



# Human Tissue (Authorisation) (Scotland) Act 2019

2019 asp 11

## PART 3

### AUTHORISATION OF REMOVAL AND USE OF PART OF BODY OF DECEASED PERSON

## CHAPTER 2

### AUTHORISATION BY OR ON BEHALF OF ADULT

#### 5 Express authorisation by adult

- (1) The 2006 Act is amended as follows.
- (2) In section 6—
  - (a) in subsection (1), after “section 3(1)” insert “ (an “express authorisation”) ”,
  - (b) after subsection (1), insert—

“(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.”,
  - (c) subsection (2) is repealed.
- (3) The title of section 6 becomes “ **Express authorisation: adult** ”.
- (4) After section 6 insert—

#### “6A Withdrawal of express authorisation: adult

- (1) An express authorisation may be withdrawn by the adult—
  - (a) in writing, or

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*Changes to legislation: There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2. (See end of Document for details)*

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- (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- (a) is treated as withdrawn by the adult to the extent that it relates to removal and use of the part for that purpose, and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)."

**Commencement Information**

**II** S. 5 in force at 26.3.2021 by S.S.I. 2021/108, reg. 2

**6 Opt-out declaration by adult**

After section 6A of the 2006 Act insert—

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**Changes to legislation:** There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2. (See end of Document for details)

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### **“6B 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.

### **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—

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- (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).”.

**Commencement Information**

**I2** S. 6 in force at 26.3.2021 by [S.S.I. 2021/108](#), [reg. 2](#)

**7 Deemed authorisation for transplantation as respects adult**

- (1) The 2006 Act is amended as follows.
- (2) After section 6C insert—

**“6D 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”),

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**Changes to legislation:** There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2. (See end of Document for details)

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- (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.”.
- (3) In section 59(3) (regulations subject to affirmative procedure), after paragraph (aa) insert—
- “(ab) regulations under section 6D(5);”.

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**Commencement Information**

- I3** S. 7 in force at 11.10.2019 for specified purposes by S.S.I. 2019/305, **reg. 2(b)**
- I4** S. 7 in force at 26.3.2021 in so far as not already in force by S.S.I. 2021/108, **reg. 2**

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

After section 6D of the 2006 Act insert—

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*Changes to legislation: There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2. (See end of Document for details)*

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**“6E 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.”.

**Commencement Information**

**I5** S. 8 in force at 26.3.2021 by S.S.I. 2021/108, reg. 2

**9 Adult incapable of understanding deemed authorisation: authorisation for transplantation by nearest relative**

After section 6E of the 2006 Act insert—

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*Changes to legislation:* There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2. (See end of Document for details)

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**“6F 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.”.

**Commencement Information**

**I6** S. 9 in force at 26.3.2021 by S.S.I. 2021/108, reg. 2

**10 Excepted body parts: authorisation for transplantation by nearest relative**

After section 6F of the 2006 Act insert—

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*Changes to legislation: There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2. (See end of Document for details)*

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**“6G 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.”.

**Commencement Information**

**I7** [S. 10](#) in force at 26.3.2021 by [S.S.I. 2021/108, reg. 2](#)

**11 Authorisation for purpose other than transplantation by nearest relative**

- (1) The 2006 Act is amended as follows.
- (2) After section 6G insert—



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*Changes to legislation:* There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2. (See end of Document for details)

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### **“6H 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.”.
- (3) Section 7 is repealed.

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*Changes to legislation: There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2. (See end of Document for details)*

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**Commencement Information**

**18** [S. 11](#) in force at 26.3.2021 by [S.S.I. 2021/108](#), [reg. 2](#)

**12 Review of section 1(1)(d) and (e) and sections 6(1A), 6B and 6D of the 2006 Act**

After section 6H of the 2006 Act insert—

**“6I 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.”.

**Commencement Information**

**19** [S. 12](#) in force at 26.3.2021 by [S.S.I. 2021/108](#), [reg. 2](#)

**Changes to legislation:**

There are currently no known outstanding effects for the Human Tissue (Authorisation) (Scotland) Act 2019, Chapter 2.