

# Human Tissue (Scotland) Act 2006

#### PART 1

#### TRANSPLANTATION ETC.

General functions of the Scottish Ministers

# Duties of the Scottish Ministers as respects transplantation, donation of body parts etc.

[F1(1)] It is the duty of the Scottish Ministers to—

- (a) promote, support and develop programmes of transplantation;
- (b) promote information and awareness about the donation for transplantation of parts of a human body;
- (c) promote the taking of any necessary measures relating to the quality and safety, storage and use of any such part donated for that purpose [F2;
- (d) promote information and awareness about how transplantation may be authorised (including, in particular, how authorisation of transplantation may be deemed to be given);
- (e) promote information and awareness about the nature of pre-death procedures, when they may be carried out and how they may be authorised].
- [F3(2) The duty under subsection (1)(d) must be carried out at least once in every calendar year.
  - (3) The Scottish Ministers must, in carrying out the duty under subsection (1)(d), have regard to the need to—
    - (a) provide information to the public about—
      - (i) how authorisation of transplantation may be deemed to be given,
      - (ii) how to give an express authorisation or make an opt-out declaration,
    - (b) provide information in health care settings about—
      - (i) how authorisation of transplantation may be deemed to be given,
      - (ii) how to give an express authorisation or make an opt-out declaration.

(4) In subsection (3)(b), "health care settings" means any place where a service is provided for or in connection with the prevention, detection or treatment of illness, other than an independent health care service (within the meaning of section 10F of the National Health Service (Scotland) Act 1978).]

#### **Textual Amendments**

- F1 S. 1 renumbered as s. 1(1) (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 2(2), 29(2); S.S.I. 2021/108, reg. 2
- F2 S. 1(1)(d)(e) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 2(1), 29(2); S.S.I. 2021/108, reg. 2
- F3 S. 1(2)-(4) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 2(3), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

II S. 1 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# 2 Assistance and support

- (1) The Scottish Ministers may provide assistance and support to any person providing, or proposing to provide, a service relating to transplantation.
- (2) Assistance and support provided under subsection (1) is to be provided on such terms, including terms as to payment, as the Scottish Ministers think fit.
- (3) In this section, "assistance" includes financial assistance.

#### **Commencement Information**

I2 S. 2 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

[F4Establishment and maintenance of register

#### **Textual Amendments**

**F4** Ss. 2A-2D and cross-heading inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 3(2)**, 29(2); S.S.I. 2021/108, reg. 2

# 2A Establishment and maintenance of register

- (1) The Scottish Ministers must make arrangements for the establishment and maintenance of a register (referred to in this Part as "the Register") for the purposes of facilitating—
  - (a) the carrying out of their duty under section 1(a),
  - (b) the removal and use of part of the body of a deceased person for transplantation that is authorised by virtue of section 6, 6D, 6E, 6F, 6G, 8, 8D, 10 or, as the case may be, 10A.
- (2) The Register must include information relating to—

- (a) persons who authorise the removal and use of a part of the person's body after the person's death for transplantation,
- (b) persons who do not authorise the removal and use of a part of the person's body after the person's death for transplantation.
- (3) The Register is not to be open to public inspection or search.
- (4) Information may be kept in the Register in any form the Scottish Ministers consider appropriate.

#### 2B Delegation of function of establishing and maintaining Register

- (1) Arrangements made by the Scottish Ministers under section 2A(1) may in particular authorise a person to establish and maintain the Register.
- (2) In this Part, "register organisation" means—
  - (a) the Scottish Ministers, or
  - (b) where a person is authorised as mentioned in subsection (1), that person.
- (3) The Scottish Ministers must publish information about arrangements under section 2A(1) so far as they authorise a person as mentioned in subsection (1).

#### **2C** Disclosure of information

- (1) The register organisation may disclose information about a person from the Register to—
  - (a) a person listed in subsection (3) for the purpose of enabling or assisting a person listed in subsection (3) to carry out functions under this Part that relate to the removal and use of a part of the body for transplantation,
  - (b) a person operating outwith Scotland for the purpose of enabling or assisting that person to carry out functions that relate to the removal and use of a part of the body for transplantation.
- (2) The power to disclose information about a person from the Register conferred by subsection (1) includes the power to disclose that there is no information kept in the Register about the person.
- (3) The persons are—
  - (a) a registered medical practitioner,
  - (b) a person (or person within a description) authorised under section 11(1)(b),
  - (c) a health worker who is acting in accordance with section 16H or 16I.
- (4) A person who receives information under subsection (1)(a) may, for the purpose of enabling or assisting a person listed in subsection (3) to carry out functions under this Part that relate to the removal and use of a part of the body for transplantation, disclose that information to a person listed in subsection (3) or (5).
- (5) The persons are—
  - (a) in relation to a person who at the relevant time is an adult—
    - (i) the adult's nearest relative,
    - (ii) any other person who is consulted under section 16H(2)(d) in relation to the adult.
  - (b) in relation to a person who at the relevant time is a child—

- (i) a person who has parental rights and parental responsibilities in relation to the child,
- (ii) a person mentioned in section 10A(4),
- (iii) any other person who is consulted under section 16I(2)(b) in relation to the child.

# 2D Power to make provision about Register

- (1) The Scottish Ministers may by regulations make provision in relation to the Register.
- (2) Regulations under subsection (1) may, in particular—
  - (a) modify section 2A(1) to add the purpose of facilitating the removal and use of part of the body of a deceased person for a purpose referred to in paragraphs (b) to (d) of section 3(1),
  - (b) modify the list in section 2A(2),
  - (c) modify the list in section 2C(3) to—
    - (i) add a person (or description of person),
    - (ii) remove, or vary the description of, a person (or description of person),
  - (d) modify the purposes for which information may be disclosed under section 2C.]

*Use of part of body of deceased person for transplantation, research etc.* 

# 3 Use of part of body of deceased person for transplantation, research etc.

- (1) Part of the body of a deceased person may be removed from the body and used, for the purposes of—
  - (a) transplantation;
  - (b) research;
  - (c) education or training;
  - (d) audit [F5 or quality assurance],

only if the requirements of subsection (2) are satisfied as respects the part.

- (2) The requirements are that—
  - (a) the removal and use for the purpose in question are authorised in accordance with section 6, [F66D, 6E, 6F, 6G, 6H, 8, 8D, 10 or, as the case may be, 10A]; and
  - (b) the removal is carried out in accordance with section 11.

#### **Textual Amendments**

- F5 Words in s. 3(1)(d) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 21, 29(2); S.S.I. 2021/108, reg. 2
- **F6** Words in s. 3(2)(a) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(a), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

I3 S. 3 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

#### 4 Disapplication of sections 3, 6 to 11 and 16 in certain circumstances

Sections 3, 6 to 11 and 16 do not apply—

- (a) to anything done for the purposes of the functions or under the authority of the procurator fiscal;
- (b) in relation to the removal of any part of the body of a deceased person during a post-mortem examination of the body or the subsequent retention and use of the part or in relation to retention and use of a part of a body to which section 36 applies;
- (c) in relation to retention and use of tissue sample to which section 38 or 47 applies or an organ to which section 40 or 48 applies;
- (d) as respects the removal, retention or use of any part of a body of a deceased person if it is the body of a person who died before the day on which section 3 comes into force and at least 100 years have elapsed since the date of the person's death.

#### **Commencement Information**

I4 S. 4 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

### 5 Consent by procurator fiscal to removal of part of body

- (1) Where a person knows, or has reason to believe, that an examination of the body of a deceased person is, or may be, required for the purposes of the functions of the procurator fiscal, the person may not, except with the consent of the procurator fiscal, remove from the body any part of it, or authorise such removal, for a purpose referred to in section 3(1).
- (2) For the purposes of subsection (1), consent by the procurator fiscal may be given verbally and if so given is to be confirmed in writing as soon as is reasonably practicable.

#### **Commencement Information**

I5 S. 5 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# 6 [F7Express authorisation: adult]

(1) An adult may authorise the removal and use of a part of the adult's body after the adult's death for one or more of the purposes referred to in section 3(1) [F8 (an "express authorisation")].

[<sup>F9</sup>(1A) An express authorisation must—

- (a) if it is for transplantation, be—
  - (i) in writing, or
  - (ii) given to the register organisation orally or in writing,
- (b) if it is for a purpose referred to in paragraphs (b) to (d) of section 3(1), be in writing.]

F10(2)	) .															

F11(3)			 													
F11(4)																
F11(5)			 													
F12(6)			 													

#### **Textual Amendments**

- F7 S. 6 title substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 5(3), 29(2); S.S.I. 2021/108, reg. 2
- F8 Words in s. 6(1) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 5(2)(a), 29(2); S.S.I. 2021/108, reg. 2
- F9 S. 6(1A) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 5(2) (b), 29(2); S.S.I. 2021/108, reg. 2
- **F10** S. 6(2) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 5(2)** (c), 29(2); S.S.I. 2021/108, reg. 2
- F11 S. 6(3)-(5) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 20(3), 29(2); S.S.I. 2021/108, reg. 2
- **F12** S. 6(6) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 27(5) (a), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

I6 S. 6 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# [F136A Withdrawal of express authorisation: adult

- (1) An express authorisation may be withdrawn by the adult—
  - (a) in writing, or
  - (b) if the express authorisation was given to the register organisation, by giving the withdrawal to the register organisation orally or in writing.
- (2) Subsection (3) applies if—
  - (a) there is in force an express authorisation by an adult of removal and use of a part of the adult's body for a purpose referred to in section 3(1), and
  - (b) the adult makes an opt-out declaration as respects removal and use of the part for that purpose.
- (3) The express authorisation—
  - (a) is treated as withdrawn by the adult to the extent that it relates to removal and use of the part for that purpose, and
  - (b) otherwise remains in force.
- (4) Subsection (5) applies if—
  - (a) there is in force at the relevant time an express authorisation by an adult of removal and use of a part of the adult's body for a purpose referred to in section 3(1), and
  - (b) a person provides evidence to a health worker that would lead a reasonable person to conclude that—
    - (i) the adult's most recent view was that the adult was unwilling for the part to be removed and used for that purpose, or

- (ii) if the adult were capable of making a decision about removal and use of the part, the adult would be unwilling in the circumstances for the part to be removed and used for that purpose.
- (5) The express authorisation—
  - (a) is treated as withdrawn by the adult to the extent that it relates to removal and use of the part for that purpose,
  - (b) otherwise remains in force, and
  - (c) to the extent that it remains in force, is treated as being in force at the relevant time for the purposes of—
    - (i) section 6D(1)(a),
    - (ii) section 6E(1)(a)(i),
    - (iii) section 6F(1)(a)(i),
    - (iv) section 6H(1)(a)(i),
    - (v) section 16F(1)(d),
    - (vi) section 16H(2)(a)(i),
    - (vii) section 16H(3)(a).]

