

SCHEDULE 10

CONSEQUENTIAL AND OTHER AMENDMENTS OF ENACTMENTS

PART 1

ACTS OF PARLIAMENT

The Adults with Incapacity (Scotland) Act 2000

21. Section 51 of the Adults with Incapacity (Scotland) Act 2000⁽¹⁾ (authority for research) shall be amended as follows—

(a) in subsection (2), at the beginning of paragraph (b) insert “Subject to subsection (3A),”;

(b) after subsection (3), insert the following subsection—

“(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; and

(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.”; and

(c) at the end insert the following subsection—

“(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.”.

(1) 2000 asp 4.