

EXPLANATORY MEMORANDUM TO
THE MENTAL CAPACITY ACT 2005 (APPROPRIATE BODY) (ENGLAND)
AMENDMENT REGULATIONS 2011

2011 No. 2645

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 instrument**
 - 2.1 This instrument amends the definition of “appropriate body” in the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 (the 2006 Regulations). It clarifies that the Secretary of State function of recognising ‘appropriate bodies’ to review research ethics relating to people who lack capacity to consent to that research derives from the National Health Service Act 2006 (the 2006 Act) and not from the Mental Capacity Act 2005 (the 2005 Act). This means this function can be conferred on the Special Health Authority established by the Health Research Authority (Establishment and Constitution) Order 2011 (the 2011 Order).
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None
4. **Legislative Context**
 - 4.1 The 2011 Order will establish a Special Health Authority to exercise Secretary of State functions under the 2006 Act relating to the approval of research, such as the recognition of research ethics committees, including ‘appropriate bodies’ under the 2005 Act. Special Health Authorities can exercise Secretary of State functions that derive from the 2006 Act but not from the 2005 Act.
 - 4.2 Section 30(1) of the 2005 Act has the effect of requiring certain intrusive research carried out on or in relation to a person without capacity to have been approved by an ‘appropriate body’, the meaning of which is to be prescribed in regulations. Regulation 2 of the 2006 Regulations provides that the appropriate body is a committee (a) established to advise on, or on matters which include, the ethics of intrusive research in relation to people who lack capacity to consent to it; and (b) recognised for that purpose by the Secretary of State. Paragraph (b) of this definition could be regarded as ambiguous and could give the impression that the recognition function of the Secretary of State here derives from the 2006 Regulations themselves (and the 2005 Act), whereas in fact it derives from the Secretary of State’s

general powers in section 2 of the 2006 Act. The amendment made by these Regulations clarifies this.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

As this instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Secretary of State intends to improve the environment for health research by creating a health research authority to combine and streamline the approvals for health research that are scattered across many organisations. Subject to Parliamentary process, legislation to establish the Health Research Authority will come into force on 1st December, creating a Special Health Authority which will exercise Secretary of State's functions under the 2006 Act relating to health research approvals. Functions intended for the Health Research Authority must be conferrable on it. Special Health Authorities can exercise Secretary of State functions that derive from the National Health Service Act 2006.

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 (which include 'appropriate bodies') should be brought together in a new body as soon as possible. The Government announced in March, in its Plan for Growth, that it would establish a Health Research Authority and, as a first step, that it would be set up as a Special Health Authority with the National Research Ethics Service as its core this year.

9. Guidance

9.1 The Department of Health is not planning further information about the clarification this instrument will make, since it will confirm a position with which interpretation and practice are already consistent. However, the Department of Health will, through its web site, provide information to research ethics committees (which include 'appropriate bodies') and to researchers (which include those conducting research that is subject to the 2005 Act) about the establishment and functions of the Health Research Authority.

10. Impact

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

10.2 No impact on the public sector is foreseen.

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 This instrument does not apply to small business.

12. Monitoring & review

12.1 The Health Research Authority's performance of the functions it exercises by direction of the Secretary of State 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 arms-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 this instrument.