



**National Institute for
Health Research**

BEST RESEARCH FOR BEST HEALTH

IMPLEMENTATION PLAN 4.1e

BUREAUCRACY BUSTING: REGULATORY AND GOVERNANCE ADVICE SERVICE

*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 element of the systems underpinning the National Institute for Health Research. Implementation Plan 4.1a summarises the actions we are taking to streamline research management. Plan 4.1e details how the advice service on research regulation will contribute. This document will be regularly updated. The latest version should be used.

Version: 6

Issue date: January 2010

Planned revision & re-issue date: July 2010

Aim

- To provide authoritative and clear regulatory and governance advice to researchers through a network of front-line advisers supported by a network of national regulatory experts.

Nature

- A network of NIHR front-line advisers, backed up by a network of national regulatory experts.
- Coordinated by the NIHR Clinical Research Network Co-ordinating Centre (CRN CC) and the Medical Research Council (MRC), and funded by the NIHR.
- The advice service links front-line advisers in the NIHR networks with national regulatory experts and other resources, supported by the NIHR Information Systems.
- At local level, the advice service:
 - provides consistent high-quality advice on working with regulation, such as the Clinical Trials Regulations and other legislation affecting clinical research;
 - refers callers confidently to the best source of written advice; and

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

- responds to queries by e-mail, phone and letter.
- At national level, the advice service:
 - codifies advice from regulators, policy makers and experts in good practice, and presents it in a user-friendly form;
 - uses the information systems of the NIHR and partners to make authoritative standard advice available to front-line advisers on issues they identify;
 - works under the UK Clinical Research Collaboration (UKCRC) umbrella with regulators, policy makers and researchers to document and publicise solutions to regulatory issues;
 - works to codify and explain differences in regulation across the UK, and where possible harmonises research governance practice UK-wide; and
 - provides authoritative and clear advice in response to specific queries forwarded by front-line advisers on behalf of researchers.

Implementation

- The national network of regulatory experts was established in 2006 under the auspices of the UKCRC.
- The NIHR CRN Coordinating Centre together with the MRC, established the coordinating mechanisms in 2006.
- The advice service was rolled out and publicised in 2007, on an interim basis, with support from individual NHS R&D offices.
- From November 2007, the local network of front-line advisers became a function of the NIHR Comprehensive Clinical Research Network (CCRN) Local Research Networks (CLRN).
- The advice service is subject to ongoing evaluation and is overseen by a multi-agency group.

Further information

Further details about the Regulatory and Governance Advice Service is available on the UKCRC website at www.ukcrc-rgadvice.org/Pages/default.aspx

Department of Health Lead:

C Marc Taylor
Head of R & D Systems and Governance
Marc.Taylor@dh.gsi.gov.uk