



**National Institute for
Health Research**

BEST RESEARCH FOR BEST HEALTH

IMPLEMENTATION PLAN 5.1a

NATIONAL INSTITUTE FOR HEALTH RESEARCH COMPREHENSIVE 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 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.

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'*Best Research for Best Health*' Implementation Plan 5.1 sets out plans for the National Institute for Health Research (NIHR) Clinical Research Network. Its purpose is to provide a world-class health service infrastructure to support clinical research in the NHS across 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 Research Network.

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

¹ *Best Research for Best Health: A new national health research strategy*. Department of Health, January 2006

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.
- 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 clinical studies to ensure that the NHS Service Support Costs of research 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 clinical research in the most appropriate locations based on a continuously updated record of research activity and accrual 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 4.1).
- To provide the NHS Infrastructure for Clinical Research for first-class research funded by the Government and its partners² through the allocation and management of NHS Service Support (e.g. additional nursing time; pathology sessions; laboratory costs; imaging; additional outpatient costs; etc.). The NIHR Comprehensive Research Network will support clinical trials and other well-designed studies conducted alongside high-quality patient care in the NHS³. Support will be open to industry partners as outlined in the partnership agreement⁴.
- 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, and in other related disciplines such as health economics and qualitative research.

² Our partners include the Research Councils, other Government research funders, and those charities that award research funds as a result of open competition across England with peer review.

³ The main role of the Topic Specific Research Networks and NIHR 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 NIHR Biomedical Research Centres. However, where our partners fund research to take place in the NHS outside these centres, the Topic Specific Research Networks and NIHR Comprehensive Research Networks will provide NHS Service Support for them.

⁴ NHS R&D Partnership Agreement with the Pharmaceutical Industry, Annex 1 of the 'Pharmaceutical Industry Competitiveness Task Force - Clinical Research report'

Structure

- The **UKCRN Co-ordinating Centre** will provide a national co-ordinating function for the NIHR Comprehensive Research Network on behalf of the National Institute for Health Research (NIHR), and in consultation with the Department of Health.
- **NIHR Comprehensive Research Network Local Research Networks (LRNs)** will be operational entities designed to support clinical research, and will be managed locally for that purpose. NIHR CRN LRNs will be established across all England within the boundaries of Strategic Health Authorities (SHA). Each SHA will work with the Department of Health and the UKCRN Co-ordinating Centre in the creation of CRN LRNs within its boundaries by assisting the Department of Health and the UKCRN in identifying NIHR CRN LRNs, and advising the UKCRN Co-ordinating Centre on the co-ordination and management of NIHR CRN LRNs. The aim will be to have the minimum number of NIHR CRN LRNs necessary to work effectively. The number will depend on natural health economies across primary, secondary, and tertiary NHS services, and on NHS R&D activity, including the local arrangements for the topic specific and primary care local research networks. The number will also depend on other relevant factors such as geography and local clinical and academic collaborations. SHAs, the UKCRN Coordinating Centre, and the Department of Health will work together to develop the arrangements for the network(s) in each SHA area (for details please see www.ukcrn.org.uk)
- Most research management and clinical support functions will be distributed across the organisations comprising the NIHR CRN LRNs. NIHR CRN LRNs will therefore site their staff across constituent organisations in line with the functions that are needed at individual locations.
- Each NIHR CRN LRN will require a host organisation, which will be an NHS organisation within the NIHR CRN LRN. The host organisation will hold the contract for the NIHR CRN LRN and will provide the high quality management services required by the NIHR CRN LRN, such as human resources, finance, premises and facilities. The host organisation will receive funding for these purposes.
- Each NIHR CRN LRN will be led by a Clinical Director (0.5fte approx.), who will be a senior and experienced clinical researcher from a NIHR CRN LRN member organisation. Clinicians of all professions are eligible. Clinical Directors will be appointed through an open and transparent process.
- The NIHR CRN LRN Clinical Director will be supported by a Senior Manager. The Senior Manager will be appointed once the Clinical Director is selected and it is expected that s/he will be employed by the host organisation. The NIHR CRN LRN will be required to demonstrate robust arrangements to support effective partnership working between the Clinical Director and Senior Manager.
- The NIHR CRN LRN management will be expected to demonstrate a commitment to working across the whole of the NIHR CRN LRN 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 clinical research.

