SCOTTISH STATUTORY INSTRUMENTS

2006 No. 390

The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006

PART 2

ADULT DONORS WHO HAVE CAPACITY

Cases in which restriction on transplants of organs are disapplied

- **2.**—(1) Subsection (1)(b) of section 17 of the Act (removal of organ or part organ from adult for transplantation) shall not apply in any case where–
 - (a) the donor is an adult who is not an adult with incapacity; and
 - (b) the conditions and requirements specified in paragraphs (3) to (5) are met.
- (2) Subsection (2)(b) of section 17 of the Act (use for transplantation of organ or part organ from an adult) shall not apply in any case where—
 - (a) the donor is an adult who is not an adult with incapacity; and
 - (b) the conditions and requirements specified in paragraphs (3) to (5) are met.
- (3) A registered medical practitioner who has clinical responsibility for the donor must have caused the matter to be referred to the Scottish Ministers.
- (4) Other than a case where the removal of the organ or part of an organ for the purpose of transplantation is authorised by an order made in any legal proceedings in or before a court, one or more qualified persons must have conducted an interview or interviews with—
 - (a) the donor in all cases; and
- (b) the recipient in any case of a directed donation, and reported to the Scottish Ministers on the matters specified in paragraphs (6) and (7).
- (5) The Scottish Ministers must be satisfied, having regard to the matters covered in the report provided to them in accordance with paragraph (4), and otherwise, that—
 - (a) no reward has been, or is to be, given in contravention of section 20 of the Act (prohibition of commercial dealings in parts of a human body for transplantation);
 - (b) the registered medical practitioner who has caused the matter to be referred to the Scottish Ministers has clinical responsibility for the donor;
 - (c) the donor has authorised the removal and use of the organ or part of an organ in question for transplantation purposes;
 - (d) there is no evidence of duress or coercion affecting the decision—
 - (i) of the donor in any case to authorise the removal and use of the organ or part of an organ in question for transplantation purposes; or
 - (ii) of the recipient in any case of a directed donation to be a recipient of the organ or part of an organ in question;

- (e) the donor has the capacity to understand-
 - (i) the nature of the medical procedure and the risk involved; and
 - (ii) that their authorisation of the removal and use of the organ or part of an organ for transplantation purposes may be withdrawn at any time before the removal of the organ or part of an organ in question;
- (f) the donor has been given sufficient information as to the nature of the medical procedure for, and the risk involved in, the removal of the organ or part of an organ in question by a person who is qualified to give that information;
- (g) in any case of a directed donation, the relationship (if any) between the donor and the recipient is as stated by each of them; and
- (h) any relevant wider implications arising from the intended donation, including the effect on any children or dependent relatives of the donor,

and given notice of their decision that they are so satisfied in accordance with paragraph (10).

- (6) The matters that must be covered in the report of any interview under paragraph (4) are-
 - (a) any evidence of an offer or reward;
 - (b) in any case of a directed donation-
 - (i) the relationship (if any) between the donor and the recipient; and
 - (ii) any evidence of duress or coercion affecting the decision of the recipient to be a recipient of the organ or part of an organ in question; and
 - (c) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.
- (7) The following matters must also be covered in the report of the interview with the donor—
 - (a) any evidence of duress or coercion affecting the decision of the donor to authorise the removal and use of the organ or part of an organ in question for transplantation purposes;
 - (b) the information given to the donor as to the nature of the medical procedure for, and the risk involved in, the removal of the organ or part of an organ in question;
 - (c) the full name of the person who gave that information and that person's qualification to give it;
 - (d) the capacity of the donor to understand-
 - (i) the nature of the medical procedure and the risk involved; and
 - (ii) that their authorisation of the removal and use of the organ or part of an organ for transplantation purposes may be withdrawn at any time before the removal of the organ or part of an organ in question; and
 - (e) any relevant wider implications arising from the intended donation, including the effect on any children or dependent relatives of the donor.
- (8) A person shall be taken to be qualified to conduct an interview under paragraph (4) if-
 - (a) the person appears to the Scottish Ministers to be suitably qualified to conduct the interview;
 - (b) the person does not have any connection with the person to be interviewed which the Scottish Ministers consider to be of a kind that might raise doubts about the ability of that person to act impartially; and
 - (c) in the case of an interview with the donor, the person conducting the interview is not the person who provided the information referred to in paragraph (7)(b).
- (9) A person conducting an interview under paragraph (4) may-

- (a) require any such interview to be conducted in private; and
- (b) in the case of a directed donation require that the recipient and the donor be interviewed separately and/or together.
- (10) The Scottish Ministers shall give notice of their decision under paragraph (5) to-
 - (a) the donor in all cases;
 - (b) the recipient in any case of a directed donation;
 - (c) in all cases the registered medical practitioner who caused the matter to be referred to the Scottish Ministers under paragraph (3); and
 - (d) in all cases the person who conducted the interview under paragraph (4).