EXPLANATORY MEMORANDUM TO

THE MENTAL CAPACITY ACT 2005 (APPROPRIATE BODY) (ENGLAND) (AMENDMENT) REGULATIONS 2006

2006 No. 3474

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 The Mental Capacity Act 2005 provides a statutory framework for people who may not be able to make their own decisions, for example because of a learning disability or an illness such as dementia. It sets out who can take decisions, in which situations, and how they should go about this.

2.2 Sections 30-34 of the Act contain provisions for the authorisation and regulation of research (including medical, social and other research) involving people who lack capacity to consent to their participation. The Act applies to all "intrusive" research (that is, research normally requiring consent) and therefore includes:

- research on a person - involving direct contact with that person
- research in relation to a person - indirect research on tissues, materials, data or information otherwise collected from the person

It does not apply to clinical trials covered under the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).

2.3 The Act requires that research under the Act has to be approved by an appropriate body. The Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 (SI 2006/2810) were made under section 30 of the Act and provide power for the Secretary of State to recognise appropriate bodies for reviewing research under the Act. These regulations identify the appropriate body as a research ethics committee.

2.4 Research ethics committees are already established in England and in reviewing a proposed study, the committee's task is to protect the dignity, rights, safety and well-being of actual or potential research participants. Such committees should provide independent, competent and timely review of the ethics of proposed studies and contain a mixture of lay and expert members.

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

3.1 This instrument amends the Mental Capacity Act 2005 (Appropriate

Body) (England) Regulations 2006 (SI 2006/2810). These Regulations were to come force on 1 February 2007 for the purposes of enabling applications for ethical approval of research to be made and determined under the Act and on 1 April 2007 for all other purposes. The amending regulations change these dates from 1 February 2007 to 1 July 2007 and the 1 April 2007 to 1 October 2007.

3.2 This instrument breaches the 21-day rule by one day. It was sent for laying on 9 January 2007, 22 days before coming into force but due to an error was not delivered to the House of Commons. The Department therefore arranged for it to be withdrawn from the Lords and laid before both Houses on 11 January 2007. The Department apologises for this error.

4. Legislative Background

4.1 The Mental Capacity Bill was introduced to Parliament in June 2004 and included provision for research involving people without capacity to consent. The clauses covering research were introduced into the Mental Capacity Bill in response to concerns expressed by the Joint Scrutiny Committee in their report which was published on 28 November 2003. The Committee was concerned that the draft Bill made no provision for adults without capacity to take part in medical research, as they recognised the need for properly constituted medical research to occur, with appropriate safeguards.

4.2 Sections 30 to 34 provide lawful authority for research to be carried out involving people without capacity, subject to strict limitations and safeguards. They also set out the requirements for approval of research of this kind, provide information on who should be consulted where the person are unable to consent, set out additional safeguards and provide a path for researchers to follow if a person loses capacity during a research project.

4.3 The Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 (SI 2006/2810) were made on 21 October 2006. The Mental Capacity Act 2005 (Appropriate Body) (England) (Amendment) Regulations 2006 amend these regulations.

5. Extent

5.1 The Act applies to England and Wales. This Instrument applies in relation to England.

6. European Convention on Human Rights

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

7. Policy background

7.1 See attached Explanatory Memorandum.

7.2 On 18 December 2006 the Department for Constitutional Affairs issued a Written Ministerial Statement announcing its timetable for the full introduction of the Mental Capacity Act 2005. The research regulations have been amended in line with this timetable. The decision to modify implementation has been necessary to allow good time to establish and develop new procedures and to ensure that there is adequate time to train the many professionals affected by the Act and the very important changes that it brings. The Mental Capacity Act Code of Practice will be available in April 2007 for researchers to absorb and use to help design their research projects and make timely applications for their approval.

8. Impact

8.1 The Regulatory Impact Assessment (RIA) for research was considered as part of the overall Act. A copy of this RIA is attached. Overall there will be no significant impact on businesses or the voluntary and charitable sector as a result of these regulations. A Race and Equality Impact Assessment has not been prepared for this instrument as an initial assessment showed that there were no specific issues to consider.

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EXPLANATORY MEMORANDUM TO

MENTAL CAPACITY ACT 2005 (APPROPRIATE BODY) (ENGLAND) REGULATIONS 2006

[2006] No. SI 2006/2810

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 The Mental Capacity Act 2005 provides a statutory framework for people who may not be able to make their own decisions, for example because of a learning disability or an illness such as dementia. It sets out who can take decisions, in which situations, and how they should go about this.

2.2 Sections 30-34 of the Act contain provisions for the authorisation and regulation of research (including medical, social and other research) involving people who lack capacity to consent to their participation. The Act applies to all "intrusive" research (that is, research normally requiring consent) and therefore includes:

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It does not apply to clinical trials covered under the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).

