

Mental Capacity Act 2005

2005 CHAPTER 9

PART 1

PERSONS WHO LACK CAPACITY

Research

30 Research

- (1) Intrusive research carried out on, or in relation to, a person who lacks capacity to consent to it is unlawful unless it is carried out—
 - (a) as part of a research project which is for the time being approved by the appropriate body for the purposes of this Act in accordance with section 31, and
 - (b) in accordance with sections 32 and 33.

(2) Research is intrusive if it is of a kind that would be unlawful if it was carried out—

- (a) on or in relation to a person who had capacity to consent to it, but
 - (b) without his consent.
- (3) A clinical trial which is subject to the provisions of clinical trials regulations is not to be treated as research for the purposes of this section.
- [^{F1}(3A) Research is not intrusive to the extent that it consists of the use of a person's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo, or the subsequent storage or use of an embryo or human admixed embryo so created.
 - (3B) Expressions used in subsection (3A) and in Schedule 3 to the Human Fertilisation and Embryology Act 1990 (consents to use or storage of gametes, embryos or human admixed embryos etc.) have the same meaning in that subsection as in that Schedule.]
 - ^{F1}(4) "Appropriate body", in relation to a research project, means the person, committee or other body specified in regulations made by the appropriate authority as the appropriate body in relation to a project of the kind in question.

Changes to legislation: There are currently no known outstanding effects for the Mental Capacity Act 2005, Section 30. (See end of Document for details)

(5) "Clinical trials regulations" means—

- (a) the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) and any other regulations replacing those regulations or amending them, and
- (b) any other regulations relating to clinical trials and designated by the Secretary of State as clinical trials regulations for the purposes of this section.

(6) In this section, section 32 and section 34, "appropriate authority" means-

- (a) in relation to the carrying out of research in England, the Secretary of State, and
- (b) in relation to the carrying out of research in Wales, the National Assembly for Wales.

Textual Amendments

F1 S. 30(3A)(3B) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), ss. 65, 68, Sch. 7 para. 25; S.I. 2009/2232, art. 2(y)

Commencement Information

S. 30 wholly in force at 1.10.2008; s. 30 not in force at Royal Assent see s. 68(1)-(3); s. 30 in force for certain purposes at 1.7.2007 and 1.10.2007 and in force at 1.10.2008 in so far as not already in force by S.I. 2006/2814, arts. 2, 3, 4 (as amended by S.I. 2006/3473, art. 2); S.I. 2007/856, arts. 2, 3, 4

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