#### **Textual Amendments**

**F13** S. 6A inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 5(4)**, 29(2); S.S.I. 2021/108, reg. 2

# [F146B Opt-out declaration: adult

- (1) An adult may make a declaration that the adult does not authorise the removal and use of a part of the adult's body after the adult's death for one or more of the purposes referred to in section 3(1) (an "opt-out declaration").
- (2) If there is in force an opt-out declaration by an adult as respects removal and use of a part of the adult's body for a purpose referred to in section 3(1), the part must not be removed and used for that purpose.
- (3) An opt-out declaration must—
  - (a) if it is as respects transplantation, be—
    - (i) in writing, or
    - (ii) made to the register organisation orally or in writing,
  - (b) if it is as respects a purpose referred to in paragraphs (b) to (d) of section 3(1), be in writing.

#### **Textual Amendments**

**F14** Ss. 6B, 6C inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 6, 29(2); S.S.I. 2021/108, reg. 2

# 6C Withdrawal of opt-out declaration: adult

- (1) An opt-out declaration may be withdrawn by the adult—
  - (a) in writing, or

- (b) if the opt-out declaration was made to the register organisation, by giving the withdrawal to the register organisation orally or in writing.
- (2) Subsection (3) applies if—
  - (a) there is in force an opt-out declaration by an adult as respects removal and use of a part of the adult's body for a purpose referred to in section 3(1), and
  - (b) the adult gives an express authorisation of removal and use of the part for that purpose.
- (3) The opt-out declaration—
  - (a) is treated as withdrawn by the adult to the extent that it relates to removal and use of the part for that purpose, and
  - (b) otherwise remains in force.
- (4) Subsections (5) to (7) apply if—
  - (a) there is in force at the relevant time an opt-out declaration by an adult as respects removal and use of a part of the adult's body for a purpose referred to in section 3(1), and
  - (b) a person provides evidence to a health worker that would lead a reasonable person to conclude that—
    - (i) the adult's most recent view was that the adult was willing for the part to be removed and used for that purpose, or
    - (ii) if the adult were capable of making a decision about removal and use of the part, the adult would be willing in the circumstances for the part to be removed and used for that purpose.
- (5) The opt-out declaration—
  - (a) is treated as withdrawn by the adult to the extent that it relates to removal and use of the part for that purpose,
  - (b) otherwise remains in force, and
  - (c) to the extent that it remains in force, is treated as being in force at the relevant time for the purposes of—
    - (i) section 6D(1)(b),
    - (ii) section 6E(1)(a)(ii),
    - (iii) section 6F(1)(a)(ii),
    - (iv) section 6G(2)(a),
    - (v) section 6H(1)(a)(ii) and (iii),
    - (vi) section 16H(2)(a)(ii),
    - (vii) section 16H(3)(b).
- (6) The adult is treated as having given an express authorisation by virtue of section 6(1) of removal and use of the part for that purpose.
- (7) The authorisation referred to in subsection (6) is treated as being in force at the relevant time for the purposes of—
  - (a) section 6D(1)(a),
  - (b) section 6E(1)(a)(i),
  - (c) section 6F(1)(a)(i),
  - (d) section 6H(1)(a)(i),
  - (e) section 16F(1)(d),
  - (f) section 16H(2)(a)(i),

#### (g) section 16H(3)(a).

#### **Textual Amendments**

**F14** Ss. 6B, 6C inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 6, 29(2); S.S.I. 2021/108, reg. 2

# [F156D Deemed authorisation for transplantation: adult

- (1) An adult is deemed to have authorised the removal and use of a part of the adult's body after the adult's death for transplantation where there is in force at the relevant time—
  - (a) no express authorisation by the adult of removal and use of any part of the adult's body for transplantation, and
  - (b) no opt-out declaration by the adult as respects removal and use of the part of the adult's body for transplantation.
- (2) Subsection (1) does not apply in relation to—
  - (a) a person who was not ordinarily resident in Scotland for a period of at least 12 months ending immediately before the relevant time (a "non-resident adult"),
  - (b) an adult who is incapable of understanding the nature and consequences of deemed authorisation,
  - (c) an excepted body part,
  - (d) a part of the adult's body (that is not an excepted body part), if a person provides evidence to a health worker that would lead a reasonable person to conclude that—
    - (i) the adult's most recent view was that the adult was unwilling for the part to be used for transplantation, or
    - (ii) if the adult were capable of making a decision about removal and use of the part, the adult would be unwilling in the circumstances for the part to be used for transplantation.
- (3) In this Part, an adult is incapable of understanding the nature and consequences of deemed authorisation if, over a significant period ending immediately before the relevant time, the person was incapable of understanding—
  - (a) that an adult may be deemed to have authorised removal and use of a part of the adult's body after the adult's death for transplantation, and
  - (b) that if authorisation is so deemed, after the adult's death part of the adult's body may be removed from the body and used for transplantation.
- (4) An example of when an adult is to be considered "incapable of understanding the nature and consequences of deemed authorisation" is if there is evidence available to a health worker, including any evidence referred to in section 16H(4), that would lead a reasonable person to conclude that the adult is so incapable.
- (5) An "excepted body part" is a part of the body specified in regulations made by the Scottish Ministers.
- (6) Before laying draft regulations under subsection (5) before the Scottish Parliament, the Scottish Ministers must consult such persons as they consider appropriate.]

#### **Textual Amendments**

F15 S. 6D inserted (11.10.2019 for specified purposes, 26.3.2021 in so far as not already in force) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 7(2), 29(2); S.S.I. 2019/305, reg. 2(b); S.S.I. 2021/108, reg. 2

# [F166E Non-resident adult: authorisation for transplantation by nearest relative

- (1) The nearest relative of a non-resident adult may authorise the removal and use of a part of the adult's body after the adult's death for transplantation where—
  - (a) there is in force at the relevant time—
    - (i) no express authorisation by the adult of removal and use of any part of the adult's body for transplantation, and
    - (ii) no opt-out declaration by the adult as respects removal and use of the part for transplantation,
  - (b) the relative has no actual knowledge that—
    - (i) the adult's most recent view was that the adult was unwilling for the part to be removed and used for transplantation, or
    - (ii) if the adult were capable of making a decision about removal and use of the part, the adult would be unwilling in the circumstances for the part to be removed and used for transplantation, and
  - (c) the relative, having had regard to any evidence referred to in section 16H(6) (a) and (b), is satisfied that—
    - (i) the adult was not unwilling for the part to be removed and used for transplantation, and
    - (ii) if the adult were capable of making a decision about removal and use of the part, the adult would not be unwilling in the circumstances for the part to be removed and used for transplantation.
- (2) For the purposes of subsection (1)(b) and (c), the mere fact that there is in force no express authorisation by the adult of removal and use of any part of the adult's body for transplantation is not to be regarded as unwillingness by the adult.
- (3) An authorisation by virtue of subsection (1) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
- (4) An authorisation by virtue of subsection (1) may not be withdrawn.]

#### **Textual Amendments**

**F16** S. 6E inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 8**, 29(2); S.S.I. 2021/108, reg. 2

# [F176F Adult incapable of understanding deemed authorisation: authorisation for transplantation by nearest relative

(1) The nearest relative of an adult who is incapable of understanding the nature and consequences of deemed authorisation may authorise the removal and use of a part of the adult's body after the adult's death for transplantation where—

- (a) there is in force at the relevant time—
  - (i) no express authorisation by the adult of removal and use of any part of the adult's body for transplantation, and
  - (ii) no opt-out declaration by the adult as respects removal and use of the part for transplantation,
- (b) the relative has no actual knowledge that—
  - (i) the adult's most recent view was that the adult was unwilling for the part to be removed and used for transplantation, or
  - (ii) if the adult were capable of making a decision about removal and use of the part, the adult would be unwilling in the circumstances for the part to be removed and used for transplantation, and
- (c) the relative, having had regard to any evidence referred to in section 16H(6) (a) and (b), is satisfied that—
  - (i) the adult was not unwilling for the part to be removed and used for transplantation, and
  - (ii) if the adult were capable of making a decision about removal and use of the part, the adult would not be unwilling in the circumstances for the part to be removed and used for transplantation.
- (2) For the purposes of subsection (1)(b) and (c), the mere fact that there is in force no express authorisation by the adult of removal and use of any part of the adult's body for transplantation is not to be regarded as unwillingness by the adult.
- (3) Before giving an authorisation by virtue of subsection (1), the nearest relative must have regard to the adult's past wishes and feelings so far as reasonably ascertainable.
- (4) An authorisation by virtue of subsection (1) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
- (5) An authorisation by virtue of subsection (1) may not be withdrawn.]

#### **Textual Amendments**

F17 S. 6F inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 9, 29(2); S.S.I. 2021/108, reg. 2

# [F186G Excepted body parts: authorisation for transplantation by nearest relative

- (1) This section applies where an adult is deemed to have authorised the removal and use of a part of the adult's body after the adult's death for transplantation by virtue of section 6D(1).
- (2) The nearest relative of the adult may authorise the removal and use of a part of the adult's body that is an excepted body part after the adult's death for transplantation where—
  - (a) there is in force at the relevant time no opt-out declaration by the adult as respects removal and use of the part for transplantation,
  - (b) the relative has no actual knowledge that—
    - (i) the adult's most recent view was that the adult was unwilling for the part to be removed and used for transplantation, or

- (ii) if the adult were capable of making a decision about removal and use of the part, the adult would be unwilling in the circumstances for the part to be removed and used for transplantation, and
- (c) the relative, having had regard to any evidence referred to in section 16H(6) (a) and (b), is satisfied that—
  - (i) the adult was not unwilling for the part to be removed and used for transplantation, and
  - (ii) if the adult were capable of making a decision about removal and use of the part, the adult would not be unwilling in the circumstances for the part to be removed and used for transplantation.
- (3) For the purposes of subsection (2)(b) and (c), the mere fact that there is in force no express authorisation by the adult of removal and use of any part of the adult's body for transplantation is not to be regarded as unwillingness by the adult.
- (4) An authorisation by virtue of subsection (2) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
- (5) An authorisation by virtue of subsection (2) may not be withdrawn.]

#### **Textual Amendments**

**F18** S. 6G inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 10**, 29(2); S.S.I. 2021/108, reg. 2

# [F196H Authorisation for purpose other than transplantation by nearest relative

- (1) The nearest relative of an adult may authorise the removal and use of a part of the adult's body after the adult's death for one or more of the purposes referred to in paragraphs (b) to (d) of section 3(1) where—
  - (a) there is in force at the relevant time—
    - (i) no express authorisation by the adult of removal and use of any part for the purpose in question,
    - (ii) no opt-out declaration by the adult as respects removal and use of the part for the purpose in question, and
    - (iii) no opt-out declaration by the adult as respects removal and use of the part for transplantation,
  - (b) the relative has no actual knowledge that—
    - (i) the adult's most recent view was that the adult was unwilling for the part to be removed and used for the purpose in question, or
    - (ii) if the adult were capable of making a decision about removal and use of the part, the adult would be unwilling in the circumstances for the part to be removed and used for the purpose in question, and
  - (c) the relative, having had regard to any evidence referred to in section 16H(6) (a) and (b), is satisfied that—
    - (i) the adult was not unwilling for the part to be removed and used for the purpose in question, and

- (ii) if the adult were capable of making a decision about removal and use of the part, the adult would not be unwilling in the circumstances for the part to be removed and used for the purpose in question.
- (2) For the purposes of subsection (1)(b) and (c), the mere fact that there is in force no express authorisation by the adult of removal and use of any part of the adult's body for the purpose in question is not to be regarded as unwillingness by the adult.
- (3) Before giving an authorisation by virtue of subsection (1) on behalf of an adult who is incapable of understanding the nature and consequences of deemed authorisation, the nearest relative must have regard to the adult's past wishes and feelings so far as reasonably ascertainable.
- (4) An authorisation by virtue of subsection (1) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
- (5) An authorisation by virtue of subsection (1) may be withdrawn by the relative.
- (6) A withdrawal by virtue of subsection (5) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.]

