
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.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- 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).