



BEST RESEARCH FOR BEST HEALTH

IMPLEMENTATION PLAN 4.1f

BUREAUCRACY BUSTING: RESEARCH ETHICS

*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 4.1f gives more detail about research ethics. This document will be regularly updated. The latest version should be used.

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Aim

To support the operation of research ethics committees so that they can work more consistently, effectively and efficiently:

- Safeguard the rights, dignity, safety and welfare of potential human research participants by providing an independent opinion on the ethical implications of a research proposal.
- Facilitate and promote ethical research.

Nature

- The head office of the National Research Ethics Service (NRES) at the National Patient Safety Agency (NPSA) is implementing a package of measures to:
 - strengthen expert support to research ethics committees;
 - speed up the review of low-risk studies; and
 - help research ethics committees improve the consistency of the service they provide and the decisions they make.

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

- The reforms follow from the recommendations in the *Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees*.
- Following consultation in January to April 2006, the NPSA published the implementation plan *Building on Improvement* in August 2006 (available at www.nres.npsa.nhs.uk).
- The NRES was launched in March 2007. It is implementing the published implementation plan to streamline operations of NHS research ethics committees over 3 years.
- The remit of research ethics committees in England is set out in the 2001 DH guidance, *Governance Arrangements for NHS Research Ethics Committees*. DH issued a revised version for comments in May 2009. It:
 - clarified which types of activity are research that requires ethical review; and
 - supported streamlined review of research activities that present no material ethical issues for human participants.
- The NRES is building capacity to screen applications, to identify research activities that present no material ethical issues for human participants, and to manage proportionately the review of such applications. The procedures involved were piloted in 2008 and a report published in November 2008 titled: 'Developing Commensurate Review: A Report of the National Research Ethics Service 'Fast Track' project. The report is available at www.nres.npsa.nhs.uk. The pilot will inform national implementation.
- The NRES is developing services to identify applications submitted before adequate peer review, or with the science poorly described; and advise applicants, or make further enquiries on behalf of the committee.
- The NRES worked with the NIHR Comprehensive Clinical Research Network (CCRN) Local Research Networks (CLRN) and NHS R&D offices to transfer responsibility for site-specific assessment to NHS hosts by April 2009.
- The NRES has launched incremental revisions of its electronic application form to take explicit account of differences between types of research and other issues.
- The NRES led collaborative work with other organisations involved in research regulation to integrate and harmonise the information required from applicants, in order to reduce the administrative burden and eliminate duplication of effort wherever possible.
 - One outcome was to integrate the information required in an application to an ethics committee with the information required for an NHS host to consider whether to permit a study to commence at that site. This improves information flows for the NIHR Co-ordinated System for gaining NHS Permission (see implementation plan 4.1c), as well as supporting site-specific assessment by NHS hosts.
 - An integrated research application system (IRAS) was launched for consultation and use in January 2008. See www.myresearchproject.org.uk. The consultation period concluded in July 2008 and a revision was released in December 2008. A management board was established in June 2008 to determine the appropriate timetable to withdraw mechanisms superseded by

the integrated system. IRAS became the IRAS partners' preferred route for new applications in April 2009.

- In step with better management of applications and of business processes, the NRES is managing a reduction in the number of research ethics committees.
- The NRES is monitoring the membership of research ethics committees to ensure that the membership reflects the diversity of society. It is also keeping members' expenses and allowances under review.
- The NRES has maintained a programme of training, accreditation, shared ethical debate and guidance on issues and arguments, and commissioned a review of decision-making, to help research ethics committees reduce inappropriate inconsistency.
- The NRES has recruited a new cadre of national research ethics advisers to support and facilitate the work of research ethics committees.

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