
SCOTTISH STATUTORY INSTRUMENTS

2006 No. 344

HUMAN TISSUE

The Human Tissue (Scotland) Act 2006 (Maintenance of Records and Supply of Information Regarding the Removal and Use of Body Parts) Regulations 2006

Made - - - - *8th June 2006*
Laid before the Scottish
Parliament - - - - *9th June 2006*
Coming into force - - *1st September 2006*

The Scottish Ministers, in exercise of the powers conferred by section 19(1) of the Human Tissue (Scotland) Act 2006⁽¹⁾, and all other powers enabling them in that behalf, hereby make the following Regulations:

PART 1

PRELIMINARY

Citation, interpretation and commencement

1.—(1) These Regulations may be cited as the Human Tissue (Scotland) Act 2006 (Maintenance of Records and Supply of Information Regarding the Removal and Use of Body Parts) Regulations 2006.

(2) In these Regulations—

“the Act” means the Human Tissue (Scotland) Act 2006;

“the 1978 Act” means the National Health Service (Scotland) Act 1978⁽²⁾;

“body part” means any part of a body of a living or deceased person other than tissue;

“donor” means a deceased or living person from whose body it is proposed to remove a body part for transplantation into another person who is alive;

“Health Board” means a board constituted by order under section 2(1)(a) of the 1978 Act⁽³⁾;

(1) 2006 asp 4.

(2) 1978 c. 29.

(3) Section 2(1) was amended by the Health and Social Services and Social Security Adjudications Act 1983 (c. 41), Schedule 7, paragraph 1; the National Health Service and Community Care Act 1990 (c. 19), section 28 (which inserted sub-sections (1)

- “health service hospital” has the meaning given by section 108(1) of the 1978 Act(4);
- “NHSBT” means NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) established by NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005(5);
- “recipient” means a living person into whom it is proposed to transplant a body part from another deceased or living person;
- “relevant section 3(1) purpose” means any purpose referred to in section 3(1) of the Act other than transplantation; and
- “Special Health Board” means a Special Health Board constituted by order under section 2(1) (b) of the 1978 Act.
- (3) These Regulations shall come into force on 1st September 2006.

PART 2

MAINTENANCE OF RECORDS

Records to be maintained by registered medical practitioner who removes body parts for transplantation

- 2.—(1) A registered medical practitioner who has removed a body part for transplantation shall compile and maintain records in accordance with this regulation.
- (2) Records shall be compiled in a permanent form in accordance with this regulation in relation to each body part which is removed for transplantation.
- (3) Where the donor was living at the time of the removal of the donor’s body part, the records compiled in accordance with paragraph (2) shall be maintained for a period of—
- (a) six years beginning with the date on which the body part is removed for transplantation; or
 - (b) three years beginning with the date on which the donor died (even although the donor dies after the expiry of that six year period),
- whichever is the later date.
- (4) Where the donor was deceased at the time of the removal of the donor’s body part, the records compiled in accordance with paragraph (2) shall be maintained for a period of six years beginning with the date on which the body part is removed for transplantation.

Records to be maintained by persons who use or retain body parts for a relevant section 3(1) purpose

- 3.—(1) Any person specified in paragraph (2) who has received a body part which is to be used or retained for a relevant section 3(1) purpose shall compile and maintain records in accordance with this regulation.
- (2) The persons specified for the purposes of paragraph (1) are—
- (a) where the body part is received in a hospital managed by a Special Health Board, that Special Health Board;

(b), (1A), (1B) and (1C)) and Schedule 9, paragraph 19(1); the [National Health Service Reform \(Scotland\) Act 2004 \(asp 7\)](#), schedule 1, paragraph 1(2) and by the [Smoking, Health and Social Care \(Scotland\) Act 2005 \(asp 13\)](#), schedule 2, paragraph 2(2).

(4) Section 108(1) provides for interpretation and construction and was amended by the Health Services Act 1980 (c. 53), Schedule 6, paragraph 6(a).

(5) S.I.2005/2529.

(b) where the body part is received in a hospital which is not managed by a Special Health Board, the Health Board for the area in which the body part is received; and

(c) where the body part is received in any other establishment that is not a hospital, the manager of that establishment.

(3) Records shall be compiled in a permanent form in accordance with this regulation in relation to each body part which is received which is to be used or retained for a relevant section 3(1) purpose.

(4) Where the donor was living at the time of the removal of the donor's body part, the records compiled in accordance with paragraph (3) shall be maintained for a period of—

(a) six years beginning with the date on which the body part is received; or

(b) three years beginning with the date on which the donor died even (although the donor dies after the expiry of that six year period),

whichever is the later date.

