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The Mental Capacity Act 2005 (Loss of Capacity During Research Project) (England) Regulations 2007, Great Britain, Stationery Office, 2007, 0110755901, 9780110755908, . Enabling power: Mental Capacity Act 2005, ss. 30 (6) (a), 34 (1) (2) (3) (b), 64 (1), 65 (1) (c). Issued: 09.01.2007. Made: -. Laid: -. Coming into force: 01.07.2007 for the purpose mentioned in regulation 1(1)(a); 01.10.2007 for all other purposes. Effect: None. Territorial extent & classification: E. For approval by resolution of each House of Parliament.

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Explanatory Memorandum sets out a brief statement of the purpose of a Statutory Instrument and provides information about its policy objective and policy implications. They aim to make the Statutory Instrument accessible to readers who are not legally qualified accompany any Statutory Instrument or Draft Statutory Instrument laid before Parliament from June 2004 onwards.

Latest Available (revised):The latest available updated version of the legislation incorporating changes made by subsequent legislation and applied by our editorial team. Changes we have not yet applied to the text, can be found in the ["Changes to Legislation"](#)™ area. The revised version is currently only available in English.

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 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 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 (S.I. 2006/2810). 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.

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](http://www.dh.gov.uk)) and can be obtained from Room 604, Wellington House, Waterloo Road, London, SE1 8UG.

9. The research in relation to P must be discontinued without delay if at any time R has reasonable grounds for believing that the requirement set out in paragraph 1 of 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 met in relation to P.

<http://eduln.org/2223.pdf>

<http://eduln.org/3201.pdf>

<http://eduln.org/117.pdf>

<http://eduln.org/1713.pdf>

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