SCOTTISH STATUTORY INSTRUMENTS

2006 No. 390

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

PART 4

CHILD DONORS

Cases in which restriction on transplants of organs or tissue are disapplied

- **5.**—(1) Section 17(1)(a) of the Act (prohibition on removal of an organ, part of an organ or tissue from a living child for transplantation) shall not apply in any case where the conditions and requirements specified in paragraphs (3), (5) and (7) to (9) are met.
- (2) Section 17(2)(a) of the Act (prohibition on use for transplantation of an organ, part of an organ or tissue from a living child) shall not apply in any case where the conditions and requirements specified in paragraphs (4) and (6) to (9) are met.
 - (3) The organ or part of an organ which is removed must be one that—
 - (a) during a domino organ transplant operation, is necessarily removed from the donor; and
 - (b) is in turn intended to be used for transplantation in respect of another living person.
 - (4) The organ or part of an organ which is used must be one as is described in paragraph (3).
 - (5) The tissue which is removed must be regenerative tissue.
 - (6) The tissue which is used must be regenerative tissue.
 - (7) A registered medical practitioner who has clinical responsibility for the donor must have-
 - (a) caused the matter to be referred to the Scottish Ministers; and
 - (b) certified within that referral to the Scottish Ministers that-
 - (i) in relation to the proposed removal or use of any organ or part of an organ, the organ or part of an organ which is to be removed or used as the case may be is one as is described in paragraph (3);
 - (ii) in relation to the proposed removal or use any tissue, the tissue which is to be removed or used as the case may be is regenerative tissue.
- (8) Other than a case where the removal of the organ, part of an organ or tissue 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;
 - (b) a person who has parental rights and parental responsibilities in relation to the donor (but who is not a local authority); and
- (c) the recipient in any case where tissue is to be removed or used, and reported to the Scottish Ministers on the matters specified in paragraphs (10) to (13).

- (9) The Scottish Ministers must be satisfied, having regard to the matters covered in the report provided to them in accordance with paragraph (8), and otherwise, that—
 - (a) no payment has been, or is to be, made 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 is a child;
 - (d) in relation to the proposed removal of any organ or part of an organ, the organ or part of an organ which is to be removed is one as is described in paragraph (3);
 - (e) in relation to the proposed use of any organ or part of an organ, the organ or part of an organ which is to be used is one as is described in paragraph (3);
 - (f) in relation to the proposed removal of any tissue, the tissue which is to be removed is regenerative tissue;
 - (g) in relation to the proposed use of any tissue, the tissue which is to be used is regenerative tissue;
 - (h) both the donor and the person who has parental rights and parental responsibilities in relation to the donor (but who is not a local authority) have been provided with sufficient information about the removal and use of the organ, part of an organ or tissue in question for transplantation;
 - (i) the donor does not indicate any unwillingness to be a donor;
 - (j) there is no evidence of duress or coercion affecting the apparent lack of unwillingness on the part of the donor to be a donor;
 - (k) in any case where tissue is to be removed or used, there is no evidence of duress or coercion affecting the decision of the recipient to be a recipient of the tissue in question; and
 - (l) in any case where tissue is to be removed or used, the relationship (if any) between the donor and the recipient is as stated by each of the persons interviewed under paragraph (8),

and given notice of their decision that they are so satisfied in accordance with paragraph (16).

- (10) The matters that must be covered in the report of any interview under paragraph (8) are-
 - (a) any evidence of an offer or reward;
 - (b) any evidence of duress or coercion affecting the apparent lack of unwillingness on the part of the donor to be a donor;
 - (c) in any case where tissue is to be removed or used, the relationship (if any) between the donor and the recipient; and
 - (d) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.
- (11) The following matters must also be covered in the report of the interview with the donor—
 - (a) whether the donor is a child;
 - (b) in any case where an organ or part of an organ is to be removed or used for transplantation purposes, the information provided to the donor about the removal and use of the organ or part of an organ in question for transplantation;
 - (c) in any case where tissue is to be removed or used, the information given to the donor as to the nature of the medical procedure for, and the risk involved in, the removal of the tissue in question;
 - (d) the full name of the person who gave that information and his qualification to give it; and

- (e) the capacity of the donor to understand the nature of the medical procedure for, and the risk involved in, the removal of the tissue in question.
- (12) The following matters must also be covered in the report of the interview with the person who has parental rights and parental responsibilities in relation to the donor (but who is not a local authority) under paragraph (8)(b)–
 - (a) the views of that person as regards the proposed removal and use of the organ, part of an organ or tissue in question for transplantation;
 - (b) in any case where an organ or part of an organ is to be removed or used for transplantation purposes, the information provided to that person about the removal and use of the organ or part of an organ in question for transplantation;
 - (c) in any case where tissue is to be removed or used, the information given to that person as to the nature of the medical procedure for, and the risk involved in, the removal of the tissue in question; and
 - (d) the full name of the person who gave that information and his qualification to give it.
- (13) The report of the interview with the recipient must also state whether there is any evidence of duress or coercion affecting the decision of the recipient to be a recipient of the tissue in question.
 - (14) A person conducting an interview under paragraph (8) may-
 - (a) require any such interview to be conducted in private; and
 - (b) require that any of the individuals mentioned in paragraph (8) be interviewed separately and/or together in any combination.
 - (15) A person shall be taken to be qualified to conduct an interview under paragraph (8) if—
 - (a) the person appears to the Scottish Ministers to be suitably qualified to conduct the interview; and
 - (b) the person does not have any connection with the person to be interviewed which the Scottish Ministers considers to be of a kind that might raise doubts about the ability of that person to act impartially.
 - (16) The Scottish Ministers shall give notice of their decision under paragraph (9) to-
 - (a) the donor;
 - (b) the recipient in any case where tissue is to be removed or used;
 - (c) the person with parental rights and parental responsibilities in relation to the donor (but who is not a local authority) who was interviewed under paragraph (8);
 - (d) the registered medical practitioner who caused the matter to be referred to the Scottish Ministers under paragraph (7); and
 - (e) the person who conducted the interview under paragraph (8).