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

2006 No.

MENTAL CAPACITY, ENGLAND

The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2006

Made - - - -	*2006*
Coming into force	
for the purpose mentioned in regulation 1(1)(a)	*1st February 2007*
for all other purposes	*1st April 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 2006 and shall come into force on—

(a) 1 February 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 April 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/[ ].

Application

2. These Regulations apply where—

(a) a person ("P")—

(i) has consented before 31 December 2007 to take part in a research project ("the project") begun before 1st April 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

Date

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