
DRAFT STATUTORY INSTRUMENTS

2006 No.

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

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(1).

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(2), 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

(1) S.I. 2006/[].

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

- (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

Date

Minister of State
Department of Health