
STATUTORY INSTRUMENTS

2006 No. 1659

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

PART 3

TRANSPLANTS

Meaning of transplantable material for the purposes of section 34 of the Act

9. For the purposes of section 34 of the Act (information about transplant operations) “transplantable material” means—

- (a) the whole or part of any of the following organs if it is to be used for the same purpose as the entire organ in the human body—
 - (i) kidney,
 - (ii) heart,
 - (iii) lung or a lung lobe,
 - (iv) pancreas,
 - (v) liver,
 - (vi) bowel,
 - (vii) larynx;
- (b) face, or
- (c) limb.

Meaning of transplantable material for the purposes of section 33 of the Act

10.—(1) Subject to paragraphs (2) and (3), for the purposes of section 33 of the Act (restriction on transplants involving a live donor), “transplantable material” means—

- (a) an organ, or part of an organ if it is to be used for the same purpose as the entire organ in the human body,
- (b) bone marrow, and
- (c) peripheral blood stem cells,

where that material is removed from the body of a living person with the intention that it be transplanted into another person.

(2) The material referred to in paragraph (1)(a) is not transplantable material for the purposes of section 33 of the Act in a case where the primary purpose of removal of the material is the medical treatment of the person from whose body the material is removed.

(3) The material referred to in paragraph (1)(b) and (c) is transplantable material for the purposes of section 33 of the Act only in a case where the person from whose body the material is removed is—

- (a) an adult who lacks the capacity, or
 - (b) a child who is not competent,
- to consent to removal of the transplantable material.

Cases in which restriction on transplants involving a live donor is disapplied

11.—(1) Section 33(1) and (2) of the Act (offences relating to transplants involving a live donor) shall not apply in any case involving transplantable material from the body of a living person (“the donor”) if the requirements of paragraphs (2) to (6) are met.

(2) A registered medical practitioner who has clinical responsibility for the donor must have caused the matter to be referred to the Authority.

(3) The Authority must be satisfied that—

- (a) no reward has been or is to be given in contravention of section 32 of the Act (prohibition of commercial dealings in human material for transplantation), and
- (b) when the transplantable material is removed—
 - (i) consent for its removal for the purpose of transplantation has been given, or
 - (ii) its removal for that purpose is otherwise lawful.

(4) The Authority must take the report referred to in paragraph (6) into account in making its decision under paragraph (3).

(5) The Authority shall give notice of its decision under paragraph (3) to—

- (a) the donor of the transplantable material or any person acting on his behalf,
- (b) the person to whom it is proposed to transplant the transplantable material (“the recipient”) or any person acting on his behalf, and
- (c) the registered medical practitioner who caused the matter to be referred to the Authority under paragraph (2).

(6) Subject to paragraph (7), one or more qualified persons must have conducted separate interviews with each of the following—

- (a) the donor,
- (b) if different from the donor, the person giving consent, and
- (c) the recipient,

and reported to the Authority on the matters specified in paragraphs (8) and (9).

(7) Paragraph (6) does not apply in any case where the removal of the transplantable material for the purpose of transplantation is authorised by an order made in any legal proceedings before a court.

(8) The matters that must be covered in the report of each interview under paragraph (6) are—

- (a) any evidence of duress or coercion affecting the decision to give consent,
- (b) any evidence of an offer of a reward, and
- (c) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.

(9) The following matters must be covered in the report of the interview with the donor and, where relevant, the other person giving consent—

- (a) the information given to the person interviewed as to the nature of the medical procedure for, and the risk involved in, the removal of the transplantable material,
- (b) the full name of the person who gave that information and his qualification to give it, and
- (c) the capacity of the person interviewed to understand—

- (i) the nature of the medical procedure and the risk involved, and
 - (ii) that the consent may be withdrawn at any time before the removal of the transplantable material.
- (10) A person shall be taken to be qualified to conduct an interview under paragraph (6) if—
- (a) he appears to the Authority to be suitably qualified to conduct the interview,
 - (b) he does not have any connection with any of the persons to be interviewed, or with a person who stands in a qualifying relationship to any of those persons, which the Authority considers to be of a kind that might raise doubts about his ability to act impartially, and
 - (c) in the case of an interview with the donor or other person giving consent, he is not the person who gave the information referred to in paragraph (9)(a).

