



BEST RESEARCH FOR BEST HEALTH

IMPLEMENTATION PLAN 5.1a (established)

NIHR COMPREHENSIVE CLINICAL RESEARCH NETWORK

*Best Research for Best Health*¹ set out a 5-year Research and Development Strategy for the NHS in England. This Implementation Plan provides more details on one of the key components of that strategy: The NIHR Comprehensive Clinical Research Network, which is a major element of the NIHR Clinical Research Network. This document will be regularly updated. The latest version should be used.

The NIHR Comprehensive Clinical Research Network has been fully implemented.

Version: 9 (final)

Issue date: The final plan was issued in July 2009 and edited in January 2010.

'Best Research for Best Health' Implementation Plan 5.1 sets out plans for the NIHR Clinical Research Network. Its purpose is to provide a world-class health service infrastructure to support clinical research in the NHS in England. It will comprise a co-ordinating centre, six topic specific research networks, a primary care research network, and a comprehensive research network. This document, Plan 5.1a, sets out further details of the NIHR Comprehensive Clinical Research Network.

The NIHR Comprehensive Clinical Research Network (NIHR CCRN) will be a major component of the overall NIHR Clinical Research Network. It will work together with the Topic Specific Research Networks and the Primary Care Research Network to provide the infrastructure for clinical research in England through the allocation and management of funding to meet the NHS Service Support Costs of NIHR Clinical Research Network Portfolio studies. In this way, support will be provided for research into all diseases and areas of clinical need.

Aim

- 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.

¹ Best Research for Best Health: A new national health research strategy. Department of Health, Jan 06

- To improve the quality, speed and co-ordination of clinical research by removing the barriers to research in the NHS.
- To streamline and performance manage NHS support for NIHR Clinical Research Network Portfolio studies to ensure that the NHS Service Support Costs of these studies are met in a timely and efficient manner.
- To unify and streamline administrative procedures associated with regulation, governance, reporting, and approvals.
- To strengthen research collaboration with industry and ensure that the NHS can meet the health research needs of industry.
- To further integrate health research and patient care.

Purpose

- To facilitate access to patients and research facilities for NIHR Clinical Research Network Portfolio studies in the most appropriate locations based on a continuously updated record of research activity and recruitment across the country.
- To streamline research management processes, including the interface with ethics committee review, thus reducing the burden on researchers and the NHS while ensuring that studies are managed to consistently high standards (see also updated Implementation Plan 4.1a, b, c, d, e and f).
- To allocate and manage funding to meet the NHS Service Support Costs (e.g. additional nursing time; pathology sessions; laboratory costs; imaging; additional outpatient costs; etc.) of NIHR Clinical Research Network Portfolio studies.² Support will be open to industry partners as outlined in the partnership agreement³.
- To signpost investigators towards support in carrying out, and developing, high quality studies. This will be achieved by signposting researchers to appropriate centres that have expertise in the design, conduct and analysis of clinical studies (for example NIHR Research Design Service - see Implementation Plan 5.9) and in other related disciplines such as health economics and qualitative research.

Structure

- The NIHR Clinical Research Network Coordinating Centre (previously known as the UK CRN CC) will provide a national co-ordinating function for the NIHR Comprehensive Clinical Research Network on behalf of the National Institute for Health Research (NIHR), and in consultation with the Department of Health.
- The NIHR Comprehensive Local Research Networks (CLRNs) will be operational entities designed to support clinical research, and will be managed locally for that purpose. NIHR CLRNs have been established across all England within the

² The main role of the Topic Specific Research Networks and Comprehensive Research Network is to support later-phase clinical trials and other well-designed studies. The focus of our support for early-phase clinical trials and other experimental medicine is through Clinical Research Facilities, Experimental Cancer Medicine Centres, and Biomedical Research Centres. However, where our partners fund research to take place in the NHS outside these centres, the Topic Specific Research Networks and Comprehensive Clinical Research Networks will provide NHS Service Support for them.

³ NHS R&D Partnership Agreement with the Pharmaceutical Industry, Annex 1 of the 'Pharmaceutical Industry Competitiveness Task Force - Clinical Research report'.

boundaries of Strategic Health Authorities (SHA). The NIHR Clinical Research Network Coordinating Centre worked with SHAs and the Department of Health to agree the national configuration of 25 NIHR CLRNs, this being the minimum number of NIHR CLRNs necessary to work effectively (for details please see www.crncc.nihr.ac.uk/index/networks/comprehensive/clrns.html).

