



FACTSHEET 16

The Care Bill – Health Research Authority

"We have been very impressed with the (Health Research Agency) during its first year ... it really has made an enormous difference as a research funder that they have come to us, engaged the research community and all their other stakeholders to ensure confidence and trust in what they are doing. We therefore welcome the alignment of responsibilities in the Bill; we think it is important that the HRA be established as (a Non Departmental Public Body), which will give it both independence and stability to continue to do what it is doing already."

Dr Nicola Perrin, Wellcome Trust, in Oral Evidence given to the Joint Committee on Draft Care and Support Bill.

This factsheet explains what changes the Care Bill will mean for an organisation called the Health Research Authority.

Context

In March 2011, the Government announced the creation of the Health Research Authority (HRA) to improve the way research is regulated in England. The HRA has been a Special Health Authority (SpHA) since December 2011 and the Bill would turn it into a Non Departmental Public Body (NDPB).

What will the Bill do?

The Care Bill turns the HRA from a SpHA into an NDPB. This will make it more independent and stable because it will have clearly defined duties and powers set out in the Bill, but it will still have to report to the Secretary of State for Health and Parliament.

The change also means that the HRA will be able to cover social care research, as well as health research, and do some work across the UK together with Wales, Scotland and Northern Ireland.

The HRA's main job is to look after the interests of the general public in health and social care research. This means making sure that for all those people who take part, or who may take part, in research, it is done in a fair, safe and ethical way.

The HRA will have a clear role. This includes everything it does at the moment such as establishing or recognising Research Ethics Committees (RECs) who approve health or social care research. The HRA is also in charge of deciding if confidential information about a patient can be used for research. This job was done by the Secretary of State until 1 April 2013.

The plan is for the HRA to become an NDPB without disrupting the way it does its job. The HRA would carry on with work that has already started, working with other organisations, to create a joined up way of approving research. As part of its job to try and make sure that research is simpler to do, the HRA will also try to make sure standards of research are applied, and inspections carried out, in a fair and balanced way.

This means that the HRA will continue to work with organisations across the country that are involved in research, such as those that provide NHS care encouraging research that is well conducted and well managed. It can also carry on preventing duplication so approval of research can happen more quickly, ensuring money is well spent. The HRA will also provide information for people carrying out research.

Another job it will need to do is to be a member of the UK Ethics Committee Authority (UKECA) which establishes RECs to act UK wide. The HRA will replace the Secretary of State for Health on this committee.

To try to make sure that the whole of the UK does things consistently the HRA will also have to work together with Wales, Scotland and Northern Ireland to agree how to make sure that research is conducted and managed appropriately. The HRA will also be able to do some jobs for Wales, Scotland and Northern Ireland if the other country wants them to.

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 free from political influence.

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

Establishing the HRA as an NDPB will give it even greater independence and stability. Its independence as an NDPB, firmly at arm's-length from ministers, will command public and patient confidence in both the work it does and the research it approves.

Establishing the HRA in primary legislation, agreed by Parliament, will reassure participants in research, the research community and research funders that the regulatory framework will remain stable, giving them long term confidence about participating in and funding research. Primary legislation will also strengthen the HRA's co-operative relationship with other regulatory bodies in order to make regulation more proportionate, standardise compliance requirements and remove duplication. It will also help the HRA 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 to benefit.

The HRA can make it easier for research to be high quality, so studies make a genuine contribution to scientific literature, using and adding to what is already known. It is not always easy for researchers to find out what evidence already exists when different names are used for the same study, and some research results are not published; this makes it more difficult to design and embark on research that is safe, ethical and scientifically sound. Primary legislation would enable the HRA to command authority and co-operation to put in place mechanisms that will ensure participation and investment are in research that explores unanswered and important questions and which, if answered, could make a real difference to future health and care.

FURTHER INFORMATION

- <http://www.hra.nhs.uk> – HRA website for information about the Special Health Authority
- <http://www.acmedsci.ac.uk/p47prid88.html> – Academy of Medical Sciences research regulation report
- http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf – The Plan for Growth