#### **Textual Amendments**

**F19** S. 6H inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 11(2)**, 29(2); S.S.I. 2021/108, reg. 2

# [F206I Review of section 1(1)(d) and (e) and sections 6(1A), 6B and 6D

- (1) The Scottish Ministers must, as soon as practicable after the end of the 5 year period—
  - (a) carry out a review of—
    - (i) the Scottish Ministers' duty under section 1(1)(d) and (e), and
    - (ii) the operation of sections 6(1A), 6B and 6D,
  - (b) set out the conclusions of the review in a report, and
  - (c) publish the report.
- (2) The report must in particular set out—
  - (a) the objectives intended to be achieved by section 6D,
  - (b) an assessment of the extent to which those objectives have been achieved, and
  - (c) an assessment of—
    - (i) the support in relation to donation for transplantation provided to relatives of persons who have authorised, or who have been deemed to have authorised, the removal of a part of the person's body for transplantation (both before and after transplantation), and
    - (ii) whether further support should be provided.
- (3) In subsection (1), "the 5 year period" means the period of 5 years beginning with the day on which sections 5 to 7 of the Human Tissue (Authorisation) (Scotland) Act 2019 come fully into force.]

Texti	nal Amendments
F20	S. 6I inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), <b>ss. 12</b> , 29(2); S.S.I. 2021/108, reg. 2
<sup>F21</sup> 7	Authorisation by adult's nearest relative
Text	al Amendments
F21	S. 7 repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), <b>ss. 11(3)</b> , 29(2); S.S.I. 2021/108, reg. 2
8	Authorisation: child 12 years of age or over
(	1) A child who is 12 years of age or over may authorise the removal and use of a pa of the child's body after the child's death for one or more of the purposes referred to in section 3(1).
[F22(1	A) An authorisation by virtue of subsection (1) must—
	(a) if it is for transplantation, be—
	(i) in writing, or
	<ul><li>(ii) given to the register organisation orally or in writing,</li><li>(b) if it is for a purpose referred to in paragraphs (b) to (d) of section 3(1), be in writing.</li></ul>
(1	B) If there is in force immediately before a child becomes an adult an authorisation be virtue of subsection (1) by the child, the authorisation is to be treated as an express authorisation by virtue of section 6(1) once the child becomes an adult.]
F23	2)
F24	3)
F24	4)
F24	5)

#### **Textual Amendments**

- **F22** S. 8(1A)(1B) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 13(2), 29(2); S.S.I. 2021/108, reg. 2
- **F23** S. 8(2) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 13(3)**, 29(2); S.S.I. 2021/108, reg. 2
- **F24** S. 8(3)-(6) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 20(4)**, 29(2); S.S.I. 2021/108, reg. 2

F25 S. 8(7) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 27(5) (b), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

I7 S. 8 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# [F268A Withdrawal of authorisation: child 12 years of age or over

- (1) An authorisation by virtue of section 8(1) may be withdrawn by the child—
  - (a) in writing, or
  - (b) if the authorisation was given to the register organisation, by giving the withdrawal to the register organisation orally or in writing.
- (2) Subsection (3) applies if—
  - (a) there is in force an authorisation by virtue of section 8(1) by a child of removal and use of a part of the child's body for a purpose referred to in section 3(1), and
  - (b) the child makes a declaration by virtue of section 8B(1) as respects removal and use of the part for that purpose.
- (3) The authorisation by virtue of section 8(1)—
  - (a) is treated as withdrawn by the child to the extent that it relates to removal and use of the part for that purpose, and
  - (b) otherwise remains in force.
- (4) Subsection (5) applies if—
  - (a) there is in force at the relevant time an authorisation by virtue of section 8(1) by a child of removal and use of a part of the child's body for a purpose referred to in section 3(1), and
  - (b) a person provides evidence to a health worker that would lead a reasonable person to conclude that—
    - (i) the child's most recent view was that the child was unwilling for the part to be removed and used for that purpose, or
    - (ii) if the child were capable of making a decision about removal and use of the part, the child would be unwilling in the circumstances for the part to be removed and used for that purpose.
- (5) The authorisation by virtue of section 8(1)—
  - (a) is treated as withdrawn by the child to the extent that it relates to removal and use of the part for that purpose,
  - (b) otherwise remains in force, and
  - (c) to the extent that it remains in force, is treated as being in force at the relevant time for the purposes of—
    - (i) section 8D(1)(a)(i),
    - (ii) section 16F(1)(e),
    - (iii) section 16I(2)(a)(i).]

#### **Textual Amendments**

**F26** S. 8A inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 13(4)**, 29(2); S.S.I. 2021/108, reg. 2

# [F278B] Opt-out declaration: child 12 years of age or over

- (1) A child who is 12 years of age or over may make a declaration that the child does not authorise the removal and use of a part of the child's body after the child's death for one or more of the purposes referred to in section 3(1).
- (2) If there is in force a declaration by virtue of subsection (1) by a child as respects removal and use of a part of the child's body for a purpose referred to in section 3(1), the part must not be removed and used for that purpose.
- (3) A declaration by virtue of subsection (1) must—
  - (a) if it is as respects transplantation, be—
    - (i) in writing, or
    - (ii) made to the register organisation orally or in writing,
  - (b) if it is as respects a purpose referred to in paragraphs (b) to (d) of section 3(1), be in writing.
- (4) If there is in force immediately before a child becomes an adult a declaration by virtue of subsection (1) by the child, the declaration is to be treated as an opt-out declaration by virtue of section 6B(1) once the child becomes an adult.

#### **Textual Amendments**

**F27** Ss. 8B, 8C inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 14**, 29(2); S.S.I. 2021/108, reg. 2

# 8C Withdrawal of opt-out declaration: child 12 years of age or over

- (1) A declaration by virtue of section 8B(1) may be withdrawn by the child—
  - (a) in writing, or
  - (b) if the declaration was made to the register organisation, by giving the withdrawal to the register organisation orally or in writing.
- (2) Subsection (3) applies if—
  - (a) there is in force a declaration by virtue of section 8B(1) by a child as respects removal and use of a part of the child's body for a purpose referred to in section 3(1), and
  - (b) the child gives an authorisation by virtue of section 8(1) of removal and use of the part for that purpose.
- (3) The declaration by virtue of section 8B(1)—
  - (a) is treated as withdrawn by the child to the extent that it relates to removal and use of the part for that purpose, and
  - (b) otherwise remains in force.
- (4) Subsections (5) to (7) apply if—

- (a) there is in force at the relevant time a declaration by virtue of section 8B(1) by a child as respects removal and use of a part of the child's body for a purpose referred to in section 3(1), and
- (b) a person provides evidence to a health worker that would lead a reasonable person to conclude that—
  - (i) the child's most recent view was that the child was willing for the part to be removed and used for that purpose, or
  - (ii) if the child were capable of making a decision about removal and use of the part, the child would be willing in the circumstances for the part to be removed and used for that purpose.
- (5) The declaration by virtue of section 8B(1)—
  - (a) is treated as withdrawn by the child to the extent that it relates to removal and use of the part for that purpose,
  - (b) otherwise remains in force, and
  - (c) to the extent that it remains in force, is treated as being in force at the relevant time for the purposes of—
    - (i) section 8D(1)(a)(ii) and (iii),
    - (ii) section 16I(2)(a)(ii).
- (6) The child is treated as having authorised removal and use of the part for that purpose by virtue of section 8(1).
- (7) The authorisation referred to in subsection (6) is treated as being in force at the relevant time for the purposes of—
  - (a) section 8D(1)(a)(i),
  - (b) section 16F(1)(e),
  - (c) section 16I(2)(a)(i).

#### **Textual Amendments**

**F27** Ss. 8B, 8C inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 14**, 29(2); S.S.I. 2021/108, reg. 2

# [F28BD Authorisation by person with parental rights and responsibilities: child 12 years of age or over

- (1) A person who, at the relevant time, has parental rights and parental responsibilities in relation to a child who is 12 years of age or over may authorise the removal and use of a part of the child's body after the child's death for one or more of the purposes referred to in section 3(1) where—
  - (a) there is in force at the relevant time—
    - (i) no authorisation by virtue of section 8(1) by the child of removal and use of any part for the purpose in question,
    - (ii) no declaration by virtue of section 8B(1) by the child as respects removal and use of the part for the purpose in question, and
    - (iii) if transplantation is not the purpose in question, no declaration by virtue of section 8B(1) by the child as respects removal and use of the part for transplantation,
  - (b) the person has no actual knowledge that—

- (i) the child's most recent view was that the child was unwilling for the part to be removed and used for the purpose in question, or
- (ii) if the child were capable of making a decision about removal and use of the part, the child would be unwilling in the circumstances for the part to be removed and used for the purpose in question, and
- (c) the person, having had regard to any evidence referred to in section 16I(4)(a) and (b), is satisfied that—
  - (i) the child was not unwilling for the part to be removed and used for the purpose in question, and
  - (ii) if the child were capable of making a decision about removal and use of the part, the child would not be unwilling in the circumstances for the part to be removed and used for the purpose in question.
- (2) For the purposes of subsection (1)(b) and (c), the mere fact that there is in force no authorisation by virtue of section 8(1) by the child of removal and use of any part of the child's body for the purpose in question is not to be regarded as unwillingness by the child.
- (3) An authorisation by virtue of subsection (1) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
- (4) Subject to subsection (6), an authorisation by virtue of subsection (1) may be withdrawn by the person who gave the authorisation.
- (5) A withdrawal by virtue of subsection (4) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
- (6) To the extent that an authorisation by virtue of subsection (1) is for the purposes of transplantation, it may not be withdrawn.]

#### **Textual Amendments**

**F28** S. 8D inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 15(2)**, 29(2); S.S.I. 2021/108, reg. 2

Authorisation as respects child who dies 12 years of age or over by person with parental rights and responsibilities

.....

