

Protecting and promoting the interests of patients and the public in health research

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The establishment of the Health Research Authority and successful transfer of the National Research Ethics Service provided welcome stability for the provision of Research Ethics Committee review.

We have put in place governance structures to enable the Health Research Authority to deliver business effectively, robustly and transparently and we have started work immediately on delivering its wider functions.

In our first three months, we have agreed plans and started work to provide the platform for the unified approval process from the Integrated Research Application System (IRAS). The first phase – e submission – will launch in June 2012. Our business plan for 2012/13 will continue and build on the momentum we have created to shape effective national roles for the Health Research Authority.



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Vision and ambitions

To develop a Health Research Authority:

- driven by our key purpose of **protecting and promoting the interests of patients and the public in health research**
- underpinned by our leadership in creating a unified health research approval process and promoting consistent, proportionate standards for compliance and inspection
- with our success being acknowledged by key stakeholders, as well as seen through improved approval times, increased numbers of research participants and projects, and greater confidence in health research.

We will work with all the relevant partners to help create an environment where:

- greater numbers of **patients and the public** can and do take part in health research, and continue to feel safe when they do
- **applying to do research** is simpler, and **getting a decision** is quicker
- **researchers** find it easier to do high-quality, ethical research
- the **NHS** appreciates how health research benefits patients and staff
- **industry** sees the UK as a great place to do health research
- more money from **charities and other research funders** goes into carrying out research, and less into getting through unnecessary hoops before it starts
- clinical trials get **registered** and research results get **published**.

Protecting and promoting the interests of patients and the public in health research

We will have strong, independent governance and advice to enable us to credibly and effectively protect and promote patient and public interests in health research:

- a working group including Association of Medical Research Charities and INVOLVE is advising us on our patient and public involvement strategy to ensure we deliver effective national roles that command the confidence of patients and the public
- we already keep abreast of emerging ethical issues in health research through advice to our board from the National Research Ethics Advisors' Panel
- our full board will soon have a chair and non-executive majority, to develop, lead and drive forward our strategic agenda and role as a public body.

Creating a unified approval process and promoting proportionate standards for compliance and inspection

Research is vital to the nation's health and wealth but the regulatory environment for health research is too complicated.

- We will facilitate timely, high-quality research by creating a unified approval process and by promoting consistent, proportionate standards for compliance and inspection. This will help put a stop to the excessive combined effect of individual legal and policy requirements for approval of health research
- A multi-agency team including the Human Tissue Authority, Medicines and Healthcare products Regulatory Agency, the National Institute for Health Research and the National Research Ethics Service is supporting us to ensure we shape effective national roles that command the confidence of patients, the public, other regulators and the health research community including life sciences.
- We will provide an advice service, guidance and information for researchers in appropriate and accessible forms.

Working in partnership

We will continue to work closely with other regulators, promoting proportionality and a unified approach, such as to support the Medicines and Healthcare products Regulatory Agency in their risk-based approach and pressure for more risk-based EU legislation on clinical trials.

Regulatory approvals for research rely on local decisions about the practical delivery of studies. Individual NHS trusts remain best placed to determine whether and how they can deliver a study. Local assessment of feasibility is vital to accurate decisions about whether and how a provider can deliver a study. But local decision making can give rise to variable practice.

We will collaborate with others to clarify respective remits and responsibilities in reviewing and managing research.

Alongside the National Institute for Health Research (NIHR)'s incentives and tools for efficient practice among NHS trusts, we will work with the NIHR Clinical Research Network to enhance consistent, streamlined and timely study set-up and delivery.

