Draft Regulations laid before Parliament under section 65(4) of the Mental Capacity Act 2005, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2007 No.

MENTAL CAPACITY, ENGLAND

The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007

Made - - - -	*2007*
Coming into force	
for the purpose mentioned in regulation 1(1)(a)	*1st July 2007*
for all other purposes	*1st October 2007*

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred upon her by sections 30(6)(a), 34(1), (2) and (3)(b), 64(1) and 65(1)(c) of the Mental Capacity Act 2005(**1**).

In accordance with section 65(4) of that Act, a draft of this instrument was laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement, territorial application and interpretation

1.—(1) These Regulations may be cited as the Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007 and shall come into force on—

(a) 1 July 2007 for the purpose of enabling applications for approval for the purposes of Schedule 1 to be made to, and determined by, an appropriate body,

(b) 1 October 2007 for all other purposes.

(2) These Regulations apply in relation to the carrying out of research in England.

(3) In these Regulations—

"the Act" means the Mental Capacity Act 2005;

"appropriate body" has the meaning given by section 30(4) of the Act and the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006(**2**).

(**1**) 2005 c.9. Section 64(1) is cited because of the meaning there given to "prescribed".
(**2**) S.I. 2006/2810, amended by S.I. 2006/ .

Application

2. These Regulations apply where—

(a) a person ("P")—

(i) has consented before 31 March 2008 to take part in a research project ("the project") begun before 1st October 2007, but

(ii) before the conclusion of the project, loses capacity to consent to continue to take part in it, and

(iii) research for the purposes of the project in relation to P would, apart from these Regulations, be unlawful by virtue of section 30 of the Act.

Research which may be carried out despite a participant's loss of capacity

3. Despite P's loss of capacity, research for the purposes of the project may be carried out using information or material relating to him if—

(a) that information or material was obtained before P's loss of capacity,

(b) that information or material is either—

(i) data within the meaning given in section 1(1) of the Data Protection Act 1998(**3**), or

(ii) material which consists of or includes human cells or human DNA,

(c) the project satisfies the requirements set out in Schedule 1, and

(d) the person conducting the project ("R") takes in relation to P such steps as are set out in Schedule 2.

Signed by authority of the Secretary of State for Health

Minister of State
Department of Health

(**3**) 1998 c.29. Section 1(1) was amended by the Freedom of Information Act 2000 (c.36), section 68(1) and (2).

SCHEDULE 1

Regulation 3(c)

Requirements which the project must satisfy

1. A protocol approved by an appropriate body and having effect in relation to the project makes provision for research to be carried out in relation to a person who has consented to take part in the project but loses capacity to consent to continue to take part in it.

2. The appropriate body is satisfied that there are reasonable arrangements in place for ensuring that the requirements of Schedule 2 will be met.

SCHEDULE 2

Regulation 3(d)

Steps which the person conducting the project must take

1. R must take reasonable steps to identify a person who—

(a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and

(b) is prepared to be consulted by R under this Schedule.

2. If R is unable to identify such a person he must, in accordance with guidance issued by the Secretary of State, nominate a person who—

(a) is prepared to be consulted by R under this Schedule, but

(b) has no connection with the project.

3. R must provide the person identified under paragraph 1, or nominated under paragraph 2, with information about the project and ask him—

(a) for advice as to whether research of the kind proposed should be carried out in relation to P, and

(b) what, in his opinion, P's wishes and feelings about such research being carried out would be likely to be if P had capacity in relation to the matter.

4. If, at any time, the person consulted advises R that in his opinion P's wishes and feelings would be likely to lead him to wish to withdraw from the project if he had capacity in relation to the matter, R must ensure that P is withdrawn from it.

5. The fact that a person is the donee of a lasting power of attorney given by P, or is P's deputy, does not prevent him from being the person consulted under paragraphs 1 to 4.

6. R must ensure that nothing is done in relation to P in the course of the research which would be contrary to—

(a) an advance decision of his which has effect, or

(b) any other form of statement made by him and not subsequently withdrawn,

of which R is aware.

7. The interests of P must be assumed to outweigh those of science and society.

8. If P indicates (in any way) that he wishes the research in relation to him to be discontinued, it must be discontinued without delay.

9. The research in relation to P must be discontinued without delay if at any time R has reasonable grounds for believing that the requirement set out in paragraph 1 of Schedule 1 is no longer met or

that there are no longer reasonable arrangements in place for ensuring that the requirements of this Schedule are met in relation to P.

10. R must conduct the research in accordance with the provision made in the protocol referred to in paragraph 1 of Schedule 1 for research to be carried out in relation to a person who has consented to take part in the project but loses capacity to consent to continue to take part in it.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under section 34 of the Mental Capacity Act 2005 (c. 9) ("the Act"). They provide for certain research, relating to people without capacity to consent to it, to be carried out lawfully where otherwise the requirements of section 30 of the Act would have to be complied with.

Regulation 1 provides that these Regulations apply in relation to research carried on in England. Regulation 1 further provides for the Regulations to come into force on 1 July 2007 for the purpose of enabling applications for approval of research protocols under the Regulations to be made and determined and on 1 October 2007 for all other purposes.

Regulation 2 provides that the Regulations apply where a research project began before 1 October 2007 and a person ("P") consented, prior to 31 March 2008, to take part in the project but has subsequently lost capacity to continue to consent.

Regulation 3 provides that research under such a project may be carried out using information or material collected prior to P's loss of capacity. The information or material must be either data within the meaning of the Data Protection Act 1998 (c. 29) or material which consists of or includes human cells or DNA. In addition the requirements of Schedules 1 and 2 must be complied with.

Schedule 1 provides that an appropriate body must have approved a protocol for the project which provides for research to be carried out in relation to a person who has consented to take part and then lost capacity. The appropriate body must also be satisfied that there are reasonable arrangements for ensuring that Schedule 2 will be complied with.

'Appropriate body' is defined in regulation 1 by reference to the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 (S.I. 2006/2810). An 'appropriate body' is a committee which is 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 which is recognised for those purposes by the Secretary of State.

'Intrusive research' is defined in section 30(2) of the Act.

Schedule 2 sets out requirements as to consultation about P's involvement in the project, as to respecting his wishes and objections and as to assuming that his interests outweigh those of science and society.

A Regulatory Impact Assessment was prepared for the Mental Capacity Act 2005 and a copy has been placed in the library of each House of Parliament. Copies are published on the Department of Health's website (www.dh.gov.uk) and can be obtained from Room 604, Wellington House, Waterloo Road, London, SE1 8UG.