- Each NIHR CRN LRN will have an Executive Committee, drawn from across the NIHR CRN LRN and chaired by the Clinical Director. It will include at least one representative from primary care, secondary care, tertiary care and mental health. The NIHR CRN LRN Executive Committee will recommend to the Network Board (see below) the appropriate levels of research infrastructure and research management support for NIHR CRN LRN constituent organisations.
- Each NIHR CRN LRN will have a Network Board, which will have representation from, and formal involvement of, all NHS organisations comprising the NIHR CRN LRN together with relevant Higher Education Institutions and other stakeholders. The Board will be chaired by a senior and experienced clinical investigator who is not the Clinical Director and not employed by the NIHR CRN LRN host organisation.

Functions and activities

The **UKCRN Co-ordinating Centre** will:

- Establish, develop, and performance manage the NIHR Comprehensive Research Network on behalf of the National Institute for Health Research (NIHR), and in consultation with the Department of Health.
- Provide the UKCRN NHS research management unit (see Implementation Plan 4.1) 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 UKCRC.
- Provide a national advice service (see Implementation Plan 4.1), 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 issues they identify
 - Work through the UKCRC with regulators, policy-makers, and trialists to document and publicise solutions to regulatory problems
 - Work with partners across the UK to codify and explain differences in regulation, and to harmonise research governance processes UK-wide.

The **NIHR Comprehensive Research Network Local Research Networks** (CRN LRNs) will deploy research management expertise to:

- Manage NHS Service Support funding for research:
 - Manage the level of activity (e.g. recruitment) for each study in every research-active NHS organisation in the LRN
 - Manage the level of network funding to be provided to each research-active NHS organisation in the LRN, 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 LRN
 - 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 4.1)

Provide support:

- Provide a local advice service, linked to the national advice service to be provided by the UKCRN Coordinating Centre, (see Implementation Plan 4.1) 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 applications for ethical review and other authorisations
- 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 4.1)
- 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 CRN LRN will be acting for NHS organisations that remain legally responsible for the outcome. A standard form of agreement could be developed to set out these delegated functions if needed

- 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 CRN LRNs will provide clinical research support staff to carry out clinical studies:

- Recruit patients to participate in funded clinical studies
- Manage the progress of patients through the research process
- Collect, collate and submit research data, including adverse event reporting
- Promote the active involvement of patients and public in research
- Work with the UKCRN Co-ordinating Centre to achieve the aims of the NIHR Comprehensive Research Network as part of the NIHR Clinical Research Network.

NHS Service Support Costs and the NHS Infrastructure for Clinical Research

- The NHS Infrastructure for clinical research is funded by NHS Service Support. Previously, the NHS Service Support Costs⁵ of externally funded non-commercial research in the NHS research have been provided to individual NHS Trusts through the Support for Science element of R&D Support Funding for NHS Providers.
- The new NHS R&D Strategy sets out the mechanisms through which the Department of Health will continue to provide the NHS costs of research that is funded by agreed partners and government.
- However, in the future, NHS Service Support will be provided through a number of separate, dedicated funding streams, each concentrating on a particular area of need. These funding streams include Technology Platforms, Clinical Research Facilities, NIHR Faculty, and NIHR Research Networks. A substantial proportion of NHS Service Support will be allocated and managed through the NIHR Comprehensive Research Network and through the Topic Specific Networks.

⁵ 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

- The Department of Health has undertaken to provide the NHS Service Support Costs necessary to support the clinical research funded by the Government and our partners, which takes place in the NHS. As the system develops, the existing allocations to Topic Specific Networks may prove insufficient to support the necessary NHS Service Support Costs of research in their portfolio. Therefore, any additional NHS Service Support Costs needed by the Topic Specific Research Networks, over and above their existing allocations, might be allocated via the NIHR Comprehensive Research Network or allocated directly via the Topic Specific Networks themselves. Further work will be needed to develop the best arrangement.

Funding

- To establish the NIHR Comprehensive Research Network, funding allocated to each NIHR CRN LRN will consist of:
 - A fixed allocation to support the NIHR CRN LRN core management team.
 - A per capita allocation for research management staff
 - A per capita allocation for research infrastructure, including research nurses (or equivalent), support for clinicians of all professions who recruit patients into UKCRN Portfolio studies, and other NHS Service Support Costs
- All NIHR CRN LRNs will receive an initial allocation to provide a core standing research infrastructure on which to build. Thereafter, funding will be increased incrementally over time to reflect growth in research activity.
- The funding provided through the NIHR Comprehensive Research Network will be additional to, and separate from, all other NHS R&D funding.

Implementation Timetable

- We plan that the NIHR Comprehensive Research Network should start work in April 2007 and be fully operational within two years.

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