(5) Where the donor was deceased at the time of the removal of the donor's body part, the records compiled in accordance with paragraph (3) shall be maintained for a period of six years beginning with the date on which the body part is received.

PART 3

SUPPLY OF INFORMATION

Information to be supplied by registered medical practitioner who removes body parts for transplantation

4. A registered medical practitioner who has removed a body part for transplantation shall supply the information specified in Schedule 1 to these Regulations to the following authorities—

(a) NHSBT in all cases; and

(b) (i) where the removal was carried out in a hospital managed by a Special Health Board, to that Special Health Board; or

(ii) where the removal was carried out in a hospital other than one managed by a Special Health Board or in any other establishment which is not a hospital, to the Health Board for the area in which the removal of the body part was carried out.

Information to be supplied by registered medical practitioner who uses or retains body parts for transplantation

5. A registered medical practitioner who has received a body part which is to be used or retained for transplantation shall supply the information specified in Parts 1 to 3 of Schedule 2 to these Regulations to the following authorities—

(a) NHSBT in all cases; and

(b) (i) where the removal was carried out in a hospital managed by a Special Health Board, to that Special Health Board; or

(ii) where the removal was carried out in a hospital other than one managed by a Special Health Board or in any other establishment which is not a hospital, to the Health Board for the area in which the removal of the body part was carried out.

Information to be supplied by persons who use or retain body parts for a relevant section 3(1) purpose

6.—(1) Any person specified in paragraph (3) who has received a body part which is to be used or retained for a relevant section 3(1) purpose shall supply the information specified in Parts 1, 2 and 4 of Schedule 2 to these Regulations to NHSBT.

(2) Any person specified in paragraph (3)(c) who has received a body part which is to be used or retained for a relevant section 3(1) purpose shall, in addition to supplying the specified information to NHSBT under paragraph (1), supply the information specified in Parts 1, 2 and 4 of Schedule 2 to these Regulations to the Health Board for the area in which the removal of the body part was carried out.

(3) The persons specified for the purposes of paragraphs (1) and (2) are—

- (a) where the body part is received in a hospital managed by a Special Health Board, that Special Health Board;
- (b) where the body part is received in a hospital which is not managed by a Special Health Board, the Health Board for the area in which the body part is received; and
- (c) where the body part is received in any other establishment that is not a hospital, the manager of that establishment.

St Andrew's House,
Edinburgh
8th June 2006

LEWIS MACDONALD
Authorised to sign by the Scottish Ministers

SCHEDULE 1

Regulation 4

REMOVAL OF A BODY PART

Part 1 –

Information about the removal

1. Name and address of the hospital or other place at which the removal of the body part from the donor was carried out.
2. Where the removal was carried out in–
 - (a) a hospital managed by a Special Health Board, the name of that Special Health Board; or
 - (b) a hospital other than one managed by a Special Health Board or in any other establishment which is not a hospital, the name of the Health Board for the area in which the removal of the body part was carried out.
3. Full name of the registered medical practitioner who removed the body part from the donor, the appointment that the registered medical practitioner holds and the place at which the registered medical practitioner holds that appointment.
4. In any case where the donor’s body part is considered unsuitable for transplantation after removal, a statement of–
 - (a) the reason for the unsuitability; and
 - (b) either–
 - (i) the manner of disposal of the body part, where the body part is so disposed of; or
 - (ii) if the body part is not so disposed of but is instead retained for the purposes of research, education, training or audit, the specific purpose or purposes for which the body part is to be so retained and used.

Part 2 –

Information about the body part and the donor

1. Description of the body part which has been removed.
2. Whether the donor was living or deceased at the time of the removal of the body part.
3. Where the donor was deceased at the time of the removal of the body part, the date and time of the donor’s death.
4. Where the donor was living at the time of the removal of the body part, the date and time of the removal of the body part.
5. Full name of the donor, the donor’s hospital case note number and, where available, the donor’s community health index (CHI) number.

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SCHEDULE 2

Regulations 5, 6(1) and (2)

RECEIPT OF A BODY PART

Part 1 –

Information about receipt

1. Name and address of the hospital or other place at which the donor's body part was received.
2. Where the body part was received in—
 - (a) a hospital managed by a Special Health Board, the name of that Special Health Board; or
 - (b) a hospital other than one managed by a Special Health Board or in any other establishment which is not a hospital, the name of the Health Board for the area in which the removal of the body part was received.
3. In any case where the donor's body part is not transplanted into a recipient, a statement of—
 - (a) the reason why not; and
 - (b) the manner of disposal of the donor's body part, where the body part is not to be retained and used for the purposes of research, education, training or audit.

