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.

(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

I1 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**

31 Requirements for approval

(1) The appropriate body may not approve a research project for the purposes of this Act unless satisfied that the following requirements will be met in relation to research carried out as part of the project on, or in relation to, a person who lacks capacity to consent to taking part in the project ("P").

(2) The research must be connected with—

(a) an impairing condition affecting P, or

(b) its treatment.

(3) "Impairing condition" means a condition which is (or may be) attributable to, or which causes or contributes to (or may cause or contribute to), the impairment of, or disturbance in the functioning of, the mind or brain.

(4) There must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the project has to be confined to, or relate only to, persons who have capacity to consent to taking part in it.

(5) The research must—

(a) have the potential to benefit P without imposing on P a burden that is disproportionate to the potential benefit to P, or

(b) be intended to provide knowledge of the causes or treatment of, or of the care of persons affected by, the same or a similar condition.

(6) If the research falls within paragraph (b) of subsection (5) but not within paragraph (a), there must be reasonable grounds for believing—

(a) that the risk to P from taking part in the project is likely to be negligible, and

(b) that anything done to, or in relation to, P will not—

(i) interfere with P's freedom of action or privacy in a significant way, or

(ii) be unduly invasive or restrictive.

(7) There must be reasonable arrangements in place for ensuring that the requirements of sections 32 and 33 will be met.

Commencement Information

I2 S. 31 wholly in force at 1.10.2008; s. 31 not in force at Royal Assent see s. 68(1)-(3); s. 31 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**

32 Consulting carers etc.

(1) This section applies if a person ("R")—

(a) is conducting an approved research project, and

(b) wishes to carry out research, as part of the project, on or in relation to a person ("P") who lacks capacity to consent to taking part in the project.

(2) 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 section.

(3) If R is unable to identify such a person he must, in accordance with guidance issued by the appropriate authority, nominate a person who—

(a) is prepared to be consulted by R under this section, but

(b) has no connection with the project.

(4) R must provide the person identified under subsection (2), or nominated under subsection (3), with information about the project and ask him—

(a) for advice as to whether P should take part in the project, and

(b) what, in his opinion, P's wishes and feelings about taking part in the project would be likely to be if P had capacity in relation to the matter.

(5) If, at any time, the person consulted advises R that in his opinion P's wishes and feelings would be likely to lead him to decline to take part in the project (or to wish to withdraw from it) if he had capacity in relation to the matter, R must ensure—

(a) if P is not already taking part in the project, that he does not take part in it;

(b) if P is taking part in the project, that he is withdrawn from it.

(6) But subsection (5)(b) does not require treatment that P has been receiving as part of the project to be discontinued if R has reasonable grounds for believing that there would be a significant risk to P's health if it were discontinued.

(7) 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 him from being the person consulted under this section.

(8) Subsection (9) applies if treatment is being, or is about to be, provided for P as a matter of urgency and R considers that, having regard to the nature of the research and of the particular circumstances of the case—

(a) it is also necessary to take action for the purposes of the research as a matter of urgency, but

(b) it is not reasonably practicable to consult under the previous provisions of this section.

(9) R may take the action if—

(a) he has the agreement of a registered medical practitioner who is not involved in the organisation or conduct of the research project, or

(b) where it is not reasonably practicable in the time available to obtain that agreement, he acts in accordance with a procedure approved by the appropriate body at the time when the research project was approved under section 31.

(10) But R may not continue to act in reliance on subsection (9) if he has reasonable grounds for believing that it is no longer necessary to take the action as a matter of urgency.

Commencement Information

I3 S. 32 wholly in force at 1.10.2008; s. 32 not in force at Royal Assent see s. 68(1)-(3); s. 32 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**

33 Additional safeguards

(1) This section applies in relation to a person who is taking part in an approved research project even though he lacks capacity to consent to taking part.

(2) Nothing may be done to, or in relation to, him in the course of the research—

(a) to which he appears to object (whether by showing signs of resistance or otherwise) except where what is being done is intended to protect him from harm or to reduce or prevent pain or discomfort, or

(b) which would be contrary to—

(i) an advance decision of his which has effect, or

(ii) any other form of statement made by him and not subsequently withdrawn,

of which R is aware.

(3) The interests of the person must be assumed to outweigh those of science and society.

(4) If he indicates (in any way) that he wishes to be withdrawn from the project he must be withdrawn without delay.

(5) P must be withdrawn from the project, without delay, if at any time the person conducting the research has reasonable grounds for believing that one or more of the requirements set out in section 31(2) to (7) is no longer met in relation to research being carried out on, or in relation to, P.

(6) But neither subsection (4) nor subsection (5) requires treatment that P has been receiving as part of the project to be discontinued if R has reasonable grounds for believing that there would be a significant risk to P's health if it were discontinued.

Commencement Information

I4 S. 33 wholly in force at 1.10.2008; s. 33 not in force at Royal Assent see s. 68(1)-(3); s. 33 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**

34 Loss of capacity during research project

(1) This section applies where a person ("P")—

(a) has consented to take part in a research project begun before the commencement of section 30, but

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

(2) The appropriate authority may by regulations provide that, despite P's loss of capacity, research of a prescribed kind may be carried out on, or in relation to, P if—

(a) the project satisfies prescribed requirements,

(b) any information or material relating to P which is used in the research is of a prescribed description and was obtained before P's loss of capacity, and

(c) the person conducting the project takes in relation to P such steps as may be prescribed for the purpose of protecting him.

(3) The regulations may, in particular,—

(a) make provision about when, for the purposes of the regulations, a project is to be treated as having begun;

(b) include provision similar to any made by section 31, 32 or 33.

Commencement Information

I5 S. 34 wholly in force at 1.10.2008; s. 34 not in force at Royal Assent see s. 68(1)-(3); s. 34 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**

Status:
Point in time view as at 02/11/2020.

Changes to legislation:
Mental Capacity Act 2005, Cross Heading: Research is up to date with all changes known to be in force on or before 03 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.