
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under sections 30, 34, 64 and 65 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 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 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 2007/833 \(W.71\)](#). 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.

“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 or her wishes and objections and as to assuming that his or her 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.