



**National Institute for
Health Research**

BEST RESEARCH FOR BEST HEALTH

IMPLEMENTATION PLAN 4.1

**BUREAUCRACY BUSTING:
GOVERNANCE, ADVICE AND ETHICS SYSTEMS**

*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 the linked components which will together provide systems underpinning the National Institute for Health Research: **GOVERNANCE, ADVICE AND ETHICS SYSTEMS**

It should be read with the implementation plans for the **NIHR COMPREHENSIVE RESEARCH NETWORK** and **NIHR INFORMATION SYSTEMS**.

This document will be regularly updated. The latest version should be used.

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Aim

- To support a vibrant and efficient research environment that commands public confidence and protects research participants; through
 - world-class research networks; and
 - action to simplify processes and save time.

Purpose

- To offer authoritative expert support for regulatory approvals and permissions to everyone who needs it.
- To unify and streamline procedures associated with regulation, approvals, management and reporting, ensuring good governance.
- To do once, whatever does not have to be done in many places.
- To maximise joint use of national standardised systems and processes.
- To support decisions with national standards, templates and data sets
- To give active support to high quality research
- To provide a one-stop shop for each research-active NHS organisation.

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

Nature

- Linked initiatives:
 - **Networks**
 - The UK Clinical Research Network Coordinating Centre (UKCRNCC) will coordinate R&D management.
 - A key function of the National Institute for Health Research (NIHR) Comprehensive Research Network (CRN) will be excellent R&D management to deliver proper governance.
 - The research-active NHS organisations that constitute the NIHR CRN will work together, locally and nationally, using R&D management approaches which minimise bureaucracy and maximise effectiveness.
 - Networks will share common procedures, integrated national R&D information systems, research passports and a national expert advice service.
 - NIHR CRN Local Research Networks (LRNs) will deploy R&D management expertise to deliver proper governance.
 - **Advice service**
 - A network of front-line advisers backed up by a network of national regulatory experts.
 - Integrated national R&D **information systems** (see plan 4.2)

Detail

1. Networks

UKCRN NHS research management unit

- A unit for NHS research management is being established in the Co-ordinating Centre for the UK Clinical Research Network (UKCRN).
- This unit is working with the Department of Health, the NHS, and UK Clinical Research Collaboration (UKCRC) partners to
 - deliver, on behalf of the NHS in England, a central single point to sign off studies which enter the NIHR Portfolio;
 - develop systems to oversee research management within NIHR CRN;
 - monitor the impact of new regulation on behalf of the UKCRC.

The NIHR Comprehensive Research Network will provide nationally networked NHS R&D management

- NIHR CRN Local Research Networks will deploy research management expertise to support and manage high quality research with proper governance.
- Research management functions will be distributed in the organisations within NIHR CRN Local Research Networks as appropriate.
- NIHR CRN Local Research Networks will coordinate and streamline R&D management across their individual areas.

- Research managers within the NIHR CRN will work together to deliver a national service. NIHR CRN Local Research Networks will share national standard procedures, supported by integrated national R&D information systems.

For organisational structures and functions, see Implementation Plan 5.1a: NIHR Comprehensive Research Network.

2. Advice service

- The advice service will link front-line advisers in the NIHR CRN Local Research Networks with national regulatory experts and other resources.
- At local research network level, the advice service will
 - provide consistent high quality advice on working with regulation 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, phone and letter;
 - provide a telephone help-line.
- At national level, the advice service 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 advisers on issues they identify;
 - work through the UKCRC with regulators, policy-makers, and trialists to document and publicise solutions to regulatory issues;
 - work with partners across the UK to codify and explain differences in regulation, and where possible harmonise research governance practice UK-wide.

3. Research ethics

- The Central Office for Research Ethics Committees (COREC) at the National Patient Safety Agency is implementing a package of measures to strengthen expert support for the ethics committee service, speed up the review of low-risk studies, and help ethics committees improve consistency. See www.corec.org.uk

Development process

- Following consultation, the NPSA is implementing plans to streamline operation of the NHS research ethics committee system: see the implementation plans at www.corec.org.uk
- DH will revise relevant guidance, including
 - NHS Permission for R&D involving NHS Patients
 - Governance Arrangements for Research Ethics Committees (RECs).