#### **Textual Amendments**

**F29** S. 9 repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 15(3)**, 29(2); S.S.I. 2021/108, reg. 2

# 10 [F30] Authorisation by person with parental rights and responsibilities: child under 12 years of age]

- [F31(A1) Subsection (1) applies in relation to a child who is under 12 years of age at the relevant time.]
  - (1) A person who [F32 at the relevant time has] parental rights and parental responsibilities in relation to the child F33... may authorise removal and use of a part of the body of the child for one or more of the purposes referred to in section 3(1) [F34] where—
    - (a) the person has no actual knowledge that—
      - (i) the child's most recent view was that the child was unwilling for the part to be removed and used for the purpose in question, or
      - (ii) if the child were capable of making a decision about removal and use of the part, the child would be unwilling in the circumstances for the part to be removed and used for the purpose in question, and
    - (b) the person, having had regard to any evidence referred to in section 16I(4)(a) and (b), is satisfied that—
      - (i) the child was not unwilling for the part to be removed and used for the purpose in question, and
      - (ii) the child would not be unwilling in the circumstances for the part to be removed and used for the purpose in question].
- [F35(1A) An authorisation by virtue of subsection (1) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
  - (1B) Subject to subsection (3), an authorisation by virtue of subsection (1) may be withdrawn by the person.
  - (1C) A withdrawal by virtue of subsection (1B) must be—
    - (a) in writing and signed, or
    - (b) given orally to a health worker.]

F36	(2)																

(3) To the extent that authorisation by virtue of subsection (1) is for the purposes of transplantation, it may not be withdrawn.

#### **Textual Amendments**

- **F30** S. 10 title substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 4(6), 29(2); S.S.I. 2021/108, reg. 2
- F31 S. 10(A1) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 4(5) (a), 29(2); S.S.I. 2021/108, reg. 2
- **F32** Words in s. 10(1) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 4(5)(b), 29(2); S.S.I. 2021/108, reg. 2
- **F33** Words in s. 10(1) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 18(2), 29(2); S.S.I. 2021/108, reg. 2
- **F34** Words in s. 10(1) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 16(2), 29(2); S.S.I. 2021/108, reg. 2
- F35 S. 10(1A)-(1C) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 16(3), 29(2); S.S.I. 2021/108, reg. 2

**F36** S. 10(2) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 16(4), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

I8 S. 10 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# [F3710A Authorisation by other persons: children

- (1) A person mentioned in subsection (4) in relation to a child who is 12 years of age or over at the relevant time may authorise the removal and use of a part of the child's body after the child's death for one or more of the purposes referred to in section 3(1) where—
  - (a) each person with parental rights and parental responsibilities who would otherwise be entitled to authorise removal and use of a part of the child's body by virtue of section 8D(1) has died or become incapable of so authorising,
  - (b) there is in force at the relevant time—
    - (i) no authorisation by virtue of section 8(1) by the child of removal and use of any part for the purpose in question,
    - (ii) no declaration by virtue of section 8B(1) by the child as respects removal and use of the part for the purpose in question, and
    - (iii) if transplantation is not the purpose in question, no declaration by virtue of section 8B(1) by the child as respects removal and use of the part for transplantation,
  - (c) the person has no actual knowledge that—
    - (i) the child's most recent view was that the child was unwilling for the part to be removed and used for the purpose in question, or
    - (ii) if the child were capable of making a decision about removal and use of the part, the child would be unwilling in the circumstances for the part to be removed and used for the purpose in question, and
  - (d) the person, having had regard to any evidence referred to in section 16I(4)(a) and (b), is satisfied that—
    - (i) the child was not unwilling for the part to be removed and used for the purpose in question, and
    - (ii) the child would not be unwilling in the circumstances for the part to be removed and used for the purpose in question.
- (2) For the purposes of subsection (1)(c) and (d), the mere fact that there is in force no authorisation by virtue of section 8(1) by the child of removal and use of any part of the child's body for the purpose in question is not to be regarded as unwillingness by the child.
- (3) A person mentioned in subsection (4) in relation to a child who is under 12 years of age at the relevant time may authorise the removal and use of a part of the child's body after the child's death for one or more of the purposes referred to in section 3(1) where—
  - (a) each person with parental rights and parental responsibilities who would otherwise be entitled to authorise removal and use of a part of the child's body by virtue of section 10(1) has died or become incapable of so authorising,
  - (b) the person has no actual knowledge that—
    - (i) the child's most recent view was that the child was unwilling for the part to be removed and used for the purpose in question, or

- (ii) if the child were capable of making a decision about removal and use of the part, the child would be unwilling in the circumstances for the part to be removed and used for the purpose in question, and
- (c) the person, having had regard to any evidence referred to in section 16I(4)(a) and (b), is satisfied that—
  - (i) the child was not unwilling for the part to be removed and used for the purpose in question, and
  - (ii) the child would not be unwilling in the circumstances for the part to be removed and used for the purpose in question.
- (4) A person who is, at the relevant time—
  - (a) a person who has (or has recently had) a significant involvement in the upbringing of the child,
  - (b) the child's brother or sister,
  - (c) the child's grandparent,
  - (d) the child's uncle or aunt,
  - (e) the child's cousin,
  - (f) the child's niece or nephew,
  - (g) a friend of longstanding of the child.
- (5) An authorisation by virtue of subsection (1) or (3) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
- (6) Subject to subsection (8), an authorisation by virtue of subsection (1) or (3) may be withdrawn by the person.
- (7) A withdrawal by virtue of subsection (6) must be—
  - (a) in writing and signed, or
  - (b) given orally to a health worker.
- (8) To the extent that an authorisation by virtue of subsection (1) or (3) is for the purposes of transplantation, it may not be withdrawn.
- (9) Relationships in different paragraphs of subsection (4) rank in the order of those paragraphs and for the purposes of that subsection a relationship of the half-blood is to be treated as a relationship of the whole blood.
- (10) Where more than one person falls within a paragraph in subsection (4), each such person ranks equally for the purpose of the paragraph, and authorisation by virtue of the paragraph in question may be given by any one of the persons falling within the paragraph.
- (11) For the purposes of subsections (1) and (3), a person's relationship with the child is to be left out of account if—
  - (a) the person, at the relevant time, was under 16 years of age,
  - (b) the person does not wish or is unable to make a decision on the issue of authorisation, or
  - (c) it is not reasonably practicable to communicate with the person in the time available.]

#### **Textual Amendments**

**F37** S. 10A inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 17**, 29(2); S.S.I. 2021/108, reg. 2

# [F38] 10B Local authority with parental rights and responsibilities in relation to child: consultation

- (1) Subsection (2) applies if—
  - (a) there is in force at the relevant time—
    - (i) an authorisation by virtue of section 8(1) by a child of removal and use of a part of the child's body for a purpose referred to in section 3(1), or
    - (ii) a declaration by virtue of section 8B(1) by a child as respects removal and use of a part of the child's body for a purpose referred to in section 3(1), and
  - (b) a local authority with parental rights and parental responsibilities in relation to the child is consulted about the child's most recent views by a health worker by virtue of section 16I(2)(b).
- (2) The local authority must, in so far as it is reasonably practicable to do so, ascertain the child's most recent views by consulting—
  - (a) the child's parents, and
  - (b) such other persons as the local authority considers appropriate.
- (3) Subsections (4) and (5) apply if a local authority with parental rights and parental responsibilities in relation to a child is deciding whether to give authorisation by virtue of section 8D or 10 as respects the child.
- (4) The local authority must, in so far as it is reasonably practicable to do so, ascertain the views of—
  - (a) the child,
  - (b) the child's parents, and
  - (c) any other person whose views the local authority considers to be relevant.
- (5) The local authority must have regard to the views of—
  - (a) the child,
  - (b) the child's parents, and
  - (c) any other person whose views the local authority considers to be relevant.]

#### **Textual Amendments**

**F38** S. 10B inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 18(3)**, 29(2); S.S.I. 2021/108, reg. 2

# [F3910C Power to make provision about decisions

- (1) The Scottish Ministers may by regulations make provision about the manner in which, or to whom—
  - (a) an express authorisation by virtue of section 6(1) may be given,

- (b) an opt-out declaration by virtue of section 6B(1) may be made,
- (c) an authorisation by virtue of section 8(1) may be given,
- (d) a declaration by virtue of section 8B(1) may be made,
- (e) an authorisation by virtue of section 16F(1) may be given.
- (2) Regulations under subsection (1) may modify this Act.]

#### **Textual Amendments**

**F39** S. 10C inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 19(2)**, 29(2); S.S.I. 2021/108, reg. 2

# [F40] 10D Withdrawal by person who is blind or unable to write

- (1) This section applies where a person who is blind or unable to write decides to withdraw—
  - (a) an authorisation by virtue of—
    - (i) section 6A(1),
    - (ii) section 6H(5),
    - (iii) section 8A(1),
    - (iv) section 8D(4),
    - (v) section 10(1B),
    - (vi) section 10A(6),
  - (b) a declaration by virtue of—
    - (i) section 6C(1),
    - (ii) section 8C(1).
- (2) The withdrawal may be—
  - (a) in writing by another person, and
  - (b) signed by an adult (a "signatory").
- (3) A withdrawal that is signed by a signatory must—
  - (a) be witnessed by one witness, and
  - (b) contain a statement made in accordance with subsection (4).
- (4) The statement must—
  - (a) state that the person, in the presence of the signatory and the witness, expressed the intention to withdraw the authorisation or, as the case may be, the declaration.
  - (b) state that the person requested the signatory to sign the withdrawal,
  - (c) be signed by the signatory and the witness in the presence of—
    - (i) each other, and
    - (ii) the person.]

#### **Textual Amendments**

**F40** S. 10D inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 20(2)**, 29(2); S.S.I. 2021/108, reg. 2

### 11 Removal of part of body of deceased person: further requirements

- (1) The removal of a part of the body of a deceased person for any of the purposes referred to in section 3(1) may be carried out only by—
  - (a) a registered medical practitioner; or
  - (b) a person [F41 (or description of person)] authorised to do so in accordance with regulations made by the Scottish Ministers.
- (2) Regulations under subsection (1)(b) may in particular provide for a registered medical practitioner to authorise the carrying out of the removal by a person [F42(or description of person)] who is not such a practitioner.
- (3) The removal of part of the body of a deceased person may not be—
  - (a) carried out for any of the purposes referred to in section 3(1) unless the person who proposes to carry it out, before doing so, complies with the requirements specified in subsection (4);
  - F43(b) .....
- (4) The requirements are that the person <sup>F44</sup>... must be satisfied—
  - (a) [F45if the person is a registered medical practitioner,] either—
    - (i) by personal examination of the body, that life is extinct; or
    - (ii) that another registered medical practitioner, by such personal examination, is so satisfied;
  - [F46(ab)] if the person is not a registered medical practitioner, that a registered medical practitioner, by personal examination of the body, is satisfied that life is extinct,]
    - (b) that, if the consent of the procurator fiscal to the carrying out of the removal is required by section 5(1), the consent has been given; and
    - (c) that the removal [F47 and use for the purpose in question] is authorised in accordance with section 6, [F48 6D, 6E, 6F, 6G, 6H, 8, 8D, 10 or, as the case may be, 10A].
- [<sup>F49</sup>(4A) For the purposes of subsection (4)(c), the person who proposes to carry out the removal is entitled to be satisfied that the removal and use for the purpose in question is authorised in accordance with the section in question if subsections (4B) and (4C) apply.
  - (4B) This subsection applies if the person who proposes to carry out the removal considers there to be an appropriate record that—
    - (a) there is in force an authorisation by virtue of section 6, 6D, 6E, 6F, 6G, 6H, 8, 8D, 10 or, as the case may be, 10A as respects—
      - (i) the deceased person, and
      - (ii) the removal and use of the part for the purpose in question,
    - (b) the authorisation was given in accordance with the section in question,
    - (c) there is in force—
      - (i) in the case of a deceased adult, no opt-out declaration by the adult as respects removal and use of the part for the purpose in question,
      - (ii) in the case of a deceased child, no declaration by virtue of section 8B(1) by the child as respects removal and use of the part for the purpose in question,

