Adults with Incapacity (Scotland) Act 2000

2000 asp 4

PART 5 S

MEDICAL TREATMENT AND RESEARCH

51 Authority for research S

(1) No surgical, medical, nursing, dental or psychological research shall be carried out on any adult who is incapable in relation to a decision about participation in the research unless—

(a) research of a similar nature cannot be carried out on an adult who is capable in relation to such a decision; and

(b) the circumstances mentioned in subsection (2) are satisfied.

(2) The circumstances referred to in subsection (1) are that—

(a) the purpose of the research is to obtain knowledge of—

(i) the causes, diagnosis, treatment or care of the adult's incapacity; or

(ii) the effect of any treatment or care given during his incapacity to the adult which relates to that incapacity; and

(b) **[**[F1]Subject to subsection (3A),**]**the conditions mentioned in subsection (3) are fulfilled.

(3) The conditions are—

(a) the research is likely to produce real and direct benefit to the adult;

(b) the adult does not indicate unwillingness to participate in the research;

(c) the research has been approved by the Ethics Committee;

(d) the research entails no foreseeable risk, or only a minimal foreseeable risk, to the adult;

(e) the research imposes no discomfort, or only minimal discomfort, on the adult; and

(f) consent has been obtained from any guardian or welfare attorney who has power to consent to the adult's participation in research or, where there is no such guardian or welfare attorney, from the adult's nearest relative.

[F2(3A) Where the research consists of a clinical trial of a medicinal product, the research may be carried out—

(a) without being approved by the Ethics Committee, if a favourable opinion on the trial has been given by an ethics committee, other than the Ethics Committee, in accordance with regulation 15 of the Medicines for Human Use (Clinical Trials) Regulations 2004; F3. . .

(b) without the consent of any guardian or welfare attorney, or the adult's nearest relative, if—

(i) it has not been practicable to contact any such person before the decision to enter the adult as a subject of the clinical trial is made, and

(ii) consent has been obtained from a person, other than a person connected with the conduct of the clinical trial, who is—

(A) the doctor primarily responsible for the medical treatment provided to that adult, or

(B) a person nominated by the relevant health care provider.

[F4(c) without the consent of any guardian or welfare attorney, or the adult's nearest relative, if—

(i) treatment is being, or is about to be, provided for an adult who is incapable in relation to a decision about participation in the research as a matter of urgency;

(ii) having regard to the nature of the clinical trial and of the particular circumstances of the case it is necessary to take action for the purposes of the clinical trial as amatter of urgency;

(iii) it has not been reasonably practicable to obtain the consent of any such person;

(iv) it has not been reasonably practicable to obtain the consent of any of the persons mentioned in paragraph (b)(ii)(A) or (B);and

(v) the action to be taken is carried out in accordance with a procedure approved by the Ethics Committee or any other ethics committee or by an appeal panel appointed underSchedule 4 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) at the time it gave its favourable opinion in relation to theclinical trial.**]]**

(4) Where the research is not likely to produce real and direct benefit to the adult, it may nevertheless be carried out if it will contribute through significant improvement in the scientific understanding of the adult's incapacity to the attainment of real and direct benefit to the adult or to other persons having the same incapacity, provided the other circumstances or conditions mentioned in subsections (1) to (3) are fulfilled.

(5) In granting approval under subsection (3)(c), the Ethics Committee may impose such conditions as it sees fit.

(6) The Ethics Committee shall be constituted by regulations made by the Scottish Ministers and such regulations may make provision as to the composition of, appointments to and procedures of the Ethics Committee and may make such provision for the payment of such remuneration, expenses and superannuation as the Scottish Ministers may determine.

(7) Regulations made by the Scottish Ministers under subsection (6) may prescribe particular matters which the Ethics Committee shall take into account when deciding whether to approve any research under this Part.

(8) In this section any reference to—

(a) a guardian shall include a reference to a guardian (however called) appointed under the law of any country to, or entitled under the law of any country to act for, an adult during his incapacity, if the guardianship is recognised by the law of Scotland;

(b) a welfare attorney shall include a reference to a person granted, under a contract, grant or appointment governed by the law of any country, powers (however expressed) relating to the granter's personal welfare and having effect during the granter's incapacity.

[F5(9) In this section—

"clinical trial on a medicinal product" means a clinical trial as defined by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004;

"an ethics committee" has the meaning given by that regulation;

"person connected with the conduct of the trial" and "relevant health care provider" have the meanings given by Schedule 1 to those regulations.**]**

Textual Amendments

F1 Words in s. 51(2)(b) inserted (1.5.2004) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 54, **Sch. 10 para. 21(a)**

F2 S. 51(3A) inserted (1.5.2004) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 54, **Sch. 10 para. 21(b)**

F3 Word in s. 51(3A)(a) repealed (12.12.2006) by The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 (S.I. 2006/2984), **reg. 3(a)**

F4 S. 51(3A)(c) inserted (12.12.2006) by The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 (S.I. 2006/2984), **reg. 3(b)**

F5 S. 51(9) inserted (1.5.2004) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 54, **Sch. 10 para. 21(c)**

Changes to legislation:
There are currently no known outstanding effects for the Adults with Incapacity (Scotland) Act 2000, Section 51.