- Most NHS research management and clinical research support functions will be distributed across the organisations comprising the NIHR CLRNs. NIHR CLRNs will therefore site their staff across constituent organisations in line with the functions that are needed at individual locations.
- Each NIHR CLRN has a host organisation, which is an NHS organisation within the NIHR CLRN. All NHS organisations were invited to apply to become Host Organisations for their local NIHR CLRN and a panel chaired by the Department of Health carried out a selection process. The host organisation will hold the contract for the NIHR CLRN and will provide the high quality corporate administrative services required by the NIHR CLRN, such as human resources, finance-related services, premises and facilities. The host organisation will receive funding for these purposes.
- Each NIHR CLRN is led by a Clinical Director, these being senior and experienced clinical researchers from NIHR CLRN member organisations. Clinical Directors are appointed through an open and transparent process, and these posts are open to clinicians of all professions.
- The NIHR CLRN Clinical Director is supported by a Senior Manager.
- Each NIHR CLRN has an Executive Group. The CLRN Executive Group is a small operational group that works closely with the Clinical Director and the Senior Manager. The group serves to support and advise the Clinical Director in developing operational plans and policies, and in operational decision-making. The group ensures the effective representation of all CLRN NHS sectors in the day-to-day management and delivery of the CLRN. As a minimum, the Executive Group consists of the Clinical Director, Senior Manager, and three or four other senior individuals drawn from across the main NHS sectors ensuring representation from primary care, acute care, mental health, and tertiary care.
- The NIHR CLRN management is expected to demonstrate a commitment to working across the whole of the NIHR CLRN to ensure that all of the participating providers of NHS services can be engaged and supported to the maximum possible extent in order to ensure the best and most efficient delivery of NIHR Clinical Research Network Portfolio studies.
- Each NIHR CLRN has a Network Board, which will have representation from, and formal involvement of, all NHS organisations comprising the NIHR CLRN together with relevant Higher Education Institutions and other stakeholders. The Board is chaired by a senior and experienced clinical investigator who is not the Clinical Director and not employed by the NIHR CLRN host organisation.

Functions and activities

The NIHR Clinical Research Network Coordinating Centre will:

- Establish, develop, and performance manage the Comprehensive Clinical Research Network on behalf of the National Institute for Health Research (NIHR), and in consultation with the Department of Health.
- Provide the national research management unit (see Implementation Plan 4.1a) which will work with the Department of Health, the NHS, and UKCRC partners to:
 - Coordinate the delivery of the NIHR systems;
 - Monitor their impact and advise those responsible for them;
 - Monitor the impact of new regulation on behalf on behalf of the NIHR.
- Provide a national advice service (see Implementation Plan 4.1b), which will:
 - Codify advice from regulators, policy-makers and experts in good practice, and present it in a user-friendly form;
 - Use IT systems to make authoritative standard advice available to front line advisors on issue they identify;
 - Work under the umbrella of the UKCRC with regulators, policy-makers, and trialists to document and publicise solutions to regulatory problem;
 - Work with partners across the UK to codify and explain differences in regulation, and to harmonise research governance processes UK-wide.

The NIHR Comprehensive Local Research Networks (NIHR CLRNs) will deploy research management expertise to:

- Allocate and manage funding to meet the NHS Service Support Costs of NIHR Clinical Research Network Portfolio studies:
 - Manage the level of activity (e.g. recruitment) for each study in every research-active NHS organisation in the NIHR CLRN;
 - Manage 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;
 - Manage, monitor, and control the use of that funding within each NHS organisation in the NIHR CLRN;
 - Collect, collate and submit research performance management data;
 - Help researchers to cost research proposals properly by identifying and quantifying Research Costs, Service Support Costs, and Treatment Costs (including Excess Treatment Costs);
 - Liaise with commissioners and Trusts in planning the treatment costs of research.
- Support and streamline research management to deliver proper governance (see updated Implementation Plan 4.1b)

- Provide support:
 - providing a local advice service, linked to the national advice service to be provided by the NIHR Clinical Research Network Coordinating Centre, (see Implementation Plan 4.1e) 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;
 - refer callers confidently to the best source of written advice;
 - respond to queries by e-mail and phone, confirming verbal advice in writing;
 - provide a telephone help-line.
 - advise researchers on the processes for application for ethical review and other authorisations;
 - advise researchers on the processes associated with NIHR Coordinated System for gaining NHS Permission (NIHR CSP)
 - work with research employers (NHS and university) to implement and manage research passports that simplify honorary contracts and related checks;
 - work with the research ethics committee system and arrange site-specific assessments to support ethical review (see Implementation Plan 4.1f);
 - work with researchers and NHS data guardians to facilitate epidemiological and survey-based research;
 - liaise with University governance offices on sponsorship issues;
 - manage the planned NIHR Information System locally;
 - improve user satisfaction with NHS R&D;
 - signpost investigators towards support in carrying out research that has been approved and funded;
 - signpost investigators towards support in developing high quality research proposals.
- Provide controls and assurances:
 - provide 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;
 - support MHRA inspectors, the Healthcare Commission and Strategic Health Authorities in identifying and correcting organisational failures;
 - work 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 will provide clinical research support staff to carry out NIHR Clinical Research Network Portfolio studies:

- Recruit patients to participate in NIHR Clinical Research Network Portfolio studies.
- Manage the progress of patients through the research process.
- Carry 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
- Collect, collate and submit research performance management data.
- Promote the active involvement of patients and public in research.
- Work 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 will not be funded to:
 - Carry out activities that are attributed to Research Costs or NHS Treatment Costs
 - Support studies that are not in the NIHR Clinical Research Network Portfolio;
 - Undertake any training other than that required to fulfil their role as NIHR Associates e.g. GCP training is acceptable;