- (d) in the case of a deceased adult who is deemed to have authorised the removal and use of a part of the adult's body for transplantation by virtue of section 6D, the deceased adult was not—
  - (i) a non-resident adult, or
  - (ii) an adult incapable of understanding the nature and consequences of deemed authorisation,
- (e) a health worker has carried out inquiries—
  - (i) in the case of a deceased adult, in accordance with section 16H(2), and
  - (ii) in the case of a deceased child, in accordance with section 16I(2).
- (4C) This subsection applies if the person who proposes to carry out the removal has no reason to believe that—
  - (a) there is in force no authorisation by virtue of section 6, 6D, 6E, 6F, 6G, 6H, 8, 8D, 10 or, as the case may be, 10A as respects—
    - (i) the deceased person, or
    - (ii) the removal and use of the part for the purpose in question,
  - (b) the authorisation was not given in accordance with the section in question,
  - (c) in the case of an authorisation given by a person other than the deceased person, the person who gave the authorisation was not entitled to do so,
  - (d) the deceased person would be unwilling in the circumstances for the part to be removed and used for the purpose in question.]

F50(	5)																

#### **Textual Amendments**

- **F41** Words in s. 11(1)(b) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(2), 29(2); S.S.I. 2021/108, reg. 2
- **F42** Words in s. 11(2) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(3), 29(2); S.S.I. 2021/108, reg. 2
- **F43** S. 11(3)(b) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(4), 29(2); S.S.I. 2021/108, reg. 2
- **F44** Words in s. 11(4) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(5)(a), 29(2); S.S.I. 2021/108, reg. 2
- **F45** Words in s. 11(4)(a) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(5)(b), 29(2); S.S.I. 2021/108, reg. 2
- **F46** S. 11(4)(ab) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(5)(c), 29(2); S.S.I. 2021/108, reg. 2
- **F47** Words in s. 11(4)(c) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(5)(d)(i), 29(2); S.S.I. 2021/108, reg. 2
- **F48** Words in s. 11(4)(c) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(5)(d)(ii), 29(2); S.S.I. 2021/108, reg. 2
- **F49** S. 11(4A)-(4C) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(6), 29(2); S.S.I. 2021/108, reg. 2
- **F50** S. 11(5) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 22(7), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

- I9 S. 11(1)(a)(3)-(5) in force at 1.9.2006 by S.S.I. 2006/251, art. 3
- 110 S. 11(1)(b)(2) in force at 1.9.2006 in so far as not already in force by S.S.I. 2006/251, arts. 2, 3, Sch.

#### 12 Removal of tissue sample to determine viability of transplantation

If it appears to a person removing, in accordance with authorisation by virtue of section [F516, 6D, 6E, 6F, 6G, 8, 8D, 10 or, as the case may be, 10A], any part of the body of a deceased person for transplantation that it is necessary or expedient to examine tissue sample removed from the part or any other part of the body to determine the viability of the transplantation (including in particular the safety of the transplant for the person who is to receive it), the person carrying out the removal may remove and secure the examination of such tissue sample from the part or the body as the person considers necessary or expedient for that purpose.

#### **Textual Amendments**

**F51** Words in s. 12 substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(b), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

III S. 12 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# 13 Preservation for transplantation

- (1) Where part of the body of a deceased person lying in premises to which this section applies is or may be suitable for use for transplantation, the managers of the premises may—
  - (a) take steps for the purpose of preserving the part for use for transplantation;
  - (b) retain the body for that purpose,

but may not move the part or body to other premises.

- (2) Authority under subsection (1)(a) extends only to—
  - (a) the taking of the minimum steps necessary for the purpose mentioned in that paragraph;
  - (b) the use of the least invasive procedure.
- (3) Authority under subsection (1)—
  - (a) extends to any person authorised to act under the authority by the managers of the premises in question;
  - (b) ceases to apply once it has been established that authorisation for removal of the part for transplantation has not been, and will not be, given.
- (4) The premises to which this section applies are—
  - (a) a health service hospital;
  - (b) premises in which a registered independent health care service is provided.
- (5) In this section—

F52 ...

"health service hospital" has the meaning given by section 108(1) of that Act; "managers" means—

- (a) where the body is lying in a health service hospital, the Health Board or Special Health Board responsible for the administration of the hospital;
- (b) where the body is lying in premises in which a registered independent health care service is provided, the person providing the service;

"registered independent health care service" means an independent health care service (as defined in [F53] section 10E of the National Health Service (Scotland) Act 1978 (c. 29)) registered under section 10P of that Act;] F54

#### **Textual Amendments**

- F52 Words in s. 13(5) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 27(6), 29(2); S.S.I. 2021/108, reg. 2
- F53 Words in s. 13(5) substituted (1.10.2010 for specified purposes, 1.4.2011 in so far as not already in force) by Public Services Reform (Scotland) Act 2010 (asp 8), s. 134(7), Sch. 17 para. 34; S.S.I. 2010/321, art. 3, Sch.; S.S.I. 2011/122, art. 2, Sch.
- **F54** Words in s. 13(5) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 27(6), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

I12 S. 13 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

### Part of body removed before day on which section 3 comes into force

#### A part—

- (a) removed—
  - (i) from the body of a deceased person before the day on which section 3 comes into force for the purposes of transplantation, research, education, training or audit;
  - (ii) other than during an examination having the characteristics of a postmortem examination (whether or not carried out for the purposes of the functions, or under the authority, of the procurator fiscal) or an anatomical examination (within the meaning of section 1(1) of the Anatomy Act 1984 (c. 14); and
- (b) held immediately before that day for use for any such purpose, may be retained and used for any such purpose.

#### **Commencement Information**

I13 S. 14 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# Existing request by adult not acted on before commencement of sections 3 and 6

- (1) Where, immediately before the coming into force of sections 3 and 6—
  - (a) there is in force a request by an adult that a part of the adult's body be used after the adult's death for transplantation either—
    - (i) in writing; or
    - (ii) [F55 given orally] (whether or not [F56 given] during the adult's last illness and whether or not [F56 given] in the presence of any witnesses); and
  - (b) the request has not been acted on,

- the request is to be treated for the purposes of this Part as if it were [F57] an express authorisation by the adult] (in writing or, as the case may be, [F55] given orally]).
- (2) In subsection (1), "writing" includes, in relation to the reference there to a request by an adult which is in force immediately before the coming into force of sections 3 and 6, representation of a character in visible form.

#### **Textual Amendments**

- **F55** Words in s. 15(1) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(c)(i), 29(2); S.S.I. 2021/108, reg. 2
- **F56** Words in s. 15(1) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(c)(ii), 29(2); S.S.I. 2021/108, reg. 2
- **F57** Words in s. 15(1) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(c)(iii), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

I14 S. 15 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# Offences: removal or use of part of body of deceased person for transplantation, research etc.

- (1) A person commits an offence if the person removes, after the day on which section 3 comes into force, a part of the body of a deceased person for any of the purposes referred to in section 3(1) or uses after that day any part so removed for any such purpose and—
  - (a) the removal or, as the case may be, the use for the purpose in question is not authorised in accordance with section 6, [F586D, 6E, 6F, 6G, 6H, 8, 8D, 10 or, as the case may be, 10A]; or
  - (b) any of the requirements in section 11(1) or (4)(a) is not satisfied as respects the part.

<sup>F59</sup> (2)
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- (3) A person guilty of an offence under subsection (1) is liable—
  - (a) on summary conviction, to—
    - (i) imprisonment for a term not exceeding 12 months;
    - (ii) a fine not exceeding the statutory maximum; or
    - (iii) both;
  - (b) on conviction on indictment, to—
    - (i) imprisonment for a term not exceeding 3 years;
    - (ii) a fine; or
    - (iii) both.

#### **Textual Amendments**

- **F58** Words in s. 16(1)(a) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(d), 29(2); S.S.I. 2021/108, reg. 2
- F59 S. 16(2) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 27(5) (c), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

I15 S. 16 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# *I*<sup>F60</sup>*Pre-death procedures relating to transplantation*

#### **Textual Amendments**

F60 S. 16A-16G and cross-heading inserted (11.10.2019 for specified purposes, 26.3.2021 in so far as not already in force) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 23(1), 29(2); S.S.I. 2019/305, reg. 2(c); S.S.I. 2021/108, reg. 2

# 16A Meaning of "pre-death procedure", "Type A procedure" and "Type B procedure"

- (1) In this Part, a "pre-death procedure" means a medical procedure—
  - (a) which is carried out on a person for the purpose of increasing the likelihood of successful transplantation of a part of the person's body after the person's death, and
  - (b) which is not for the primary purpose of safeguarding or promoting the physical or mental health of the person.
- (2) In this Part, a pre-death procedure is—
  - (a) a "Type A procedure" if it is a pre-death procedure or category of predeath procedure specified in regulations made by the Scottish Ministers under section 16B(1),
  - (b) )a "Type B procedure" if it is a pre-death procedure or category of predeath procedure specified in regulations made by the Scottish Ministers under section 16C(1).

# 16B Type A procedures

- (1) The Scottish Ministers may by regulations specify a pre-death procedure or category of pre-death procedure as a Type A procedure for the purposes of sections 16D to 16F.
- (2) Regulations under subsection (1) may make different provision for different procedures or categories of procedure and in particular may specify that a pre-death procedure or category of pre-death procedure is a Type A procedure only where that procedure is carried out in a particular way.
- (3) Regulations under subsection (1) may specify a pre-death procedure (or category of pre-death procedure) as a Type A procedure only if the Scottish Ministers consider that it is appropriate that the carrying out of the procedure or, as the case may be, the category of procedure should be in accordance with section 16E.
- (4) Before laying draft regulations under subsection (1) before the Scottish Parliament, the Scottish Ministers must consult such persons as they consider appropriate.

