

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 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 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 [SI number]. 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.