



National Institute for Health Research

RESEARCH SUPPORT SERVICES

Introduction

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

In May 2011, the NIHR adopted the Research Support Services, a framework of good practice and standard procedures to simplify and speed up local research management as well as managing operational risk proportionately.

This document sets out how the NIHR Research Support Services framework will harmonise and streamline complex local research management and governance processes in a risk-proportionate environment.

Overview

The NIHR Research Support Services provide a national framework for local NHS research management. This framework enables front line staff to collaborate in offering a consistent professional streamlined service, with proportionate procedures, to support clinical research in the NHS in England.

The framework is designed to achieve the following aims.

- Bureaucracy – cut red tape and gold-plating of regulation.
- Accountability – enable the public to hold public bodies to account.
- Efficiency – cut the costs of administration.
- Autonomy – enable front line staff to use their professional judgement.
- Safety – protecting patients and organisations from unsafe research.

Aim

Research Support Services complement the Government's intention to rationalise the regulation of health research:

- To improve the quality, speed and efficiency of research and research processes in the NHS by enabling NHS Trust R&D Departments to collaborate in providing a consistent professional front line service within a national framework.
- To harmonise and streamline the often inconsistent, lengthy and costly local processes for funded health research in the NHS, and build consensus on a

proportionate risk-based interpretation of policies and rules by NHS Trust R&D Departments. The national standards for research are set out in the [Research Governance Framework for Health and Social Care](#).

Government policy

The NHS Constitution confirmed the commitment of the NHS to the promotion and conduct of research to improve the current and future health and care of the population. Research is a core part of the NHS.

The NHS White Paper *Equity and Excellence: Liberating the NHS* stated the Government's intention to cut the bureaucracy involved in medical research and to bring forward plans for radical simplification.

The Government's *Plan for Growth* (March 2011) announced policies and actions to address the complexity of health research regulation and governance.

Paragraph 2.192 states:

“At a local level, the Government will radically transform the incentives for efficiency in research initiation and delivery. In May, the Government will launch a framework of good practice and standard procedures called the NIHR Research Support Services to facilitate consistent local research management and greatly improve performance. NHS Trusts which adopt these standards will stop unnecessary duplication of checks. They will publish metrics regularly on their performance. They will have access to NIHR financial support for these activities. For clinical trials, the NIHR will from 2012 publish outcomes against public NIHR benchmarks, including an initial benchmark of 70 days or less from the time a Provider receives a valid research protocol to the time when that Provider recruits the first patient for that study.”

Since the autumn 2011, the NIHR is making this a condition of new contracts and performance will affect funding from 2013.

Background

The practices of R&D Departments generally developed in the NHS in response to the Research Governance Framework for Health and Social Care. However, in too many NHS Trusts, the R&D Departments adopted a risk-averse approach that led to lengthy and costly processes for obtaining permission for clinical research to take place in the NHS, and which added an unnecessary burden to the ongoing management of that research activity.

It is widely recognised that this situation reflected a lack of effective and consistent systems, processes and support. Most Trust R&D Departments have endeavoured to support clinical research in their organisation, which appears most successful where local management of research is seen as a core business priority. The lack of standardised systems and processes, as well as the lack of an agreed risk-based approach to granting permissions and managing research projects, led to inconsistencies when interpreting the principles set out in the Research Governance Framework for Health and Social Care and legislation.

Many departments in NHS Trusts, including human resources, finance, information governance and pharmacy, play key roles in ensuring clinical research is set up and managed efficiently and effectively. Trust R&D Departments are responsible for a range of activities, including sponsorship of research studies and management of grants and other research income, as well as supporting researchers developing proposals.

The NIHR Research Support Services harmonise and streamline systems and processes to increase NHS Trust R&D Departments' speed and efficiency in setting up research, while also promoting consistency, transparency, professional judgement and local accountability.

Scope

Between 2009 and 2011, the NIHR developed and tested the Research Support Services framework to:

- Agree delivery time-lines for use in the NHS.
- Develop tools to help Trust Boards, Research Managers and Investigators to identify early the options, risks and mitigation strategies to provide high quality research in the NHS.
- Develop national standard operating procedures (SOPs) to support delivery of high quality research in the NHS and supported by competencies and training needs.
- Establish a monitoring system for collecting and publishing performance information to recognise success.