# 16C Type B procedures

- (1) The Scottish Ministers may by regulations specify a pre-death procedure or category of pre-death procedure (other than one specified in regulations under section 16B(1)) as a Type B procedure for the purposes of section 16D and 16E.
- (2) Regulations under subsection (1)—
  - (a) may also make provision about—
    - (i) the circumstances in which Type B procedures may be carried out,
    - (ii) the way in which the carrying out of Type B procedures may be authorised,
    - (iii) the process for authorisation of Type B procedures, and
    - (iv) the carrying out of Type B procedures, and
  - (b) may make different provision for different procedures or categories of procedure.
- (3) Regulations under subsection (1) may specify a pre-death procedure (or category of pre-death procedure) as a Type B procedure only if the Scottish Ministers consider that it is appropriate that the procedure or, as the case may be, the category of procedure should be subject to provision mentioned in subsection (2)(a)(i) to (iv).
- (4) Before laying draft regulations under subsection (1) before the Scottish Parliament, the Scottish Ministers must consult such persons as they consider appropriate.

#### 16D Restrictions on carrying out of pre-death procedures

- (1) A pre-death procedure may be carried out only if it is a Type A procedure or Type B procedure.
- (2) A Type A procedure may be carried out only in accordance with section 16E.
- (3) A Type B procedure may be carried out only in accordance with—
  - (a) section 16E, and
  - (b) any provision made in regulations under section 16C(1) in relation to that procedure (or category of procedure).

#### 16E Carrying out of Type A and Type B procedures

- (1) A Type A procedure or Type B procedure may be carried out only if—
  - (a) the health worker who is to carry out the procedure or who has authorised a person to carry out the procedure considers that the requirements of subsection (2) are met,
  - (b) that health worker—
    - (i) has no actual knowledge that the person was unwilling for the procedure to be carried out,
    - (ii) has had regard to the person's past wishes and feelings so far as reasonably ascertainable (having had regard to any evidence referred to in section 16H(6)(c) or 16I(4)(c)), and
    - (iii) is satisfied that if the person were capable of making a decision about authorisation of the procedure, the person would not be unwilling for the procedure to be carried out,

- (c) the use of a part of the person's body for transplantation is authorised by virtue of section 6, 6D, 6E, 6F, 6G, 8, 9, 10 or, as the case may be, 10A,
- (d) in the case of a Type A procedure, the carrying out of the procedure is authorised under section 16F, and
- (e) in the case of a Type B procedure, the carrying out of the procedure is authorised in accordance with any provision made under section 16C(1) in relation to that procedure (or category of procedure).
- (2) The requirements mentioned in subsection (1)(a) are met if—
  - (a) in the view of the health worker primarily responsible for the person's medical treatment, the person is likely to die imminently (including as a result of the withdrawal of life-sustaining treatment),
  - (b) where the person is receiving life-sustaining treatment, the decision to withdraw that treatment has been taken by that health worker,
  - (c) the carrying out of the procedure is necessary (see subsection (3)),
  - (d) the carrying out of the procedure is not likely to cause more than minimal discomfort to the person, and
  - (e) the carrying out of the procedure is not likely to harm the person.
- (3) For the purposes of subsection (2)(c), the carrying out of a procedure is necessary if either of the following apply—
  - (a) it is necessary to carry it out for the purpose of ascertaining whether a part of the person's body is suitable for transplantation,
  - (b) it is necessary to carry it out for the purpose of increasing the likelihood of successful transplantation of a part of the person's body.

#### **16F** Authorisation of Type A procedures

- (1) For the purposes of section 16E(1)(d), the carrying out of a Type A procedure is authorised in relation to a person if—
  - (a) the person has expressly authorised the carrying out of the procedure,
  - (b) in the case of an adult who, at the relevant time, has not expressly authorised the carrying out of any procedure, if the adult's nearest relative is, at the relevant time, entitled to authorise the removal and use of a part of the adult's body by virtue of section 6E or 6F and the adult's nearest relative authorises the carrying out of the procedure,
  - (c) in the case of a child who, at the relevant time, has not expressly authorised the carrying out of any procedure—
    - (i) if a person who has parental rights and parental responsibilities in relation to the child is, at the relevant time, entitled to authorise the removal and use of a part of the child's body by virtue of section 8D or 10 and that person authorises the carrying out of the procedure,
    - (ii) if a person is, at the relevant time, entitled to authorise the removal and use of a part of the child's body by virtue of section 10A and that person authorises the carrying out of the procedure,
  - (d) in the case of an adult who, at the relevant time, has not expressly authorised the carrying out of any procedure, there is in force an express authorisation by the adult of removal and use of a part of the adult's body for transplantation,
  - (e) in the case of a child who, at the relevant time, has not expressly authorised the carrying out of any procedure, there is in force an authorisation by virtue

- of section 8 by the child of removal and use of a part of the child's body for transplantation, or
- (f) in the case of an adult, the adult is deemed by virtue of section 6D to have authorised the removal and use of a part of the adult's body for transplantation.
- (2) For the purposes of subsection (1)(b), the nearest relative of an adult may not give authorisation—
  - (a) if the relative has actual knowledge that the adult was unwilling for the procedure to be carried out, or
  - (b) unless the relative—
    - (i) has had regard to the adult's past wishes and feelings so far as reasonably ascertainable (having had regard to any evidence referred to in section 16H(6)(c)), and
    - (ii) is satisfied that if the adult were capable of making a decision about authorisation of the procedure, the adult would not be unwilling for the procedure to be carried out.
- (3) For the purposes of subsection (1)(c), a person may not give authorisation—
  - (a) if the person has actual knowledge that the child was unwilling for the procedure to be carried out, or
  - (b) unless the person—
    - (i) has had regard to the child's past wishes and feelings so far as reasonably ascertainable (having had regard to any evidence referred to in section 16I(4)(c)), and
    - (ii) is satisfied that if the child were capable of making a decision about authorisation of the procedure, the child would not be unwilling for the procedure to be carried out.
- (4) Where a person has expressly authorised the carrying out of one or more Type A procedures under subsection (1)(a), subsection (1)(f) does not authorise the carrying out of a Type A procedure not mentioned in that authorisation.
- (5) An authorisation under subsection (1)(a), (b) or (c) must be—
  - (a) in writing, or
  - (b) given orally to a health worker.

# 16G Authorisation of Type A procedures: transitory provision

- (1) Until section 6D comes into force, section 16E(1)(b)(ii) applies as if the words "(having had regard to any evidence referred to in section 16H(6)(c) or 16I(4)(c))" were omitted.
- (2) Until section 6D comes into force, section 16F applies as if—
  - (a) in subsection (1)—
    - (i) for paragraph (b) there were substituted—
      - "(b) in the case of an adult, a person who is entitled to authorise the removal and use of a part of the adult's body by virtue of section 7(1), (2) or (3) authorises the carrying out of the Type A procedure,",
    - (ii) for paragraph (c) there were substituted—
      - "(c) in the case of a child, a person who is entitled to authorise the removal and use of a part of the

child's body by virtue of section 9(1), (2) or (3) or 10(1) authorises the carrying out of the Type A procedure,",

- (iii) paragraphs (d) to (f) were omitted,
- (b) in subsection (2)(b)(i), the words "(having had regard to any evidence referred to in section 16H(6)(c))" were omitted,
- (c) in subsection (3)(b)(i), the words "(having had regard to any evidence referred to in section 16I(4)(c))" were omitted,
- (d) subsection (4) were omitted.]

# [F6116H Duty to inquire: adult

- (1) A health worker must act in accordance with subsection (2) before the earlier of—
  - (a) the carrying out of a pre-death procedure in relation to an adult, or
  - (b) the removal of part of the body of a deceased adult for any of the purposes referred to in section 3(1).
- (2) The health worker must—
  - (a) take reasonable steps to inquire into whether there is in force—
    - (i) an express authorisation by the adult,
    - (ii) an opt-out declaration by the adult,
  - (b) if subsection (3) applies, inquire into whether the adult—
    - (i) is a non-resident adult (within the meaning given by section 6D(2) (a)),
    - (ii) is an adult who is incapable of understanding the nature and consequences of deemed authorisation (within the meaning given by section 6D(3)),
  - (c) in the case of an adult who is incapable of understanding the nature and consequences of deemed authorisation, inquire into the adult's past wishes and feelings so far as reasonably ascertainable, and
  - (d) in any case inquire, by consulting (so far as is reasonably practicable) the persons referred to in subsection (5), into the adult's most recent views in relation to—
    - (i) the carrying out of pre-death procedures in relation to the adult, and
    - (ii) the removal and use of a part of the adult's body for a purpose referred to in section 3(1).
- (3) This subsection applies in relation to an adult if there is in force at the relevant time—
  - (a) no express authorisation by the adult of removal and use of any part of the adult's body for transplantation, and
  - (b) no opt-out declaration by the adult as respects removal and use of the part of the adult's body for transplantation.
- (4) When acting in accordance with subsection (2)(b)(ii), the health worker must consult (so far as is reasonably practicable) any person who has indicated a wish to provide evidence that the adult is an adult who is incapable of understanding the nature and consequences of deemed authorisation.
- (5) The persons referred to in subsection (2)(d) are—
  - (a) the nearest relative of the adult,

- (b) any person who has indicated to a health worker a wish to provide evidence mentioned in subsection (6), and
- (c) such other persons as the health worker considers appropriate.
- (6) The evidence referred to in subsection (5)(b) is evidence—
  - (a) that the adult's most recent view was that the adult was willing or, as the case may be, unwilling for a part of the adult's body to be removed and used for a purpose referred to in section 3(1),
  - (b) that if the adult were capable of making a decision about removal and use of a part, the adult would be willing or, as the case may be, unwilling in the circumstances for part of the adult's body to be removed and used for a purpose referred to in section 3(1).
  - (c) about the adult's views in relation to the carrying out of a pre-death procedure in relation to the adult.

#### **Textual Amendments**

**F61** Ss. 16H, 16I inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 24, 29(2); S.S.I. 2021/108, reg. 2

#### 16I Duty to inquire: child

- (1) A health worker must act in accordance with subsection (2) before the earlier of—
  - (a) the carrying out of a pre-death procedure in relation to a child, or
  - (b) the removal of part of the body of a deceased child for any of the purposes referred to in section 3(1).
- (2) The health worker must—
  - (a) take reasonable steps to inquire into whether there is in force—
    - (i) an authorisation by virtue of section 8(1) by the child,
    - (ii) a declaration by virtue of section 8B(1) by the child, and
  - (b) inquire, by consulting (so far as is reasonably practicable) the persons referred to in subsection (3), into the child's most recent views in relation to—
    - (i) the carrying out of pre-death procedures in relation to the child, and
    - (ii) the removal and use of a part of the child's body for a purpose referred to in section 3(1).
- (3) The persons referred to in subsection (2)(b) are—
  - (a) a person who, at the relevant time, has parental rights and parental responsibilities in relation to the child,
  - (b) if a person is entitled to authorise removal and use of a part of the child's body by virtue of section 10A, that person,
  - (c) any person who has indicated to a health worker a wish to provide evidence mentioned in subsection (4), and
  - (d) such other persons as the health worker considers appropriate.
- (4) The evidence referred to in subsection (3)(c) is evidence—
  - (a) that the child's most recent view was that the child was willing or, as the case may be, unwilling for a part of the child's body to be removed and used for a purpose referred to in section 3(1),

- (b) that if the child were capable of making a decision about removal and use of a part, the child would be willing or, as the case may be, unwilling in the circumstances for a part of the child's body to be removed and used for a purpose referred to in section 3(1),
- (c) about the child's views in relation to the carrying out of a pre-death procedure in relation to the child.]

