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STATUTORY INSTRUMENTS

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**2006 No. 2984**

**The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006**

**Amendment of the Adults with Incapacity (Scotland) Act 2000**

**3.** In section 51 of the Adults with Incapacity (Scotland) Act 2000<sup>(1)</sup> (authority for research) in subsection (3A)—

- (a) omit “and” at the end of paragraph (a); and
- (b) after paragraph (b), insert—
  - “(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 a matter 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 under Schedule 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 the clinical trial.”.

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<sup>(1)</sup> [2000 asp 4](#); section 51 was amended by paragraph 21 of Part 1 of Schedule 10 to [S.I. 2004/1031](#).