other than that required to fulfil their role as NIHR Associates e.g. GCP training is acceptable.

## NHS Service Support

NHS Service Support Funding meets the NHS Service Support<sup>1</sup> resource requirements of eligible funded non-commercial research via a number of dedicated funding streams each concentrating on a particular area of need. A substantial proportion of NHS Service Support is allocated and managed via the NIHR CRN.

Different Clinical Research Networks are expected to require different NHS support to achieve their objectives. For example, a mental health research network may require additional clinical psychology support for its research, while a stroke research network may require additional radiology support for its research. Although the specific nature of a requirement may be different (psychology *c.f.* radiology), the general nature of the requirement (NHS service support) is similar.

The type of support that will be provided through the NIHR Clinical Research Network includes some or all of the following:

- Clinical Leadership
- Local Research Network Manager
- Research Nurses (or similar staff)
- Data Managers
- Secretarial support
- Junior medical staff sessions
- Other clinical staff sessions relevant to the topic area (e.g. clinical psychology, community psychiatric nursing, physiotherapy, occupational therapy).
- Appropriate diagnostic test or clinical services costs, such as:
  - Pharmacy support
  - Pathology support
  - Radiology support
  - Information technology support.
  - Essential running costs.

## Further Information

Full details on progress and key events are available from NIHR CRN website at [www.crncc.nihr.ac.uk/](http://www.crncc.nihr.ac.uk/).

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<sup>1</sup> See Attributing Revenue Costs of Externally Funded Non-Commercial Research in the NHS (ARCO) on the [DH website](#).