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SCOTTISH STATUTORY INSTRUMENTS

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**2006 No. 390**

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

**PART 3**

**ADULTS WITH INCAPACITY ACTING AS DONORS**

**Cases in which restriction on transplants of organs are disapplied**

**3.—**(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 with incapacity; and
- (b) the conditions and requirements specified in paragraphs (3) and (5) to (7) 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 in any case where—

- (a) the donor is an adult with incapacity; and
- (b) the conditions and requirements specified in paragraphs (4) to (7) 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) 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 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).

(6) 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; and
- (b) where it is reasonable and practicable to do so, one or more of the following individuals—
  - (i) the donor's nearest relative;
  - (ii) the donor's primary carer;
  - (iii) the donor's named person;
  - (iv) any guardian, continuing attorney or welfare attorney of the donor; and
  - (v) any other person appearing to the person conducting the interview to have an interest in the welfare of the donor where these views have been made known to the person conducting the interview,

and reported to the Scottish Ministers on the matters specified in paragraphs (8) to (10).

(7) The Scottish Ministers must be satisfied, having regard to the matters covered in the report provided to them in accordance with paragraph (6), 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 is an adult with incapacity;
- (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) the donor has been provided with information about the removal and use of the organ or part of an organ in question for transplantation;
- (g) the donor does not indicate unwillingness to be a donor;
- (h) there is no evidence from any interview of any person mentioned in paragraph (6)(b) that the donor had previously indicated any unwillingness to be a donor; and
- (i) there is no evidence of duress or coercion affecting the apparent lack of unwillingness on the part of the donor to be a donor,

and given notice of their decision that they are so satisfied in accordance with paragraph (13).

(8) The matters that must be covered in the report of any interview under paragraph (6) 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; and
- (c) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.

(9) The following matters must also be covered in the report of the interview with the donor—

- (a) whether the donor is an adult with incapacity;
- (b) the information provided to the donor about the removal and use of the organ or part of an organ in question for transplantation; and
- (c) the full name of the person who gave that information and that person's qualification to give it.

(10) The report of any interview with any of the individuals mentioned in paragraph (6)(b) must also state whether there is any evidence of the donor having previously indicated any unwillingness to be a donor.

(11) A person shall be taken to be qualified to conduct an interview under paragraph (6) 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.

(12) A person conducting an interview under paragraph (6) may—

- (a) require any such interview to be conducted in private; and

- (b) require that the donor and any of the individuals mentioned in paragraph (6)(b) be interviewed separately and/or together in any combination.
- (13) The Scottish Ministers shall give notice of their decision under paragraph (7) to—
  - (a) the donor;
  - (b) any of the individuals mentioned in paragraph (6)(b) who have been interviewed under paragraph (6);
  - (c) the registered medical practitioner who caused the matter to be referred to the Scottish Ministers under paragraph (5); and
  - (d) the person who conducted the interview under paragraph (6).

#### **Cases in which restriction on transplants of regenerative tissue are disapplied**

4.—(1) Subsection (1)(c) of section 17 of the Act (removal of tissue from adult with incapacity for transplantation) shall not apply in any case where the conditions and requirements specified in paragraphs (3) and (5) to (8) are met.

(2) Subsection (2)(c) of section 17 of the Act (use for transplantation of tissue from an adult with incapacity) shall not apply in any case where the conditions specified in paragraphs (4) to (8) are met.

- (3) The tissue which is removed must be regenerative tissue.
- (4) The tissue which is used must be regenerative tissue.
- (5) 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 the tissue which is to be removed or used as the case may be is regenerative tissue.
- (6) The following conditions are fulfilled—
  - (a) there is no other adult who could act as a donor of the tissue in question;
  - (b) removal of the tissue entails no foreseeable risk, or only a minimal foreseeable risk, to the donor;
  - (c) removal of the tissue imposes no discomfort, or only a minimal discomfort, on the donor; and
  - (d) the donor does not indicate unwillingness to be a donor.

(7) Other than a case where the removal of the 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) the recipient; and
- (c) where it is reasonable and practicable to do so, one or more of the following individuals—
  - (i) the donor's nearest relative;
  - (ii) the donor's primary carer;
  - (iii) the donor's named person;
  - (iv) any guardian, continuing attorney or welfare attorney of the donor; and
  - (v) any other person appearing to the person conducting the interview to have an interest in the welfare of the donor where these views have been made known to the person conducting the interview,

and reported to the Scottish Ministers on the matters specified in paragraphs (9) to (12).

(8) The Scottish Ministers must be satisfied, having regard to the matters covered in the report provided to them in accordance with paragraph (7), 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 is an adult with incapacity;
- (d) in relation to the proposed removal of any tissue, the tissue which is to be removed is regenerative tissue;
- (e) in relation to the proposed use of any tissue, the tissue which is to be used is regenerative tissue;
- (f) the conditions specified in paragraph (6) are fulfilled;
- (g) the donor has been provided with information about the removal and use of the tissue in question for transplantation;
- (h) the donor does not indicate unwillingness to be a donor;
- (i) there is no evidence from any interview of any person mentioned in paragraph (7)(c) that the donor had previously indicated any unwillingness to be a donor;
- (j) there is no evidence of duress or coercion affecting the apparent unwillingness of the donor to be a donor;
- (k) 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) the relationship (if any) between the donor and the recipient is as stated by each of the persons interviewed under paragraph (7),

and given notice of their decision that they are so satisfied in accordance with paragraph (15).

(9) The matters that must be covered in the report of any interview under paragraph (7) 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) 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.

(10) The following matters must also be covered in the report of the interview with the donor—

- (a) whether the adult is an adult with incapacity;
- (b) the information given to the donor about the removal and use of the tissue in question for transplantation; and
- (c) the full name of the person who gave that information and that person's qualification to give it.

(11) 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.

(12) The report of the interview with any of the individuals mentioned in paragraph (7)(c) must also state whether there is any evidence of the donor having previously indicated any unwillingness to be a donor.

(13) A person shall be taken to be qualified to conduct an interview under paragraph (7) 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.
- (14) A person conducting an interview under paragraph (7) may–
- (a) require any such interview to be conducted in private; and
  - (b) require that any of the individuals mentioned in paragraph (7) be interviewed separately and/or together in any combination.
- (15) The Scottish Ministers shall give notice of their decision under paragraph (8) to–
- (a) the donor;
  - (b) the recipient;
  - (c) any of the individuals mentioned in paragraph (7)(c) who have been interviewed under paragraph (7);
  - (d) the registered medical practitioner who caused the matter to be referred to the Scottish Ministers under paragraph (5); and
  - (e) the person who conducted the interview under paragraph (7).