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STATUTORY INSTRUMENTS

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**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**

*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).

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(1) 2000 asp4.