NHS Service Support Costs and the NHS Infrastructure for Clinical Research

- The NHS Infrastructure for clinical research is funded by NHS Service Support. Previously, funding to meet the NHS Service Support Costs⁴ of externally funded non-commercial research has been provided to individual NHS Trusts through the Support for Science element of R&D Support Funding for NHS Providers.
- The Government's health research strategy *Best Research for Best Health* sets out the mechanisms through which the Department of Health will continue to provide funding to meet the NHS costs of research that is funded by agreed partners and government.
- With the implementation of *Best Research for Best Health*, NHS Service Support will now be provided through a number of separate, dedicated funding streams, each concentrating on a particular area of need. These funding streams include, Clinical Research Facilities, NIHR Faculty, and the NIHR Clinical Research Network. A substantial proportion of NHS Service Support will be allocated and managed through the NIHR Comprehensive Clinical Research Network and through the Topic Specific Networks.
- The Department of Health has undertaken to provide the NHS Service Support necessary to support the clinical research funded by the Government and our partners, research which is part of the NIHR Clinical Research Portfolio and takes place in the NHS. As the system develops, the existing allocations to Topic Specific Networks may prove insufficient to provide the necessary NHS Service Support for research in their portfolio. Therefore, any additional NHS Service Support needed by the Topic Specific Research Networks, over and above that provided through

⁴ See Attributing Revenue Costs of Externally Funded Non-Commercial Research in the NHS (ARCO) at www.dh.gov.uk/research for a definition of the costs associated with NHS R&D

their existing allocations, will be provided via the NIHR Comprehensive Clinical Research Network.

Funding

- To establish the NIHR Comprehensive Clinical Research Network, the Stage 1 (2007/08) funding allocated to each NIHR CLRN consisted of:
 - A fixed allocation to support the NIHR CLRN management team;
 - A per capita (of population served) allocation for research management staff;
 - A per capita (of population served) allocation for research infrastructure, including research support staff (including research nurses, or equivalent), support for clinicians of all professions who recruit patients into NIHR Clinical Research Network Portfolio studies, and other NHS Service Support.
- In 2007/08, all NIHR CLRNs received an initial allocation to provide a core standing research infrastructure on which to build. Hereafter, funding will be increased incrementally over time to reflect growth in research activity.
- The funding provided through the NIHR Comprehensive Clinical Research Network will be additional to, and separate from, all other NIHR funding.
- In 2008/09, Stage 2 funding was made available. All NIHR CLRNs continued to receive the fixed and per capita allocations as in 2007/08. In addition each CLRN also received a flexible allocation (Activity Based Funding) calculated on the basis of past activity for that CLRN. This will be recalculated annually.
- It is recognised that there is a need to allocate additional funding to enable CLRNs to identify and overcome local barriers to supporting research. This funding, known as “Key Service Support”, was made available for two years from April 2008 (with a review at 18 months) and is intended to pay for the re-engineering processes for the provision of pharmacy and imaging support in particular, and for the local change management that will be required to achieve such re-engineering.

Implementation Timetable

- The NIHR Comprehensive Clinical Research Network started work in April 2007 and will be fully operational within two years.
- Key dates are as follows:
 - January 2006 – Government health research strategy *Best Research for Best Health* published confirming intention to establish a Clinical Research Network covering the population of England.
 - September 2006 – 10 NHS Research Managers (one from each SHA region) seconded part-time to UKCRNCC to assist with establishing NIHR CLRNs.
 - December 2006 - 25 NIHR CLRNs confirmed by DH following consultation with NHS organisations.
 - January 2007 – all NHS organisations invited to apply to become NHS Host Organisations for NIHR CLRNs.
 - February 2007 – first NIHR Comprehensive Clinical Research Network National meeting.

- February 2007 – nominations invited for NIHR CLRN Network Board membership.
- March 2007 – Host Organisations selected for each NIHR CLRN.
- May 2007 – second NIHR Comprehensive Clinical Research Network National meeting.
- May / June 2007 – initial NIHR CLRN Network Board meetings held.
- June / July 2007 – NIHR CLRN Clinical Director appointments confirmed.
- July 2007 – Stage 1 NIHR CLRN funding available.
- September 2007 – NIHR CLRN senior managers appointed.
- September 2007 – third NIHR Comprehensive Clinical Research Network National meeting.
- January 2008 – fourth NIHR Comprehensive Clinical Research Network National meeting.
- April 2008 – Stage 2 NIHR CLRN funding available
- June 2008 – NIHR CLRNs submit Operational Plans and Outline Use of Resources for 2008/09
- November 2008 – NIHR CSP launched
- April 2009 – NIHR Comprehensive Clinical Research Network fully operational.

Further Information

Full details on progress and key events are available from NIHR CRN website at www.crncc.nihr.ac.uk/index.html.

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