STATUTORY INSTRUMENTS

2006 No. 1659

The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006

PART 2

PERSONS WHO LACK CAPACITY TO CONSENT

Storage and use of relevant material

Deemed consent to storage and use of relevant material: England and Wales

3.—(1) This regulation applies in any case falling within paragraphs (a) and (b) of section 6 of the Act (storage and use involving material from adults who lack capacity to consent).

(2) An adult ("P") who lacks capacity to consent to an activity of a kind mentioned in section 1(1)(d) or (f) of the Act (storage or use of material for purposes specified in Schedule 1) which involves material from P's body, is deemed to have consented to the activity where—

(a) the activity is done for a purpose specified in paragraph 4 or 7 of Part 1 of Schedule 1 to the Act (the purposes of obtaining information relevant to another person and of transplantation) by a person who is acting in what he reasonably believes to be P's best interests;

(b) the activity is done for the purpose of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations;

(c) the activity is done on or after the relevant commencement date for the purpose of intrusive research which is carried out in accordance with the requirements of section 30(1)(a) and (b) of the Mental Capacity Act 2005 (approval by appropriate body and compliance with sections 32 and 33 of that Act);

(d) the activity is done on or after the relevant commencement date for the purpose of intrusive research—

(i) section 34 of the Mental Capacity Act 2005 (loss of capacity during research project) applies in relation to that research, and

(ii) the activity is carried out in accordance with regulations made under section 34(2) of that Act; or

(e) the activity is done before the relevant commencement date for the purpose of research which, before that date, is ethically approved within the meaning of regulation 8.

Deemed consent to storage and use of relevant material: Northern Ireland

4.—(1) This regulation applies in any case falling within paragraphs (a) and (b) of section 6 of the Act (storage and use involving material from adults who lack capacity to consent).

(2) An adult ("P") who lacks capacity to consent to an activity of a kind mentioned in section 1(1)(d) or (f) of the Act which involves material from P's body, is deemed to have consented to the activity where—

(a) the activity is done for a purpose specified in paragraph 4 or 7 of Part 1 of Schedule 1 to the Act (the purposes of obtaining information relevant to another person and of transplantation) by a person who is acting in what he reasonably believes to be P's best interests;

(b) the activity is done for the purpose of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations; or

(c) the activity is done for the purpose of research which is ethically approved within the meaning of regulation 8.

Analysis of DNA

Purposes for which DNA may be analysed without consent: England and Wales

5.—(1) This regulation applies for the purposes of paragraph 12 of Schedule 4 to the Act (excepted purposes relating to DNA of adults who lack capacity to consent).

(2) In any case falling within sub-paragraph (1)(a)(i) and (b) of that paragraph (DNA manufactured by the body of a person who under the law of England and Wales lacks capacity to consent), the purposes for which DNA manufactured by the body of a person ("P") who lacks capacity to consent to analysis of the DNA may be analysed are—

(a) any purpose which the person carrying out the analysis reasonably believes to be in P's best interests;

(b) the purposes of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations;

(c) the purposes of intrusive research which is carried out on or after the relevant commencement date in accordance with the requirements of section 30(1)(a) and (b) of the Mental Capacity Act 2005 (approval by appropriate body and compliance with sections 32 and 33 of that Act);

(d) the purposes of intrusive research—

(i) which is carried out on or after the relevant commencement date,

(ii) in relation to which section 34 of the Mental Capacity Act 2005 (loss of capacity during research project) applies, and

(iii) which is carried out in accordance with regulations made under section 34(2) of that Act; or

(e) research which is carried out before the relevant commencement date and which, before that date, is ethically approved within the meaning of regulation 8.

Purposes for which DNA may be analysed without consent: Northern Ireland

6.—(1) This regulation applies for the purposes of paragraph 12 of Schedule 4 to the Act (excepted purposes relating to DNA of adults who lack capacity to consent).

(2) In any case falling within sub-paragraph (1)(a)(i) and (b) of that paragraph (DNA manufactured by the body of a person who under the law of Northern Ireland lacks capacity to consent), the purposes for which DNA manufactured by the body of a person ("P") who lacks capacity to consent to analysis of the DNA may be analysed are—

(a) any purpose which the person carrying out the analysis reasonably believes to be in P's best interests;

(b) the purposes of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations; or

(c) research which is ethically approved within the meaning of regulation 8.

Purposes for which DNA may be analysed without consent: Scotland

7.—(1) This regulation applies for the purposes of paragraph 12 of Schedule 4 to the Act.

(2) In any case falling within sub-paragraph (1)(a)(ii) and (b) of that paragraph (DNA manufactured by the body of a person who under the law of Scotland is an adult with incapacity), the purposes for which DNA manufactured by the body of an adult ("P") with incapacity may be analysed are—

(a) any purpose for which the person carrying out the analysis has obtained the consent of any person who has authority to consent to analysis of P's DNA by virtue of—

(i) a welfare power of attorney within the meaning of section 16(2),

(ii) an intervention order under section 53, or

(iii) a guardianship order under section 58,

of the Adults with Incapacity (Scotland) Act 2000;

(b) a clinical trial which is authorised and conducted in accordance with the clinical trials regulations; or

(c) surgical, medical, nursing, dental or psychological research which is permitted under section 51 of the Adults with Incapacity (Scotland) Act 2000(**1**).

Ethical approval

Ethical approval for the purposes of regulations 3 to 6

8.—(1) Research is ethically approved within the meaning of this regulation if approval is given by a research ethics authority in the circumstances specified in paragraph (2).

(2) The circumstances are that—

(a) the research is in connection with disorders, or the functioning, of the human body,

(b) there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the research has to be confined to, or relate only to, persons who have capacity to consent to taking part in it, and

(c) there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out in circumstances such that the person carrying out the research is not in possession, and not likely to come into possession, of information from which the person from whose body the defined material has come can be identified.

(3) "Defined material"—

(a) in relation to ethical approval for the purposes of regulations 3(2)(e) and 4(2)(c), means the relevant material involved in an activity of a kind mentioned in section 1(1)(d) or (f) of the Act, and

(b) in relation to ethical approval for the purposes of regulations 5(2)(e) and 6(2)(c), means the bodily material in relation to which an analysis of DNA is to be carried out.

(**1**) 2000 asp4.

(4) "Research ethics authority" has the meaning given by regulation 2 of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006(**2**).

(**2**) S.I.2006/1260.