
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.