2.3 The Act requires that research under the Act has to be approved by an appropriate body. These Regulations are made under section 30 of the Act and provide power for the Secretary of State to recognise appropriate bodies for reviewing research under the Act. These regulations identify the appropriate body as a research ethics committee.

2.4 Research ethics committees are already established in England and in reviewing a proposed study the committee's task is to protect the dignity, rights, safety and well-being of actual or potential research participants. Such committees should provide independent, competent and timely review of the ethics of proposed studies and contain a mixture of lay and expert members.

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

3.1 This instrument defines 'appropriate body' for the purposes of section 30(4) of the Mental Capacity Act 2005 . These Regulations are subject

to negative resolution procedure, as provided for in section 65(2) of the Act.

3.2 The Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 which are subject to the parliamentary procedure, have been laid in Parliament on 20 October 2006 under the power in section 30(4)(a) of the Act. The effect of these Regulations is outlined below.

4. Legislative Background

4.1 The Mental Capacity Bill was introduced to Parliament in June 2004 and included provision for research involving people without capacity to consent. The clauses covering research were introduced into the Mental Capacity Bill in response to concerns expressed by the Joint Scrutiny Committee in their report which was published on 28 November 2003. The Committee was concerned that the draft Bill made no provision for adults without capacity to take part in medical research, as they recognised the need for properly constituted medical research to occur, with appropriate safeguards.

4.2 Sections 30 to 34 provide lawful authority for research to be carried out involving people without capacity, subject to strict limitations and safeguards. They also set out the requirements for approval of research of this kind, provide information on who should be consulted where the person are unable to consent, set out additional safeguards and provide a path for researchers to follow if a person loses capacity during a research project.

5. Extent

5.1 The Act applies to England and Wales. This Instrument applies in relation to England.

6. European Convention on Human Rights

6.1 The Rt. Hon.Rosie Winterton MP has made the following statement regarding Human Rights:

In my view the provisions of the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 are compatible with the Convention rights.

7. Policy background

7.1 During the passage of the Act, it was recognised that the appropriate bodies to be recognised for reviewing research under the Act would likely be research ethics committees.

7.2 The Government consulted between 13 June and 5 September 2006 on the details of the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 together with the Mental Capacity Act (Loss of Capacity during Research Project) (England) Regulations 2006. The consultation paper was distributed via email to groups and individuals who had asked to be kept in touch with these issues during the passage of the Act and was publicised in the Department of Constitutional Affairs' Mental Capacity Act implementation newsletter. The consultation was also published on the Department of Health's and the Department of Constitutional Affairs' websites and a link to the site went into the Department of Health's Chief Executive's Bulletin, distributed to all Chief Executives in Health and Social Care.

7.3 There were 38 responses to the consultation and a consultation meeting was organised by the Medical Research Council to inform the consultation. A summary of consultation responses and the Government's response to the consultation was published on 23 October 2006 and can be found at www.dh.gov.uk/Consultations/ResponsesToConsultations

7.4 The consultation question on the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 asked whether the proposed arrangements for appointing the appropriate body that approves research are suitable. Respondents were generally supportive of the proposal that research ethics committees, recognised by the Secretary of State, should be the appropriate body. Some stressed the need for appropriate training for committee members and respondents also requested more information about how the system would work and how it would affect social care.

7.5 NHS research ethics committees were established in England in 1991 following the publication of Department of Health guidance HSG(91)5. The appointing authorities for NHS research ethics committees are the Strategic Health Authorities in England. NHS research ethics committees are independent of the researcher and the organisations funding and hosting research. Training and accreditation for NHS committees is provided by the Central Office of Research Ethics Committees (COREC) to ensure national consistency. Before it can proceed, all research involving NHS patients requires approval from an NHS research ethics committee. Research governance is a core standard for health care and health care organisations have to take this standard into account in discharging their duty of quality under Section 45 of the Health and Social Care (Community Health and Standards) Act 2003.

7.6 The Mental Capacity Act is not limited to research in a healthcare setting but includes social care research and social sciences research. Research ethics committees operating in these settings may be recognised by the Secretary of State, provided that they meet recognition criteria that will be published in the near future.

7.7 The research ethics service will provide training and support to ensure that sufficient research ethics committees are familiar with the requirements of the Act, and with the ethical issues related to mental capacity.

8. Impact

8.1 The Regulatory Impact Assessment (RIA) for research was considered as part of the overall Act. A copy of this RIA is attached. Overall there will be no significant impact on businesses or the voluntary and charitable sector as a result of these regulations. A Race and Equality Impact Assessment has not been prepared for this instrument as an initial assessment showed that there were no specific issues to consider.

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