FACTSHEET 8

The draft Care and Support Bill – Health Research Authority (HRA)

"There was widespread acknowledgment that the Government's speed in setting up the Health Research Authority has been important in demonstrating its commitment to support the life science sector in the UK"

(Academy of Medical Sciences, Cancer Research UK and Wellcome Trust joint meeting report on transforming the regulation and governance of health research in the UK , Feb 2012).

Context

In March 2011, the Government announced the creation of the Health Research Authority (HRA) to streamline the regulation of research. The HRA was established as a Special Health Authority (SpHA) in December 2011 as an interim measure ahead of primary legislation to establish it as a Non Departmental Public Body (NDPB), as soon as Parliamentary time allows.

What will the draft Bill do?

The draft Care and Support Bill abolishes the HRA as a SpHA and **establishes it as a statutory NDPB**, giving it greater independence and stability.

As a NDPB, the HRA's ability to fulfil its **key purpose of protecting and promoting the interests of participants, potential participants and the general public in health and social care research** would be strengthened. The HRA's independence as a NDPB would support it to promote the interests of those people by facilitating the conduct of good quality, ethical research.

The HRA will have clear functions. These include all the functions the SpHA currently undertakes, for example functions relating to Research Ethics Committees (RECs). They also include the function of approving the exceptional processing of confidential patient information for research purposes, a responsibility which will be transferred from the Secretary of State to the SpHA by April 2013.

The intention is for a smooth transition from the existing SpHA to the new NDPB. The HRA would continue work that has already started, through cooperation with other bodies, to **create a unified approval process for research**. In meeting its duty to promote the coordination and standardisation of practice, the HRA would continue to promote consistent, proportionate standards for compliance and inspection.

In this way, the HRA would continue to have a role as part of a national system of research governance, **promoting a proportionate approach among all those involved in research**, including for example, NHS providers. The HRA could continue to reduce duplication in approval processes for research and publish guidance on the landscape for regulation, governance and inspection.

Other functions conferred directly on the HRA would complement its role in relation to RECs. These include the responsibility, currently held by the Secretary of State, as a member of the UK Ethics Committee Authority (UKECA).

The HRA would also be able to take on functions beyond the health service in England, for example, those relating to social care and, subject to the outcome of consultation and secondary legislation, the regulation of embryo research. To enable a harmonised approach to research regulation across the UK to continue, the HRA would have powers to undertake certain functions on behalf of Wales, Scotland and Northern Ireland by agreement. The HRA would also be under a duty to cooperate with the devolved authorities with a view to streamlining regulation of the ethics of research.

Case study 1 – Protecting the interests of patients and the public in health research

The HRA SpHA runs a National Research Ethics Service (NRES) which reviews over 6,000 applications per year through its 80 research ethics committees (RECs) with 1,200 voluntary members. Research is core to NHS and other care services, helping them improve the current and future health and well-being of the people they serve. However, research sometimes involves a degree of risk, so regulation provides participants, potential participants and the public with assurance that there are appropriate safeguards in place.

A REC is a group of people appointed to review whether research proposals are ethical. Research must conform to recognised ethical standards, which include respecting the dignity, rights, safety and well-being of those who take part. Each REC includes members of the public and people with specific knowledge who can help the committee understand particular aspects of research proposals. RECs help ensure that any risks of taking part in a research project are kept to a minimum and explained to participants in full. All REC members are given training to understand research ethics and the committees are independent of the researchers, the organisations funding the research, and the organisations where the research will take place.

Strengthening the HRA's independence by establishing it as an NDPB will increase public confidence in the protection NRES currently provides, ensuring that the HRA acts, and is seen to act, in the interests of patients and the public whose interests it must protect, and is free from political influence.

Case study 2 – Promoting the interests of patients and the public in health research

The HRA can help research begin more quickly by streamlining approvals through unifying processes, making regulation more proportionate, standardising expectations and removing duplication. NDPB status will additionally assist the HRA to realise benefits for patients by facilitating good-quality, ethical research studies that improve care, give earlier access to potential new treatments, and increase knowledge. This will increase opportunities to participate in research by making this country a more attractive place for international companies to do research, encouraging investment in the UK and enabling patients and the public here to benefit. The stability of an NDPB can reassure funders that work to streamline the health research environment will continue and is not subject to a change of government, giving them the confidence to invest in our economy for the long-term.

The HRA can make it easier for research to be high quality, so studies increase knowledge, using and adding to what is already known. It is not always easy for researchers to find what evidence already exists when different names are used for the same study, and some research results are not published. Simple new mechanisms could make it easier to identify research studies through a unique identification system and standards for study titles, as well as making it easier to access the current evidence by ensuring studies are published. With NDPB status, the HRA would have the authority to put in place mechanisms that will ensure participation and investment is in research that explores unanswered and important questions and which, if answered, could make a real difference to the future of health and care.

FURTHER INFORMATION

- HRA website for information about the Special Health Authority: **http://www.hra.nhs.uk**
- Academy of Medical Sciences research regulation report: **http://www.acmedsci.ac.uk/p47prid88.html**
- The Plan for Growth: **http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf**
- Consultation on proposals to transfer functions from the HFEA to HTA: **http://www.dh.gov.uk/health/files/2012/06/Consultation-on-proposals-to-transfer-functions-from-the-Human-Fertilisation-and-Embryology-Authority-and-the-Human-Tissue-A.pdf**

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