# EXPLANATORY MEMORANDUM TO

# THE HEALTH RESEARCH AUTHORITY (ESTABLISHMENT AND CONSTITUTION) ORDER 2011

**2011 No. 2323**

**AND**

# THE HEALTH RESEARCH AUTHORITY REGULATIONS 2011

**2011 No. 2341**

**1.** This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

## 2. Purpose of the instruments

2.1 The Order establishes a new Special Health Authority called the Health Research Authority to facilitate and promote research relating to the health service, through research ethics committees which check that research proposals meet ethical standards, and to establish, and appoint members to, those committees. The Regulations make provision about the accountability of the Health Research Authority, its membership and procedure.

## 3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

## 4. Legislative Context

4.1 Subject to Parliamentary approval, the current Health and Social Care Bill when enacted will abolish the National Patient Safety Agency and Strategic Health Authorities. These instruments create a new Special Health Authority and confer on it those bodies' functions relating to research ethics committees. It is intended that the Special Health Authority will pave the way for a Health Research Authority Non-Departmental Public Body to be set up by means of future primary legislation.

## 5. Territorial Extent and Application

5.1 These instruments apply to England.

## 6. European Convention on Human Rights

As these instruments are subject to negative resolution procedure and do not amend primary legislation, no statement is required.

## 7. Policy background

7.1 UK health research activities, and the UK's international position in the life sciences, are being seriously undermined by an overly complex regulatory and governance environment. It has become far too difficult to navigate the complex national and local processes for research approvals. This is evidenced by a fall in the UK's global share of patients in clinical trials, and by the increased time and costs of navigating the UK's complex research approval processes for both clinical trials and other types of health research. The life sciences sector employs over 100,000 people and invests heavily in R&D, accounting for over 28 per cent of all business R&D. The current situation is stifling research here and driving medical science overseas.

7.2 The NHS White Paper (July 2010) said: 'The Government will cut the bureaucracy involved in medical research. We have asked the Academy of Medical Sciences to conduct an independent review of the regulation and governance of medical research. In the light of this review we will consider the legislation affecting medical research, and the bureaucracy that flows from it, and bring forward plans for radical simplification.'

7.3 The report of the Academy of Medical Sciences review (January 2011) recommended, based on the evidence received and subsequent engagement with stakeholders, the creation of a new body to bring together the functions relating to research ethics committees currently conferred on the National Patient Safety Agency and certain functions relating to the establishment of, and appointment of members to, such committees, in order to maintain standard procedures across ethics opinions for all types of study. The Academy recommended that this new body should rationalise the regulation and governance of all health research and it is intended to provide for this, in so far as this is possible in advance of primary legislation, separately from the current instruments.

7.4 The Government announced in The Plan for Growth (March 2011) that it would create a new body, that is a Non-Departmental Public Body, to combine and streamline the approvals for health research which are at present scattered across many organisations, and as a first step would establish this year a Special Health Authority with the functions relating to research ethics committee as its core.

7.5 These instruments, therefore, establish the Health Research Authority as a Special Health Authority to fulfil this commitment. Its detailed functions will be set out in Directions made by the Secretary of State under the National Health Service Act 2006. Initially, it is established with an executive only board which, for the purposes of proportionate governance, cost-effectiveness and stability, reflects the established management of the research ethics committee service. It is intended that the Order and Regulations will be amended in 2012 to provide for the Health Research Authority to have a chair and non-executive

members as well, from the point where it will have conferred on it certain additional functions, such as functions relating to confidential patient information.

## 8. Consultation outcome

8.1 The Government asked the Academy of Medical Sciences to conduct an independent review of the regulation and governance of medical research. Some 280 written submissions were received in response to the Academy's calls for evidence. The Academy reported in January and recommended that existing bodies' functions relating to research ethics committees should be brought together in a new body as soon as possible. The Government announced in March that it would establish a Special Health Authority with those functions this year.

## 9. Guidance

9.1 The Department of Health will provide publicity about the establishment of the Health Research Authority to research ethics committees and researchers through the web sites of the National Patient Safety Agency and the National Institute for Health Research.

## 10. Impact

10.1 No impact on the private or voluntary sector is foreseen.

10.2 No impact on the public sector is foreseen from these instruments in isolation. They contribute to the transfer of functions from the National Patient Safety Agency and Strategic Health Authorities which will enable the abolition of those bodies by the current Health and Social Care Bill when enacted, subject to Parliamentary approval.

10.3 An Impact Assessment has not been prepared for these instruments.

## 11. Regulating small business

11.1 The legislation does not apply to small business.

## 12. Monitoring & review

12.1 The Health Research Authority's performance of its functions will be reviewed by the Department of Health in accordance with the standard framework agreement which the Department of Health is introducing for all its arm's-length bodies.

## 13. Contact

Bill Davidson at the Department of Health (tel: 0113 254 6184 or email: bill.davidson@dh.gsi.gov.uk) can answer any queries regarding the instruments.