SCOTTISH STATUTORY INSTRUMENTS

2006 No. 390

HUMAN TISSUE

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

Made - - - -	*29th June 2006*
Coming into force - -	*1st September 2006*

The Scottish Ministers, in exercise of the powers conferred by sections 17(3), (4), (5) and (7), 18(2) and 59(1)(b) of the Human Tissue (Scotland) Act 2006(**1**) and all other powers enabling them in that behalf, hereby make the following Regulations, a draft of which has, in accordance with section 59(3) of that Act, been laid before and approved by resolution of the Scottish Parliament:

PART 1

PRELIMINARY

Citation, interpretation and commencement

1.—(1) These Regulations may be cited as the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.

(2) In these Regulations–

"the Act" means the Human Tissue (Scotland) Act 2006;

"the 2000 Act" means the Adults with Incapacity (Scotland) Act 2000(**2**);

"the 2003 Act" means the Mental Health (Care and Treatment) (Scotland) Act 2003(**3**);

"adult with incapacity" is–

(a) for the purposes of regulation 2 a person who is incapable within the meaning of section 1(6) of the 2000 Act in relation 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;

(**1**) 2006 asp 4.
(**2**) 2000 asp 4.
(**3**) 2003 asp 13.

(b) for the purposes of regulation 3, an adult in respect of whom section 47 of the 2000 Act(**4**) applies in relation to the domino organ transplant operation in question; and

(c) for the purposes of regulation 4, an adult to whom section 18 of the Act applies.

"continuing attorney" shall be construed in accordance with section 15 of the 2000 Act;

"directed donation" means the removal of an organ or part of an organ from a donor on condition that the organ or part of an organ in question is used for transplantation into a recipient specified in advance by the donor and agreed by the recipient;

"donor" means a living person from whom it is proposed to remove an organ, part of an organ or any tissue;

"named person" has the meaning given by section 329 of 2003 Act;

"nearest relative" has the meaning given by section 254 of the 2003 Act;

"primary carer" has the meaning given by section 87 of the 2000 Act(**5**);

"recipient" means a person into whom it is proposed to transplant an organ, part of an organ or any tissue; and

"welfare attorney" shall be construed in accordance with section 16 of the 2000 Act.

(3) These Regulations shall come into force on 1st September 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).

(**4**) Section 47 of the 2000 Act was amended by the 2003 Act, Schedule 4, paragraph 9 and Schedule 5, Part 1 and the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), section 35(2)(f).

(**5**) Section 87 of the 2000 Act was amended by the 2003 Act, Schedule 5, Part 1, the Civil Partnership Act 2004 (c. 33), Schedule 30, and S.S.I. 2005/465, Schedule 1, paragraph 28.

(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).

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).

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).

PART 5

DECISION MAKING PROCESS

Right to reconsideration of Scottish Ministers' decision

6.—(1) The Scottish Ministers may at their own instance reconsider any decision made by them under regulations 2(5), 3(7), 4(8) or 5(9)–

(a) at any time before or after they give notice of that decision under regulations 2(10), 3(13), 4(15) or 5(16);

(b) on the ground that–

(i) any information given for the purpose of the decision was in any material respect false or misleading;

(ii) new information (including information relating to a change of circumstances), which is relevant and material to their decision, becomes available to them; or

(iii) their decision was made in ignorance of, or was based on a mistake as to, some material fact.

(2) A specified person may in any case require the Scottish Ministers to reconsider any decision made by them which is notified to that specified person under regulations 2(10), 3(13), 4(15) or 5(16).

(3) The right under paragraph (2) is exercisable by giving to the Scottish Ministers, in such manner as they may direct, notice of exercise of the right.

(4) A notice under paragraph (3) shall contain or be accompanied by such other information as the Scottish Ministers may reasonably require.

(5) On receipt of the information required by paragraph (4), the Scottish Ministers shall provide to the person requiring the reconsideration–

(a) a copy of each report made under regulation 2(4), 3(6), 4(7) or 5(8) of the interviews that were conducted in the case; and

(b) a statement of the Scottish Ministers' reasons for their decision.

(6) The person requiring the reconsideration may also make prior to the reconsideration such written representations and comments as that person considers to be relevant to the reconsideration.

