EXPLANATORY MEMORANDUM TO

THE MENTAL CAPACITY ACT 2005 (LOSS OF CAPACITY DURING RESEARCH PROJECT) (ENGLAND) REGULATIONS 2007

2007 No.

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 contains a number of powers to allow the detailed requirements to be set out in Regulations. These Regulations are made under section 34 of the Act. Section 34 provides a power for the Secretary of State to make regulations. The Regulations give existing research projects that involve people who consented but then lost capacity a legal basis to continue.

2.4 Research that has ethical approval and has started before 1 October 2007 but finishes before 1 October 2008 will not be required to comply with section 30 of the Act. The Mental Capacity Act 2005 (Commencement No.1) (Amendment) Order 2006 delays commencement of sections 30 - 34 of the Act in these circumstances.

2.5 Where the conditions set out in the Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007 are met, the regulations allow material to continue to be used for the lifetime of the study even where the conditions set out in section 31 aren't satisfied.

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

3.1 This instrument makes the first use of powers under sections 34. These Regulations are subject to the affirmative resolution procedure, as provided for in section 65(2) of the Act.

3.2 The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007, which are subject to the affirmative parliamentary procedure, have been laid in draft before Parliament on 9th January 2007 under the power in section 65(4) 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 is unable to consent, set out additional safeguards and provide a power enabling the Secretary of State to make special provision where a person loses capacity during a project in which he agreed to participate before the coming into force of the Act.

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 (Loss of Capacity during Research Project) (England) Regulations 2007 are compatible with the Convention rights.

7. Policy background

7.1 During the passage of the Act, the Government recognised the importance of a smooth transition to the new arrangements.

7.2 During the passage of the Act, the Government also recognised that there needed to be clarity about the status of existing collections or findings so that they did not have to be automatically discarded because of later loss of capacity. However, it was not felt appropriate to automatically exempt from control those studies started before the Act came into force. The Act therefore includes provision for regulations to provide lawful authority for research to continue on material or information taken from a person before they lost capacity.

7.3 The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007 only apply where a person has consented to take part in a research project which started before 1 October 2007, but before the end of the project loses capacity. They allow a researcher to continue to use information or material obtained with consent before the loss of capacity. The regulations set out that information or material is either data within the meaning of the Data Protection Act 1998, or material which consists of or includes human cells or human DNA. The continuation of the project is subject to meeting the requirements of Schedules 1 and 2. Schedule 1 requires that an 'appropriate body' has approved a protocol making appropriate provision for such research to be carried on. The appropriate body must be satisfied, in particular, about the arrangements in place to meet the safeguards in Schedule 2. Schedule 2 repeats the relevant safeguards from section 32 and 33 of the main Act. Section 31 criteria do not apply here.

7.4 The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007 do <u>not</u> apply to existing studies that enrolled people who lacked capacity (for example, ongoing projects involving adults with dementia or learning difficulties). The draft Regulations will also <u>not</u> apply to situations where the researchers wish to go back to a person who lacks capacity in order to take more tissue or DNA samples or data. Such projects will need to have approval under section 30 of the Act when it is commenced on 1 October 2007.

7.5 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.

7.6 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

7.7 The consultation question on the Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations asked whether the proposed arrangements for research involving people who consented but then lost capacity struck the right balance between the need to allow long-term research to continue whilst respecting the past and present wishes of participants. Generally respondents thought that the proposed arrangements in the regulations did strike the right balance. However respondents also had requests for further information, including requests for guidance on who is able to act as a consultee and hierarchies for decision making. There is a requirement for the Government to issue statutory guidance on professional consultees (Section 32(3)) and this will be issued at a later stage.

7.8 A few respondents raised the concern that reapplying to an appropriate body for approval for existing projects, where someone had once consented, was a large administrative burden. However, during the passage of the Act the Government made clear that it was important that all people without capacity were offered the protections that the Act contained. For this reason an 'existing projects' clause to exempt existing projects from regulation by the Act was not introduced. The Government believe that the draft Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations strike an appropriate balance between protecting the person, promoting research and minimising bureaucracy and most respondents to the consultation agreed with this.

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.

9. Contact

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