Delivery

Clinical research needs a professional workforce trained in research support to deliver NIHR Research Support Services in the NHS. This will be delivered by:

- The NIHR Comprehensive Clinical Research Network for research supported by the NIHR Clinical Research Network¹,
- Developing existing NHS Trust R&D Departments into local research support services to sustain other clinical research activity.

The NIHR Research Support Services in NHS Trusts continue to remain clearly within the scope of the local Trust management board's responsibility, which includes ensuring:

- Integration across the research portfolio (NIHR and non-NIHR supported activity)
- Alignment with broader strategic objectives within the Trust and / or local economy.
- Clear accountability for delivery.

¹ The DH document setting out the 'Eligibility Criteria for NIHR Clinical Research Network Support' is published at: [http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Portfolio/Documents/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support%20-%20Version%204%20\(February%202011\).pdf](http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Portfolio/Documents/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support%20-%20Version%204%20(February%202011).pdf)

Close linkages with other NHS Trust services (including human resources, finance and pharmacy) together with strong support from the Chief Executive/Senior management Board is essential to delivery.

The NIHR encourages joint arrangements between NHS organisations and their partners – particularly academic partners - for supporting clinical research in order to streamline processes reduce delays and lower barriers.

Focus

The primary focus of the Research Support Services is to facilitate NIHR-supported research. This includes all research funded by the NIHR, as well as research funded by the NIHR's partners and supported by the NIHR through the NIHR Clinical Research Network and other NIHR-funded research infrastructure.

The concepts and standard procedures in the Research Support Services framework will also facilitate other health research in the NHS (i.e. research that is not funded or supported by the NIHR) in the organisations for which the Secretary of State for Health is accountable. In this way, the NIHR will help NHS Chief Executives to meet their personal accountability in a proportionate and consistent way.

The NIHR has already implemented new systems and processes aimed at creating a vibrant and efficient research environment in England, including the NIHR Co-ordinated System for gaining NHS Permission (NIHR CSP) and the Research Passport scheme. These are helping to deliver a simplified and streamlined approach to administrative procedures.

The NIHR established a national unit within the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) to coordinate excellent research management and deliver appropriate research governance for studies managed through the NIHR Clinical Research Network (NIHR CRN) Portfolio.

Implementation

The NIHR Research Support Services has been adopted as standard process across the NHS to:

- Facilitate the development of NHS Trust R&D Departments as NIHR Research Support Services to emphasise their dual role in:
 - delivering to national standards;
 - collaborating with national systems to support high quality research; as well as
 - protecting their patients and own organisations from unsafe research

The NIHR will:

- Expect organisations to develop and publish a board approved operational capability statement.
- Implement a planning and readiness assessment toolkit for general use in identifying early and managing early the risks associated with research.

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- Develop competencies for staff of the NIHR Research Support Services.
- Support the delivery of training and education to develop competencies and promote collaboration in the use of standard processes.
- Work with partners to align Research Support Services with information services.
- Allow NIHR Flexibility and Sustainability Funding to be used by NHS Trusts for staff training and development in research management subject to evidence of outcomes showing that they are using the national standards, systems and operating procedures. Flexibility and Sustainability Funding may also be used to train core research management staff to establish the base capability needed to begin to demonstrate such outcomes.
- Where beneficial, encourage the establishment of joint NHS Trust / University research support services.
- Publish comparisons of outcomes against appropriate benchmarks. For clinical trials, the NIHR will publish outcomes against public NIHR benchmarks, including an initial benchmark of 70 days or less from the time a provider receives a valid research protocol to the time when that provider recruits the first patient for that study. This will be part of a balanced scorecard measuring competent initiation and delivery of research studies.
- Future NIHR funding to providers of NHS services will become conditional on evidence of outcomes demonstrating professional management of the initiation and delivery of health research. From autumn 2011, the NIHR is making this a condition of new contracts and performance will affect funding from 2013.

Timetable

May 2011 – the NIHR adopted the Research Support Services framework.

Autumn 2011 – new contracts include conditions that organisations are playing their part in the national research governance system and delivering competent performance against benchmarks.

From 2013 – NIHR funding becomes subject to evidence of outcomes demonstrating professional management of the initiation and delivery of health research.

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