- Working with UKCRC partners and through UKCRC processes, the Department of Health has issued an updated model contract for contract pharmaceutical clinical trials. It will,
 - issue model contracts for investigations of medical devices and studies conducted via Contract Research Organisations), with guidance on costing²,
 - finalise and roll out research passports,
 - develop model agreements enabling care organisations to meet their duties by working jointly through networks.
- The Department of Health, the UKCRN and Strategic Health Authorities (SHAs) are collaborating in joint planning to establish the NIHR Comprehensive Research Network for England with research management functions for NIHR research that meet NHS bodies' duties, enabling prompt NHS permission.
- The UKCRN
 - is establishing a national coordination system for research management and a coordinating centre for the national advice service;
 - with the Department of Health, is organising and supporting a process for each NIHR CRN local research network to
 - draw up and implement a research management plan that creates a high quality responsive local service, networked to operate as part of a national research management service;
 - provide research management functions and expertise at the locations where they are most needed;
 - ensure all parts of the clinical research system exercise their responsibilities properly to deliver effective governance.

Eligibility

- These services will be designed to
 - help researchers prepare and conduct studies to high quality; and
 - enable organisations operating within the responsibilities of the Health Secretary to meet their duties efficiently and effectively
 - enable industry and public funders to rely on predictable systems.
- All organisations and individuals in England that provide care, fund research, employ researchers or review or regulate research will be eligible to use them.
- The services will be available to organisations and individuals in Scotland, Wales and Northern Ireland in the context of UK-wide co-operation in health R&D and contribution of appropriate funding.
- UKCRC members will be invited to consider whether it should be a term of contract or condition of grant for all funding members of the UKCRC that

² See NHS Finance Manual: Detailed Guidance 30, Income Generation in the NHS, 30.47 to 30.54

their contractors and grant-holders collaborate in these national systems, using standard processes.

Funding

- NHS R&D allocations to NHS providers for research management will transition to the new system over a two-year period.
- UKCRC partners will be invited to contribute in cash or in kind, and to propose additional functionality for which they are willing to pay.

Monitoring and Performance Management

- Performance of networks, centres, services and systems will be monitored annually against agreed metrics, informed by questionnaires and other methods of measuring user satisfaction.
- An annual report to the NIHR and UKCRC Boards will be published after discussion.
- The structure and working methods will be subject to five-yearly review.

Implementation Timetable

- Development and set-up in year one.
- National advice service and research passports integrated with NIHR CRN during year two.
- Unified management systems and integrated national R&D information systems from year three.

The indicative timetable is:

- January 2006 - R&D strategy confirmed intention to establish integrated governance and advice systems.
- January to April 2006 – NPSA consultation on NHS RECs
- July 2006 – Piloting of advice service began
- August 2006 – Streamlining of research ethics system began
- September 2006 – Piloting and evaluation of research passports began
- January 2007 – 18 NIHR CRN Local Research Networks (LRNs) identified covering 7 SHAs in England
- January to March 2007 – UKCRN works with SHAs to commence implementation of CRN LRNs.
- January to March 2007 – UKCRN develop procedure for single sign-off of regulatory issues to enable streamlined local NHS permission.
- January to April 2007 – After piloting, COREC, NHS R&D Forum, UKCRN and DH finalise procedure for NHS organisations to undertake site-specific assessment for ethical review.
- April 2007 – NIHR CRN LRNs begin operation.

- April to June 2007 – Advice service rolled out across NIHR CRN LRNs with backup from national experts.
- April 2007 – roll-out of standard procedures begins, including NHS site assessment for ethics and single sign-off.
- April 2007 – DH issues research passport guidance.
- April to September 2007 – UKCRN works with universities and NIHR partners to establish research passports as a standard operating procedure for NIHR CRN LRNs.

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