NATIONAL ASSEMBLY FOR WALES

S T A T U T O R Y I N S T R U M E N T S

2007 No. (W.)

MENTAL CAPACITY, WALES

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

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.

These Regulations apply in relation to research carried on in Wales.

Regulation 1 provides for the Regulations to come into force on 1 February 2007 for the purpose of enabling applications for approval of research protocols under the Regulations to be made and determined and on 1 April 2007 for all other purposes.

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

Regulation 3 provides that research 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 consist of or includes human cells or DNA. In addition, it provides that 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 with respects to 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) (Wales) Regulations 2007 [SI number]. An 'appropriate body' is a committee which is—

(i) 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
(ii) recognised for those purposes by the National Assembly for Wales or 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 Appraisal has been prepared for the Mental Capacity Act 2005 and a copy has been placed in the library of the National Assembly for Wales.

STATUTORY INSTRUMENTS

2007 No. (W.)

MENTAL CAPACITY, WALES

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

Made	*2007*
Coming into force	*1 April 2007*

The National Assembly for Wales makes the following Regulations in exercise of the power conferred upon it by sections 30(6), 34(1), (2) and (3), 64(1) and 65(1) of the Mental Capacity Act 2005(**1**).

Citation, commencement, territorial application and interpretation

1.—(1) The title of these Regulations is as the Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007 and they 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 on of research in Wales.

(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) (Wales) Regulations 2006(**2**).

"P" has the meaning given by regulation 2;

"R" has the meaning given by regulation 3.

(**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 person ("P")—

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

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

(c) 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 P if—

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

(b) all the information or material relating to P which is used in the research was obtained before P's loss of capacity

(c) that information or material is either—

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

(ii) material which consists of and/or includes human cells or human DNA; and

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

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(**1**).

Date
The Presiding Officer of the National Assembly

(**1**) 1998 c.29.

SCHEDULE 1

Regulation 3

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 must be satisfied that there are reasonable arrangements in place for ensuring that the requirements of Schedule 2 will be met.

SCHEDULE 2

Regulation 3

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 R must, in accordance with guidance issued by the appropriate authority, 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 that person—

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

(b) what, in that person's 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, any time, the person consulted advises R that in his or her opinion P's wishes and feelings would be likely to lead P to wish to withdraw from the project if he or she 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 that person 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 P's which has effect, or

(b) any other form of statement made by P 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 or she wishes the research in relation to him or her to be discontinued, it must be discontinued without delay.

9. The research must be discontinued without delay if at any time R has reasonable grounds for believing that one or more of the requirements set out in 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 being 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 take part in it.