Decisions of the Authority: procedure for certain cases

12.—(1) In any case to which paragraph (2), (3) or (4) applies, the Authority’s decision as to the matters specified in regulation 11(3) shall be made by a panel of no fewer than 3 members of the Authority.

- (2) A case falls within this paragraph if—
- (a) the donor of the transplantable material is a child, and
 - (b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.
- (3) A case falls within this paragraph if—
- (a) the donor of the transplantable material is an adult who lacks capacity to consent to removal of the material, and
 - (b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.
- (4) A case falls within this paragraph if—
- (a) the donor of the transplantable material is an adult who has capacity to consent to removal of the material, and
 - (b) the case involves—
 - (i) paired donations,
 - (ii) pooled donations, or
 - (iii) a non-directed altruistic donation.

(5) In this regulation—

“non-directed altruistic donation” means the removal (in circumstances not amounting to a paired or pooled donation) of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him;

“paired donations” means an arrangement under which—

- (a) transplantable material is removed from a donor (“D”) for transplant to a person who is not genetically related or known to D, and
- (b) transplantable material is removed from another person for transplant to a person who is genetically related or known to D; and

“pooled donations” means a series of paired donations of transplantable material, each of which is linked to another in the same series (for example, transplantable material from D is transplanted to the wife of another person (“E”), transplantable material from E is transplanted

to the partner of a third person (“F”) and transplantable material from F is transplanted to D’s son).

Right to reconsideration of Authority’s decision

13.—(1) The Authority may reconsider any decision made by it under regulation 11(3) if it is satisfied that—

- (a) any information given for the purpose of the decision was in any material respect false or misleading, or
- (b) there has been any material change of circumstances since the decision was made.

(2) A specified person may in any case require the Authority to reconsider any decision made by it under regulation 11(3).

(3) “Specified persons”, in relation to such a decision, are—

- (a) the donor of the transplantable material or any person acting on his behalf,
- (b) the recipient of the material or any person acting on his behalf, and
- (c) the registered medical practitioner who caused the matter to be referred to the Authority under regulation 11(2).

(4) The right under paragraph (2) is exercisable by giving to the Authority, in such manner as it may direct, notice of exercise of the right.

(5) A notice under paragraph (4) shall contain or be accompanied by such other information as the Authority may reasonably require.

(6) On receipt of the information required by paragraph (5), the Authority shall provide to the person requiring the reconsideration—

- (a) a copy of each report made under regulation 11(6) of the interviews that were conducted in the case, and
- (b) a statement of the Authority’s reasons for its decision.

(7) Paragraphs (1) to (6) do not apply to a decision made by the Authority on reconsideration in pursuance of a notice under this regulation.

Procedure on reconsideration

14.—(1) Reconsideration shall be by way of fresh decision made at a meeting of the Authority.

(2) The meeting shall take place as soon as reasonably practicable after the provision of the reports and statement required by regulation 13(6), having regard to the need to allow time for the information contained in that material to be taken into account.

(3) Where a member of the Authority has taken part in the making of a decision subject to reconsideration (whether under regulation 12 or otherwise), he is disqualified from participating in the Authority’s reconsideration of it.

(4) On reconsideration under regulation 13(2)—

- (a) the person (“A”) by whom the reconsideration is required under regulation 13(2) shall be entitled to require that he or his representative be given an opportunity to appear before and be heard at the meeting of the Authority at which the decision is reconsidered, and
- (b) the members of the Authority in attendance at the meeting at which the decision is reconsidered shall consider any such written representations and comments.

(5) The Authority shall give a notice of its decision to A.

(6) If on reconsideration the Authority upholds the previous decision, the notice under paragraph (5) shall include a statement of the reasons for the Authority's decision.

(7) "Reconsideration" means reconsideration in pursuance of a notice under regulation 13.