STATUTORY INSTRUMENTS

2006 No. 1659

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

PART 3

TRANSPLANTS

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).