2016 CHAPTER 18

PART 8

RESEARCH

PROSPECTIVE

Approved research projects

Research

132.—(1) Intrusive research carried out on, or in relation to, a person who is 16 or over and lacks capacity to consent to it is unlawful unless it is carried out—

(a) as part of an approved research project (see subsection (3)); and

(b) in accordance with sections 135 to 137.

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

(a) on or in relation to a person who had capacity to consent to it; but

(b) without that person's consent.

(3) In this section "approved research project" means a research project which is for the time being approved for the purposes of this Part by the appropriate body in accordance with section 134.

(4) In this Part "appropriate body", in relation to a research project, means the person, committee or other body which is specified in regulations made for

the purposes of this subsection as the appropriate body in relation to a project of the kind in question.

(5) Section 133 supplements this section.

Section 132: exception for clinical trials

133.—(1) This section applies for the purposes of section 132.

(2) A clinical trial which is subject to the provisions of clinical trials regulations is not to be treated as research.

(3) In subsection (2) "clinical trials regulations" means—

(a) the Medicines for Human Use (Clinical Trials) Regulations 2004 and any other regulations replacing those regulations or amending them; and

(b) any other regulations relating to clinical trials that are designated by regulations made for the purposes of this subsection.

Approval of research projects

134.—(1) The appropriate body may approve a research project for the purposes of this Part only if it is 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 is 16 or over and 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) 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.

(4) 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.

(5) If the research falls within paragraph (b) of subsection (4) 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 nothing done to, or in relation to, P as part of the project will—

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

(ii) be unduly invasive or restrictive.

(6) Without prejudice to subsection (5), there must be reasonable grounds for believing that no serious intervention will be carried out in respect of P as part of the project unless the intervention is one that could lawfully be carried out in respect of P if it were not part of the project (for example, because the conditions of Part 2 are met).

(7) There must be reasonable arrangements in place for ensuring that the requirements of sections 135 to 137 will be met.

(8) In this section—

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

"serious intervention" is to be read in accordance with section 63.

Requirement to consult nominated person, carer etc

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

(a) is conducting a research project approved under section 134; and

(b) wishes to carry out research, as part of the project, on or in relation to a person ("P") who is 16 or over and 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, 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 R must, in accordance with guidance issued by the Department, appoint a person who—

(a) is prepared to be consulted by R under this section; and

(b) has no connection with the project.

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

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

(b) what, in that person's 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 that person's opinion P's wishes and feelings would be likely to lead P to decline to take part in the project (or to wish to withdraw from it) if P had capacity in relation to the matter, R must ensure—

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

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

(6) Subsection (5)(b) does not require treatment that P has been receiving as part of the project to be discontinued if the treatment can lawfully be carried out despite P having withdrawn from the project.

(7) In subsection (2)(a) "in a professional capacity" means under a contract of employment, under any other contract with any person, or as a volunteer for any organisation.

(8) The fact that a person within subsection (2)(a) is—

(a) an attorney under a lasting power of attorney, or an enduring power of attorney, granted by P,

(b) P's deputy, or

(c) P's nominated person,

does not prevent that person from being the person consulted under this section.

(9) This section is subject to section 136 (urgent treatment).

Section 135: exception for urgent treatment

136.—(1) This section applies if—

(a) section 135 applies;

(b) treatment is being, or is about to be, provided for P as a matter of urgency; and

(c) R considers that, having regard to the nature of the research and the particular circumstances of the case—

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

(ii) it is not practicable to consult under section 135.

(2) R may take the action if—

(a) R has the agreement of a medical practitioner who is not involved in the organisation or conduct of the research project; or

(b) where it is not practicable in the time available to obtain that agreement, R acts in accordance with a procedure approved by the appropriate body at the time when the research project was approved under section 134.

(3) But R may not continue to act in reliance on subsection (2) if R has reasonable grounds for believing that it is no longer necessary to take the action as a matter of urgency.

Additional safeguards

137.—(1) This section applies in relation to a person ("P") who is 16 or over and is taking part in a research project approved under section 134 even though P lacks capacity to consent to taking part.

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

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

(b) which is the carrying out or continuation of treatment of P and would be contrary to—

(i) an effective advance decision to refuse treatment which has been made by P, or

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

of which the person conducting the research project ("R") is aware.

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

(4) If P indicates (in any way) a wish to be withdrawn from the project P must be withdrawn without delay.

(5) P must be withdrawn from the project, without delay, if at any time R has reasonable grounds for believing that any requirement set out in section 134(2) to (7) is no longer met in relation to research being carried out on, or in relation to, P.

(6) Subsections (4) and (5) do not require treatment that P has been receiving as part of the project to be discontinued if the treatment can lawfully be carried out despite P having withdrawn from the project.

(7) In this section—

(a) "an effective advance decision to refuse treatment" means a decision which, under the common law relating to advance decisions, has the same effect as if at the material time P—

(i) refused consent to the treatment's being carried out or continued; and

(ii) had capacity to refuse that consent; and

(b) "the material time" means the time when the question arises whether the treatment should be carried out or continued.

Status:
This version of this cross heading contains provisions that are prospective.

Changes to legislation:
Mental Capacity Act (Northern Ireland) 2016, Cross Heading: Approved research projects is up to date with all changes known to be in force on or before 16 September 2019. 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.
View outstanding changes

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:
Whole provisions yet to be inserted into this Act (including any effects on those provisions):

– s. 288(1)(a)-(c)s. 288(1)(e)(i)(2)-(8) coming into force by S.R. 2019/163 art. 2(3)Sch. Pt. 3