#### **Textual Amendments**

**F61** Ss. 16H, 16I inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 24, 29(2); S.S.I. 2021/108, reg. 2

# [F6216J Meaning of "health worker"

- (1) In sections 1 to 16K, "health worker" means—
  - (a) a registered medical practitioner,
  - (b) a registered nurse,
  - (c) a person (or person within a description) in so far as that person is (or persons of that description are) authorised by a person listed in subsection (2) to exercise the functions of a health worker under sections 6A to 16I.
- (2) The persons are—
  - (a) a registered medical practitioner,
  - (b) a registered nurse,
  - (c) a Health Board,
  - (d) a Special Health Board,
  - (e) the Common Services Agency for the Scottish Health Service.
- (3) An authorisation under subsection (1)(c) may, in particular—
  - (a) authorise a person (or description of person) to exercise some or all of the functions of a health worker under sections 6A to 16I,
  - (b) authorise a person (or description of person) to exercise functions in relation to particular cases or classes of case,
  - (c) authorise different persons (or descriptions of person) to exercise different functions.
- (4) An authorisation under subsection (1)(c) may be given only if the person listed in subsection (2) considers that the person (or the description of person) has the appropriate skills, qualifications or experience to carry out the functions in respect of which the authorisation is given.
- (5) An authorisation under subsection (1)(c) may be revoked—
  - (a) in the case of an authorisation given to a description of person by a person other than a registered medical practitioner or a registered nurse, by the person who gave that authorisation, and
  - (b) in any other case, by any person listed in subsection (2).
- (6) The Scottish Ministers may give directions (of a general or specific nature) to persons listed in subsection (2) in relation to authorisations under subsection (1)(c).

- (7) A person listed in subsection (2) must comply with any direction given to the person under subsection (6) when authorising a person (or description of person) under subsection (1)(c).
- (8) The Scottish Ministers may by regulations—
  - (a) modify the list in subsection (1),
  - (b) modify the list in subsection (2),

so as to add to, amend or remove any entry on the list.]

#### **Textual Amendments**

**F62** S. 16J inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 27(2)**, 29(2); S.S.I. 2021/108, reg. 2

# [F6316K Interpretation and meaning of "relevant time"

- (1) In sections 1 to 16J and this section—
  - "excepted body part" has the meaning given in section 6D(5),
  - "express authorisation" has the meaning given in section 6(1),
  - "Health Board" means a board constituted by order under section 2(1)(a) of the National Health Service (Scotland) Act 1978,
  - "health worker" has the meaning given in section 16J(1),
  - "incapable of understanding the nature and consequences of deemed authorisation" has the meaning given in section 6D(3),
  - "medical treatment", in relation to a person, means any procedure or treatment that has the purpose of safeguarding or promoting the person's physical or mental health.
  - "non-resident adult" has the meaning given in section 6D(2)(a),
  - "opt-out declaration" has the meaning given in section 6B(1),
  - "pre-death procedure" has the meaning given in section 16A,
  - "register organisation" has the meaning given in section 2B(2),
  - "Special Health Board" means a board constituted by order under section 2(1) (b) of the National Health Service (Scotland) Act 1978,
  - "writing" includes representation of a character in visible form.
- (2) For the purposes of sections 1 to 16J, this section and section 50, "relevant time" means—
  - (a) in relation to a living person, when—
    - (i) in the view of the health worker primarily responsible for the person's medical treatment, the person is likely to die imminently (including as a result of the withdrawal of life-sustaining treatment),
    - (ii) where the person is receiving life-sustaining treatment, the decision to withdraw that treatment has been taken by that health worker, and
    - (iii) in the case of a person who is 12 years of age or over, that health worker is of the view that the person is incapable by reason of ill health of making a decision about the removal and use of a part of the person's body for a purpose referred to in section 3(1),
  - (b) in relation to a deceased person, immediately before the person's death.]

#### **Textual Amendments**

**F63** S. 16K inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 27(4)**, 29(2); S.S.I. 2021/108, reg. 2

Restrictions on transplants involving live donor

# 17 Restrictions on transplants involving live donor

- (1) Subject to subsections (3) to (5) and (8), a person commits an offence—
  - (a) if—
- (i) the person removes an organ, part of an organ, or any tissue from the body of a living child intending that it be used for transplantation; and
- (ii) when the person removes the organ, part or tissue, the person knows, or might reasonably be expected to know, that the other person from whose body the person removes it is a living child;
- (b) if—
- (i) the person removes an organ or part of an organ from the body of a living adult intending that it be used for transplantation; and
- (ii) when the person removes the organ or part, the person knows, or might reasonably be expected to know, that the adult from whose body the person removes it is alive; or
- (c) if—
- (i) the person removes any tissue from the body of a living adult with incapacity intending that it be used for transplantation; and
- (ii) when the person removes the tissue the person knows, or might reasonably be expected to know, that the adult from whose body the person removes it is alive and an adult with incapacity.
- (2) Subject to subsections (3) to (5) and (8), a person commits an offence—
  - (a) if—
- (i) the person uses for transplantation an organ, part of an organ or any tissue which has come from the body of a living child; and
- (ii) when the person does so, the person knows, or might reasonably be expected to know, that it has come from the body of a living child;
- (b) if—
- (i) the person uses for transplantation an organ or part of an organ which has come from the body of a living adult; and
- (ii) when the person does so, the person knows, or might reasonably be expected to know, that it has come from the body of a living adult; or
- (c) if—
- (i) the person uses for transplantation any tissue which has come from the body of a living adult with incapacity; and
- (ii) when the person does so, the person knows, or might reasonably be expected to know, that it has come from the body of a living adult with incapacity.
- (3) The Scottish Ministers may by regulations provide that subsection (1)(b) or (2)(b) does not apply in a case where—

- (a) the Ministers are satisfied that—
  - (i) no reward has been or is to be given in contravention of section 20; and
  - (ii) such other conditions as may be specified in the regulations are satisfied; and
- (b) such other requirements as may be specified in the regulations are complied with.
- (4) The Scottish Ministers may by regulations provide that subsection (1)(a) or (c) or (2) (a) or (c) does not apply in a case where—
  - (a) a person—
    - (i) removes regenerative tissue; or
    - (ii) uses such tissue;
  - (b) the Ministers are satisfied that—
    - (i) no reward has been or is to be given in contravention of section 20;
    - (ii) such other conditions, as may be specified in the regulations are satisfied; and
  - (c) such other requirements as may be specified in the regulations are complied with.
- (5) The Scottish Ministers may by regulations provide that subsection (1)(a) or (b) or (2) (a) or (b) does not apply in a case where—
  - (a) a person—
    - (i) removes an organ or part of an organ as described in subsection (6); or
    - (ii) uses such an organ or part so removed;
  - (b) the Ministers are satisfied that—
    - (i) no reward has been or is to be given in contravention of section 20;
    - (ii) such other conditions, as may be specified in the regulations are satisfied; and
  - (c) such other requirements as may be specified in the regulations are complied with.
- (6) The organ or part of an organ is one that—
  - (a) during a domino organ transplant operation, is necessarily removed from—
    - (i) a child; or
    - (ii) an adult with incapacity; and
  - (b) is in turn intended to be used for transplantation in respect of another living person.
- (7) Regulations under subsection (3), (4) or (5) must include provision as to appeals against decisions made in relation to matters which fall to be decided under the regulations.
- (8) Where under—
  - (a) subsection (3) an exception from subsection (1)(b) or (2)(b) is in force, a person does not commit an offence under subsection (1)(b) or, as the case may be, (2)(b) if the person reasonably believes that the exception applies;
  - (b) subsection (4) an exception from subsection (1)(a) or (c) or (2)(a) or (c) is in force, a person does not commit an offence under subsection (1)(a) or (c)

- or (2)(a) or (c), as the case may be, if the person reasonably believes that the exception applies;
- (c) subsection (5) an exception from subsection (1)(a) or (b) or (2)(a) or (b) is in force, a person does not commit an offence under subsection (1)(a) or (b) or (2)(a) or (b), as the case may be, if the person reasonably believes that the exception applies.
- (9) A person guilty of an offence under this section is liable on summary conviction to—
  - (a) imprisonment for a term not exceeding 12 months;
  - (b) a fine not exceeding level 5 on the standard scale; or
  - (c) both.

# (10) In this section—

"adult with incapacity" is—

- (a) for the purposes of subsections (1)(c) and (2)(c), an adult to whom section 18 applies;
- (b) for the purposes of subsection (6)(a)(ii), an adult in respect of whom section 47 of the Adults with Incapacity (Scotland) Act 2000 (asp 4) applies in relation to the domino organ transplant operation in question;

"domino organ transplant operation" means a transplant operation performed on a living person by a registered medical practitioner—

- (a) which is designed to safeguard or promote the physical health of the person by transplanting organs or parts of organs into the person; and
- (b) by so doing, necessitates the removal of an organ or part of an organ from the person which in turn is intended to be used for transplantation in respect of another living person;

"regenerative tissue" means tissue which is able to be replaced in the body of a living person by natural processes if the tissue is injured or removed;

"reward" means any description of financial or other material advantage, but does not include any payment in money or money's worth for defraying or reimbursing—

- (a) the cost of removing, transporting, preparing, preserving or storing the organ (or part) or tissue;
- (b) any liability incurred in respect of expenses incurred by a third party in, or in connection with, any of the activities referred to in paragraph (a);
- (c) any expenses or loss of earnings incurred by the person from whose body the organ (or part) or tissue comes so far as reasonably and directly attributable to the person's supplying it from the person's body.

### **Modifications etc. (not altering text)**

- C1 S. 17(1)(a)(b)(2)(a)(2)(b) excluded (1.9.2006 with application in accordance with art. 3(1)) by Human Tissue (Scotland) Act 2006 (Human Organ Transplants Act 1989 Transitional and Savings Provisions) Order 2006 (S.S.I. 2006/420), arts. 1(1), 3(2)
- C2 S. 17(1)(a) excluded (1.9.2006) by Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (S.S.I. 2006/390), regs. 1(3), 5(1)
- C3 S. 17(1)(a)(b)(2)(a)(2)(b) excluded (1.9.2006 with application in accordance with art. 2(1)) by Human Tissue (Scotland) Act 2006 (Human Organ Transplants Act 1989 Transitional and Savings Provisions) Order 2006 (S.S.I. 2006/420), arts. 1(1), 2(5)
- C4 S. 17(1)(b) excluded (1.9.2006) by Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (S.S.I. 2006/390), regs. 1(3), **3(1)**

- C5 S. 17(1)(b) excluded (1.9.2006) by Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (S.S.I. 2006/390), regs. 1(3), 2(1)
- C6 S. 17(1)(c) excluded (1.9.2006) by Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (S.S.I. 2006/390), regs. 1(3), 4(1)
- C7 S. 17(2)(a) excluded (1.9.2006) by Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (S.S.I. 2006/390), regs. 1(3), 5(2)
- C8 S. 17(2)(b) excluded (1.9.2006) by Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (S.S.I. 2006/390), regs. 1(3), 3(2)
- C9 S. 17(2)(b) excluded (1.9.2006) by Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (S.S.I. 2006/390), regs. 1(3), **2(2)**
- C10 S. 17(2)(c) excluded (1.9.2006) by Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (S.S.I. 2006/390), regs. 1(3), 4(2)

#### **Commencement Information**

- I16 S. 17(1) (2)(6)-(10) in force at 1.9.2006 by S.S.I. 2006/251, art. 3
- I17 S. 17(3)-(5) in force at 12.5.2006 only for the purpose of enabling regulations to be made to come into force on or after 1st September 2006; and 1.9.2006 in so far as not already in force by S.S.I. 2006/251, arts. 2, 3, Sch.