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

(8) For the purposes of paragraph (2) a "specified person" is the recipient of a notice under regulation 2(10), 3(13), 4(15) or 5(16) or any person acting on the recipient's behalf.

Procedure on reconsideration

7.—(1) Reconsideration shall be by way of fresh decision made by the Scottish Ministers.

(2) Reconsideration shall take place as soon as reasonably practicable after the provision of the reports and statement required by regulation 6(5) and the provision of any written representations and comments allowed by regulation 6(6), having regard to the need to allow time for the information contained in that material to be taken into account.

(3) On reconsideration–

(a) the person by whom the reconsideration is required under regulation 6(2) shall be entitled to require that they or their representative be given an opportunity to appear before and be heard by the Scottish Ministers at the time that the decision is reconsidered; and

(b) the Scottish Ministers shall consider any written representations and comments provided to them under regulation 6(6).

(4) The Scottish Ministers shall give a notice of their decision–

(a) to the person who required the reconsideration and to each of the persons mentioned in regulations 2(10), 3(13), 4(15) or 5(16) where the reconsideration was required under regulation 6(2); and

(b) to the persons mentioned in regulations 2(10), 3(13), 4(15) or 5(16) where the Scottish Ministers initiated the reconsideration under regulation 6(1),

and a notice under this regulation is to be treated as if it were a decision under regulation 2(5), 3(7), 4(8) or 5(9) as the case may be.

(5) If on reconsideration the Scottish Ministers uphold their previous decision, the notice under paragraph (4) shall include a statement of the reasons for their decision.

(6) "Reconsideration" means reconsideration under regulation 6.

Appeal to the Court of Session

8.—(1) Any specified person who is aggrieved by the decision in any notice under regulations 2(10), 3(13), 4(15), 5(16) or 7(4) may appeal to the Court of Session against that decision.

(2) For the purposes of paragraph (1) a "specified person" is the recipient of the notice or any person acting on the recipient's behalf.

St Andrew's House,
Edinburgh
29th June 2006

LEWIS MACDONALD
Authorised to sign by the Scottish Ministers

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for cases in which the prohibitions of transplants between living persons under section 17 of the Human Tissue (Scotland) Act 2006 ("the Act") do not apply.

Part 1 (Preliminary):

Regulation 1 contains the citation, interpretation and commencement provisions to be applied to the Regulations. The Regulations will be come into force on 1 September 2006, being the date when the Act comes into force (by S.S.I. 2006/251).

Part 2 (Adult donors who have capacity):

Regulation 2 specifies the circumstances in which transplants of organs or parts of organs from the body of a living adult donor who has capacity may be carried out without contravening the restrictions set out in section 17(1)(b) and (2)(b) of the Act.

- the restrictions are disapplied if the adult is not an adult with incapacity and if certain conditions and requirements laid down in regulation 2 are met.
- these conditions and requirements include that the matter has been referred to the Scottish Ministers and that, after certain required interviews have taken place, the Scottish Ministers are satisfied as to certain matters. Those matters relate to authorisation, information given to the donor, lack of reward for the donor and notification of the decision of the Scottish Ministers.
- under this regulation, the donor will be interviewed in all cases, whilst the recipient of the organ or part organ will also be interviewed in the case of a directed donation (as defined in regulation 1(2)).

Part 3 (Adults with incapacity acting as donors):

Regulation 3 specifies the circumstances in which transplants of organs or parts of organs from the body of a living adult with incapacity for transplantation may be carried out without contravening the restrictions set out in section 17(1)(b) and (2)(b) of the Act.

- section 17(5) of the Act enables those restrictions to be disapplied in relation to domino organ transplant operations only where the donor is an adult with incapacity; a "domino organ transplant operation" is defined in section 17(1) of the Act.
- the restrictions are disapplied under regulation 3 where the adult is an adult with incapacity and where certain conditions and requirements laid down in that regulation are met.
- these conditions and requirements include: that the organ or part organ is one that is or has been removed during a domino organ transplant operation; that the matter has been referred to the Scottish Ministers; and that, after certain required interviews have taken place, the Scottish Ministers are satisfied as to certain matters. Those matters on which the Scottish Ministers must satisfy themselves relate to confirmation that the donor is an adult with incapacity, that the organ or part organ to be removed or used is one that is or has been removed during a domino organ transplant operation, that the adult does not indicate unwillingness to be a donor and that there is no evidence that the adult has in the past previously indicated any unwillingness to be a donor, that information has been given to the donor and that there is no evidence of any reward.