Part 2 –

Information about the body part

1. Description of the body part which has been received.
2. Name and address of the hospital or other place at which the removal of the body part from the donor was carried out.
3. If the donor's body part was removed outside the United Kingdom—
 - (a) the name of the country in which the body part was removed; and
 - (b) the reference number allocated to the body part by NHSBT.

Part 3 –

Information about transplant

1. Where the body part is transplanted into a recipient, the full name of the registered medical practitioner who carried out the transplant, the appointment that the registered medical practitioner holds and the place at which the registered medical practitioner holds that appointment.
2. Full name of the recipient.
3. Date and time that the transplant was carried out.
4. In any case where the donor is genetically related to the recipient, a description of the relationship.
5. If the transplant was carried out in a health service hospital, a statement indicating each case where—

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- (a) the recipient was entitled to the provision of the treatment by virtue of regulations made by the Council of the European Communities under Article 42 of the Treaty establishing the European Community⁽⁶⁾;
- (b) the recipient was a national of another country who was entitled to be provided with the treatment by virtue of an agreement entered into between the European Community and that other country; or
- (c) the treatment of the recipient was provided under an arrangement for providing health care mutually agreed between the Government of the United Kingdom and the Government of a country or territory specified in Schedule 2 to the National Health Service (Charges to Overseas Visitors) (Scotland) Regulations 1989⁽⁷⁾.

Part 4 –

Information about a relevant section 3(1) purpose

1. Where the body part is received and is to be retained and used for any relevant section 3(1) purpose (research, education, training or audit), the specific purpose or purposes for which the body part is to be retained and used.
2. A statement of the date and the manner of disposal of the body part after the purpose or purposes for which the body part was to be retained and used is served.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations replace the Human Organ Transplants (Supply of Information) Regulations 1989, made under section 3(1) of the Human Organ Transplants Act 1989 (that Act is repealed by the Human Tissue (Scotland) Act 2006 (“the 2006 Act”) (section 61 and the Schedule)). They come into force on 1st September 2006, being the date on which the 2006 Act comes into force (by [S.S.I. 2006/251](#)). They make provision for–

- the maintenance of records regarding the removal of parts from human bodies for transplantation and the use or retention, for any other purpose referred to in section 3(1) of the 2006 Act, of parts removed from bodies of deceased or living persons;
- the provision of information as may be so specified with respect to the removal of parts from human bodies for transplantation, the use or retention for that purpose of parts removed or the use or retention for any other purpose referred to in section 3(1) of the 2006 Act of parts removed from bodies of deceased or living persons.

Regulation 2 places a requirement on registered medical practitioners who remove a body part for transplantation to compile and maintain records. Records, in the case of a living donor, are to be maintained for 6 years from the date of removal or 3 years from the date of the donor’s death (even although the donor dies after the expiry of that six year period), whichever is the longer. In the case

⁽⁶⁾ The reference to the Treaty is to it as renumbered in accordance with the Treaty of Amsterdam (Cmnd. 3780).

⁽⁷⁾ S.I. 1989/364 amended by S.I. 1992/411, 1994/1770, 1998/251 and S.S.I. 2004/369.

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of a cadaveric donation, records are to be maintained for 6 years from the date of removal of the body part in question.

Regulation 3 places a requirement on certain specified persons who have received a body part which is to be used or retained for a relevant section 3(1) purpose (defined in regulation 1(2) as being any purpose other than transplantation referred to in section 3(1) of the 2006 Act), namely research, education, training or audit. Identical record keeping requirements are imposed on those persons as on registered medical practitioners under regulation 2 in terms of periods for keeping of records.

Regulation 4 places a requirement on a registered medical practitioner who has removed a body part for transplantation to supply the information specified in Schedule 1 to the Regulations to NHSBT and to either the relevant Special Health Board or the Health Board for the area in which the removal was carried out. The specified information to be supplied is information about the removal and information about the body part and the donor.

Regulation 5 places a similar requirement on a registered medical practitioner to supply information as that under regulation 4, but in this case the requirement is on a registered medical practitioner who receives a body part for transplantation. The information to be supplied is specified in Parts 1 to 3 of Schedule 2 to the Regulations, being information about receipt, the body part and the transplant.

Regulation 6 places a requirement on other specified persons who receive a body part which is to be used or retained for a relevant section 3(1) purpose, again research, education, training or audit. Paragraph (1) requires any of the persons specified in paragraph (3) to supply the specified information to NHSBT. Paragraph (2) places an additional requirement on the manager of any establishment which is not a hospital, to supply the information to the local Health Board in addition. The information to be supplied is specified in Parts 1, 2 and 4 of Schedule 2, being information about receipt, the body part and the research, education, training or audit in question.