# Meaning of adult with incapacity for purposes of section 17(1)(c) and (2)(c)

- (1) This section applies to an adult—
  - (a) who, in the opinion of the Scottish Ministers, is an adult who is incapable in relation to a decision about the removal from the adult of regenerative tissue for transplantation; and
  - (b) in respect of whom a certificate has been issued by the Ministers in accordance with subsection (2) that they are of this opinion.
- (2) A certificate for the purposes of subsection (1) is to be in a form prescribed in regulations by the Scottish Ministers and is to specify the period during which the certificate is in force, being a period which—
  - (a) the Scottish Ministers consider appropriate to the condition or circumstances of the adult; but
  - (b) does not exceed one year from the date of the certificate.
- (3) In this section, "incapable" has the same meaning as it has in section 1(6) of the Adults with Incapacity (Scotland) Act 2000.

#### **Commencement Information**

- I18 S. 18(1)(3) in force at 1.9.2006 by S.S.I. 2006/251, art. 3
- I19 S. 18(2) in force at 1.9.2006 in so far as not already in force by S.S.I. 2006/251, arts. 2, 3, Sch.

Records, information etc.: removal and use of parts of human bodies for transplantation etc.

# 19 Records, information etc.: removal and use of parts of human bodies for transplantation etc.

(1) The Scottish Ministers may by regulations make provision requiring such persons (or descriptions of persons) as may be specified in the regulations to—

- (a) maintain in accordance with the regulations records in connection with 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 parts removed from bodies of deceased or living persons;
- (b) provide to the Scottish Ministers, or to such authority as may be specified in the regulations, such 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 parts removed from bodies of deceased or living persons.
- (2) The Scottish Ministers must keep a record of information provided to them in pursuance of regulations made under subsection (1).
- (3) Any such authority as may be specified in such regulations must keep a record of information provided to it in pursuance of the regulations.
- (4) A person commits an offence if—
  - (a) the person fails without reasonable excuse to comply with regulations under subsection (1); or
  - (b) in purported compliance with such regulations, the person knowingly or recklessly supplies information which is false or misleading in a material respect.
- (5) A person guilty of an offence under—
  - (a) subsection (4)(a) is liable on summary conviction to a fine not exceeding level 3 on the standard scale;
  - (b) subsection (4)(b) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

#### **Commencement Information**

- 120 S. 19(1) in force at 1.9.2006 in so far as not already in force by S.S.I. 2006/251, arts. 2, 3, Sch.
- I21 S. 19(2)-(5) in force at 1.9.2006 by S.S.I. 2006/251, art. 3

### **Trafficking**

# 20 Prohibition of commercial dealings in parts of a human body for transplantation

- (1) A person commits an offence if the person—
  - (a) gives or receives a reward for the supply of, or for an offer to supply, any part of a human body for transplantation;
  - (b) seeks to find a person willing to supply any part of a human body for transplantation for reward;
  - (c) offers to supply any part of a human body for transplantation for reward;
  - (d) initiates or negotiates an arrangement involving the giving of a reward for the supply of, or for an offer to supply, any part of a human body for transplantation;

- (e) takes part in the management or control of a body corporate or a group of persons whose activities consist of or include the initiation or negotiation of such arrangements.
- (2) Without prejudice to subsection (1)(b) and (c), a person commits an offence if the person causes to be published or distributed, or knowingly publishes or distributes, an advertisement—
  - (a) inviting persons to supply, or offering to supply, any part of a human body for transplantation for reward; or
  - (b) indicating that the advertiser is willing to initiate or negotiate an arrangement referred to in subsection (1)(d).
- (3) A person who engages in an activity to which subsection (1) or (2) applies does not commit an offence under that subsection if the person is designated by the Scottish Ministers for the purposes of this subsection as a person who may lawfully engage in the activity.
- (4) A person guilty of an offence under subsection (1) is liable—
  - (a) on summary conviction, to—
    - (i) imprisonment for a term not exceeding 12 months;
    - (ii) a fine not exceeding the statutory maximum; or
    - (iii) both;
  - (b) on conviction on indictment, to—
    - (i) imprisonment for a term not exceeding 3 years;
    - (ii) a fine; or
    - (iii) both.
- (5) A person guilty of an offence under subsection (2) is liable on summary conviction to—
  - (a) imprisonment for a term not exceeding 12 months;
  - (b) a fine not exceeding level 5 on the standard scale; or
  - (c) both.
- (6) In this section—

"advertisement" includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons;

"reward" has the same meaning as in section 17.

#### **Commencement Information**

I22 S. 20 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

#### 1<sup>F64</sup>20A Offences under section 20 committed outside UK

- (1) If—
  - (a) a person who is habitually resident in Scotland, or who is a UK national and not habitually resident in Northern Ireland, does an act outside the United Kingdom, and
  - (b) the act, if done in Scotland, would constitute an offence under section 20(1), and

(c) the part of the human body to which the act relates consists of or includes a human organ,

the person is guilty in Scotland of that offence.

- (2) In this section "United Kingdom national" means an individual who is—
  - (a) a British citizen, a British overseas territories citizen, a British National (Overseas) or a British Overseas citizen,
  - (b) a person who under the British Nationality Act 1981 is a British subject, or
  - (c) a British protected person within the meaning of that Act.
- (3) Where a person outside the United Kingdom commits an offence under section 20(1) the person may be prosecuted, tried and punished for the offence—
  - (a) in a sheriff court district in which the person is apprehended or in custody, or
  - (b) in a sheriff court district determined by the Lord Advocate,

as if the offence had been committed in that district.

- (4) Where subsection (3) applies, the offence is, for all purposes incidental to or consequential on the trial and punishment, deemed to have been committed in that district.
- (5) In this section "sheriff court district" is to be construed in accordance with section 307(1) of the Criminal Procedure (Scotland) Act 1995 (interpretation).]

#### **Textual Amendments**

**F64** S. 20A inserted (1.7.2022) by Health and Care Act 2022 (c. 31), **ss. 170(2)**, 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)

Summary proceedings for offences under section 17, 19(4) or 20(2)

#### 21 Summary proceedings for offences under section 17, 19(4) or 20(2)

- (1) Summary proceedings in pursuance of section 17, 19(4) or 20(2) may be commenced at any time within the period of 6 months from the date on which evidence sufficient in the opinion of the Lord Advocate to justify the proceedings comes to the Lord Advocate's knowledge.
- (2) Subsection (3) of section 136 of the Criminal Procedure (Scotland) Act 1995 (c. 46) (date of commencement of summary proceedings) has effect for the purposes of subsection (1) as it has effect for the purposes of that section.
- (3) For the purposes of subsection (1), a certificate of the Lord Advocate as to the date on which the evidence in question came to the Lord Advocate's knowledge is conclusive evidence of the date on which it did so.

#### **Commencement Information**

I23 S. 21 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

#### Authorisation for transplantation to have priority

# 22 Authorisation by virtue of Part 1 for transplantation to have priority

- (1) If there is in force [F65 at the relevant time[F66 an express authorisation by an adult]] of removal and use of any part of the adult's body for transplantation, the authorisation takes priority as respects the part over—
  - (a) any authorisation by the adult by virtue of section 29(1), or any request by the adult by virtue of section 4(1) of the Anatomy Act 1984 (c. 14) ("the 1984 Act"), which is also in force at that time;
  - (b) any right of any other person to give authorisation as respects the deceased adult by virtue of section 30(1) or (2).
- [F67(1A)] Where an adult is deemed to have authorised the removal and use of a part of the adult's body for transplantation by virtue of section 6D(1), the authorisation takes priority as respects the part over—
  - (a) any authorisation by the adult by virtue of section 29(1), or any request by the adult by virtue of section 4(1) of the 1984 Act, which is in force at the relevant time,
  - (b) any right of any other person to give authorisation as respects the deceased adult by virtue of section 30(1) or (2).]
  - (2) If there is in force [F68at the relevant time authorisation by a] child by virtue of section 8(1) of removal and use of a part of the child's body for transplantation, the authorisation takes priority as respects the part over—
    - (a) any authorisation by the child by virtue of section 31(1), or any request by the child by virtue of section 4(1) of the 1984 Act, which is also in force at that time;
    - (b) any right of any other person to give authorisation as respects the deceased child by virtue of section 32(1) or (2).

<sup>F69</sup> (3)
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- (4) Any right of any other person to authorise, by virtue of section [F708D, 10 or 10A] removal and use of a part of a F71... child's body for transplantation takes priority as respects the part over—
  - (a) any authorisation by the child by virtue of section 31(1), or any request by the child by virtue of section 4(1) of the 1984 Act, which is in force [<sup>k72</sup>at the relevant time];
  - (b) any right of another person to give authorisation as respects the deceased child by virtue of section 32(1) or (2).

#### **Textual Amendments**

- **F65** Words in s. 22(1) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 4(8)(a), 29(2); S.S.I. 2021/108, reg. 2
- **F66** Words in s. 22(1) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(e)(i), 29(2); S.S.I. 2021/108, reg. 2
- F67 S. 22(1A) inserted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(e)(ii), 29(2); S.S.I. 2021/108, reg. 2
- **F68** Words in s. 22(2) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 4(8)(b), 29(2); S.S.I. 2021/108, reg. 2

- **F69** S. 22(3) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), **ss. 28(3)** (e)(iii), 29(2); S.S.I. 2021/108, reg. 2
- F70 Words in s. 22(4) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 28(3)(e)(iv), 29(2); S.S.I. 2021/108, reg. 2
- F71 Words in s. 22(4) repealed (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 4(8)(d)(i), 29(2); S.S.I. 2021/108, reg. 2
- F72 Words in s. 22(4)(a) substituted (26.3.2021) by Human Tissue (Authorisation) (Scotland) Act 2019 (asp 11), ss. 4(8)(d)(ii), 29(2); S.S.I. 2021/108, reg. 2

#### **Commencement Information**

I24 S. 22 in force at 1.9.2006 by S.S.I. 2006/251, art. 3

# **Changes to legislation:**

There are currently no known outstanding effects for the Human Tissue (Scotland) Act 2006, Part 1.