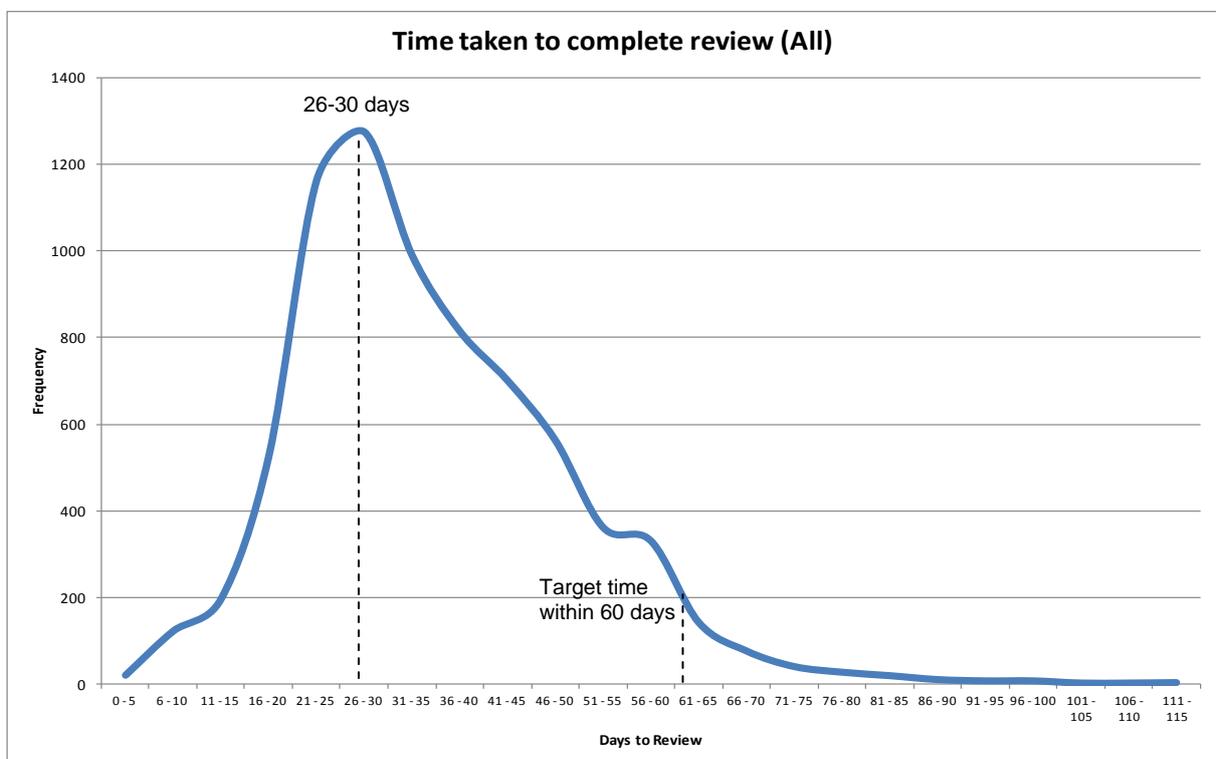
Building on success

The National Research Ethics Service is a core component of the Health Research Authority. It reviews over 6000 applications per year through its 80 Research Ethics Committees with 1,200 voluntary Research Ethics Committee members.

Ethical review is the most important protection for research participants. Research Ethics Committees help ensure that any risks of taking part in a research project are kept to a minimum and explained to participants in full. Their approval is a key reassurance to potential participants. All research involving NHS patients has to have this approval before it can start.

The National Research Ethics Service has transformed the system for ethics review, speeding up the process (see graph for review times in 2010/11), eliminating duplication and introducing efficiencies which have seen the number of committees in England fall from 200 in 2002 to 80 today. This transformation has included improvements in:

- standard operating procedures
- time to approval
- support and advice
- proportionate reviews
- quality assurance for consistent practice and decision-making
- national training
- efficient correspondence with applicants.



Time taken to review all applications

For further information visit www.hra.nhs.uk

The Department of Health has established the Health Research Authority with its core purpose of protecting and promoting the interests of patients and the public in health research. It will protect patients from unethical research while enabling them to benefit from participating in research by simplifying processes for ethical research. This role is intended to reduce the regulatory burden on research-active businesses, universities, charities and the NHS and to improve the timeliness of decisions about research and so the cost-effectiveness of its delivery in the UK. Next steps include:

- appointment of an **independent chair and non-executive directors** this summer, supporting the Health Research Authority to develop as a public body at arm's length from Government and perform its functions credibly and effectively
- draft legislation for the Health Research Authority's **long-term stability and independence** as a non-Departmental public body, planned for pre-legislative scrutiny in the Parliamentary session starting in spring 2012
- **further functions** for the Health Research Authority, in particular approving exceptional use of confidential patient information for research.

Through the National Institute for Health Research, the Department of Health is also radically transforming the incentives for local efficiency in research initiation and delivery, with tools and support to enable improved performance that is transparent and accountable:

- **incentivising performance** – through publishing performance against benchmarks, such as recruitment of participants to time and target and of the first participant within 70 days of a valid research application, with the latter affecting future NIHR funding to NHS providers
- **improving consistency in local NHS research management** – through NIHR Research Support Services tools to encourage risk-proportionate standard procedures
- **embedding good practice throughout the NHS** – by promoting a visible commitment to research from NHS chief executives, rapid and responsive escalation of exceptions and executive oversight of performance metrics
- **facilitating combined and streamlined research approvals** – by co-operating with the Health Research Authority to interface NIHR and HRA systems for processing research applications.

The National Institute for Health Research will support the Health Research Authority's creation of a unified approval process and consistent, proportionate standards for compliance and inspection.