- under this regulation, the donor will be interviewed in all cases and, where it is reasonable and practicable to do so, one or more of the adult's nearest relative, primary carer, named person, guardian, continuing attorney or welfare attorney will also be interviewed to ascertain their views as to the adult's past wishes and feelings on the issue of donation, thus following the approach taken in relation to other interventions in the adult's affairs under the Adults with Incapacity (Scotland) Act 2000.

Regulation 4 specifies the circumstances in which transplants of tissue from the body of a living adult with incapacity for transplantation may be carried out without contravening the restrictions set out in section 17(1)(c) and (2)(c) of the Act.

- section 17(4) of the Act enables those restrictions to be disapplied in relation to regenerative tissue only where the donor is an adult with incapacity; "regenerative tissue" is defined under section 17(10) of the Act.
- the restrictions are therefore disapplied under regulation 4 where the adult is an adult with incapacity and where certain conditions and requirements laid down in that regulation are met. These conditions and requirements include: that the tissue that is or has been removed is regenerative tissue; that the matter has been referred to the Scottish Ministers; and that, after certain required interviews have taken place, the Scottish Ministers are satisfied as to certain matters. Those matters on which the Scottish Ministers must satisfy themselves relate to confirmation that the donor is an adult with incapacity, that the tissue that is to be removed or used is regenerative tissue, that the adult does not indicate unwillingness to be a donor and that there is no evidence that the adult has in the past previously indicated any unwillingness to be a donor, that information has been given to the donor and that there is no evidence of any reward.
- under this regulation, the donor will be interviewed in all cases and, where it is reasonable and practicable to do so, one or more of the adult's nearest relative, primary carer, named person, guardian, continuing attorney or welfare attorney will also be interviewed to ascertain their views as to the adult's past wishes and feelings on the issue of donation, thus again following the approach taken in relation to other interventions in the adult's affairs under the Adults with Incapacity (Scotland) Act 2000. The recipient will also be interviewed in all cases under this regulation because of the nature of this kind of donation.

Part 4 (Child donors):

Regulation 5 specifies the circumstances in which transplants of organs, parts of organs or tissue from the body of a living child donor may be carried out without contravening the restrictions set out in section 17(1)(a) and (2)(a) of the Act.

- section 17(4) of the Act enables those restrictions to be disapplied in relation to regenerative tissue only in relation to a child donor
- section 17(5) of the Act enables the restrictions on organ transplants to be disapplied in relation to a child donor only where the organ or part organ is one that has been removed during a domino organ transplant operation.
- the restrictions are therefore disapplied under regulation 5 where certain conditions and requirements laid down in that regulation are met. These conditions and requirements include: that any organ or part organ to be removed or used is one that is or has been removed during a domino organ transplant operation; that any tissue that is or has been removed is regenerative tissue; that the matter has been referred to the Scottish Ministers; and that, after certain required interviews have taken place, the Scottish Ministers are satisfied as to certain matters. Those matters on which the Scottish Ministers must satisfy themselves relate to confirmation that: the donor is a child; that the organ or part organ to be removed or used is one that is or has been removed during a domino organ transplant operation; that the tissue that is to be removed or used is regenerative tissue; that the child does not indicate unwillingness to be a donor; that information has been given to the donor and that there is no evidence of any reward.

- under this regulation, the donor will be interviewed in all cases as will a person who has parental rights and parental responsibilities in relation to the child in order to seek their views on the proposed donation. The recipient will also be interviewed under this regulation in all cases involving the removal or use of regenerative tissue from a child because of the nature of that kind of donation.

Part 5 (Decision making process):

Regulation 6 provides a right of reconsideration of the Scottish Ministers' decision as to the matters specified in regulations 2(5), 3(7), 4(8) or 5(9). This right may be exercised by the Scottish Ministers at their own instance in certain circumstances or by the recipient of a notice of a decision by the Scottish Ministers under those regulations.

Regulation 7 makes provision about the procedure to be followed for reconsideration.

Regulation 8 provides for a right of appeal to the Court of Session against a decision of the Scottish Ministers which is notified to that person under regulations 2(10, 3(13), 4(15), 5(16) or 7(4).