



## **BEST RESEARCH FOR BEST HEALTH**

### **IMPLEMENTATION PLAN 4.1g**

### **BUREAUCRACY BUSTING: NIHR RESEARCH SUPPORT SERVICES**

*Best Research for Best Health*<sup>1</sup> 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: NIHR Research Support Services. This document will be regularly updated. The latest version should be used.

*Version: 2*

*Issue date: January 2010*

*Planned revision & re-issue date: July 2010*

#### **Aim**

To improve the quality, speed and efficiency of research and research processes in the NHS by facilitating the reconfiguration of NHS Trust R&D Departments within a national framework for the NIHR Research Support Services.

#### **Purpose**

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 are set out in the Research Governance Framework for Health and Social Care. The NIHR will implement a national programme to:

- Agree delivery timelines for use in the NHS.
- Develop national standard operating procedures to support delivery of the standards and timelines; supported by guides to risk management, competencies and training needs.
- Establish a monitoring system for collecting and publishing performance information.

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<sup>1</sup> *Best Research for Best Health*: A New National Health Research Strategy. The NHS contribution to health research in England. Department of Health. 2006.

- Manage a process to embed these in use.
- Adopt an outcome-focused system to recognise success.

## Background

The NHS Constitution confirms 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 Operating Framework for the NHS in England for 2009/10 contains a specific aim to double the number of patients recruited into clinical trials and other well-designed studies. The Department of Health has been working with Chief Executives of key research-active NHS organisations to develop a strategy to incentivise NHS organisations to participate in high-quality research and to ensure successful delivery of this aim, alongside better strategic partnerships between the NHS and the life sciences industries.

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

It is recognised that this situation reflects a lack of effective 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. This lack of standardised systems and processes, as well as the lack of an agreed risk-based approach to granting permissions and managing research projects, has led to inconsistencies when interpreting the principles set out in the Research Governance Framework for Health and Social Care and relevant legislation, such as the Human Tissue Act.

Many complain that this situation is hindering not facilitating research. The NIHR held a workshop on 30 April 2009 on "Dismantling the Barriers to Clinical Research". The workshop identified priorities for action needed to address specific barriers to clinical research in England, and advised the NIHR to proceed with the professionalisation of Trust R&D offices and to promote the establishment of "NIHR research support services". The outcome of this workshop is available at [www.nihr.ac.uk/events/Pages/Dismantling\\_Barriers.aspx](http://www.nihr.ac.uk/events/Pages/Dismantling_Barriers.aspx).

Discussions with industry under the auspices of the Office for Life Sciences reinforced the impact of these issues on the nation's competitiveness as an environment for clinical research. As a result, it was included in the government's blueprint for life sciences (see box).

Extract from:

**'Life Sciences Blueprint: A statement from the Office for Life Sciences' July 2009**

The Government will support the NHS in creating a national framework for professional local management of health research, transitioning R&D Departments to become NIHR Research Support Services Departments adopting standard operating procedures and a shared risk-based approach in order to create a step-change in speed and reliability for commercial and non-commercial trials in the UK.

By April 2010

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. The NIHR recognises that 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 focus of this NIHR Implementation Plan is to harmonise and streamline those systems and processes essential to increasing the speed and efficiency of Trust R&D Departments' role in setting up research, while also promoting local accountability.

### **Delivering NIHR research support services**

The NIHR plans to develop a national framework for the "NIHR Research Support Services". Clinical research needs a professional workforce trained in research support to deliver NIHR Research Support Services in the NHS. The NIHR Research Support Services will be delivered by:

- the NIHR Comprehensive Clinical Research Network (for research supported by the NIHR Clinical Research Network that is in the NIHR portfolio); and
- by developing existing NHS Trust R&D Departments into local research support services to support other clinical research activity (including NIHR-funded research activity such as the NIHR Biomedical Research Centres and Units, NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), and individual NIHR Programmes and project grants).

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);
- fit with broader strategic objectives within the Trust and / or local economy; and
- clear accountability for delivery.

Close linkages with other NHS Trust services (including human resources, finance and pharmacy) together with strong support from the Chief Executive will help deliver this.

The NIHR will actively encourage 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 of NIHR research support services**

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

The NIHR has already implemented many 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, which are helping to deliver a simplified and streamlined approach to administrative procedures. The NIHR has established a national unit within the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) to coordinate excellent research management and deliver proper research governance for studies managed through the NIHR Clinical Research Network (NIHR CRN) Portfolio.

### **Implementation**

The NIHR will implement a national programme to support professional research management across the NHS through the following actions:

- 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.
- Work with relevant parties to agree a simple, common classification of risk for research involving patients in the NHS and consensus on proportionate action in NHS Trusts to manage risk.
- Work with the best to develop a toolkit for general use.
- Agree timelines for the national standards to be delivered through research support services.
- Agree competencies for staff of NIHR Research Support Services.
- Support the delivery of a training and education programme for the delivery of research support services (to develop competencies and use standard processes).

- Allow NIHR Flexibility and Sustainability Funding to be used by NHS Trusts for staff training and development in research management when their R&D Departments join the NIHR research support services network and adopt the national standards, systems and operating procedures and work towards accreditation.
- Where beneficial, encourage the establishment of joint NHS Trust / University research support services.
- Work with partners to develop an outcome-focused national system to recognise successful delivery of NIHR standards for research support services.
- Feed back performance information, and publish performance against standards for research support services.

### **Implementation Timetable**

**By March 2010** – Work with regulators to agree structured approaches to risk assessment and a risk management check list for clinical trials; and by April 2010 issue a draft guide to risk management, thereby enabling key risks to be identified as early as possible in the research study life cycle.

**By March 2010** – Develop a draft toolkit of standard operating procedures (SOPs) for research support services.

**By March 2010** – Develop draft guidance on competencies to be delivered by research support services staff for roll out with training packages by June 2010.

**By December 2010** – Complete an embedding phase and by January 2011 draw lessons for continuous improvement.

**By March 2011** – Implement an outcome-focused national system to recognise delivery of NIHR standards for research support services.

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