



# Human Tissue (Authorisation) (Scotland) Act 2019

2019 asp 11

**The Bill for this Act of the Scottish Parliament was passed by the Parliament on 11th June 2019 and received Royal Assent on 18th July 2019**

An Act of the Scottish Parliament to make provision about authorisation of the removal and use of part of the body of a deceased person for transplantation and other purposes; and for connected purposes.

## PART 1

### OVERVIEW OF ACT

#### 1 Overview of Act

This Act is arranged as follows—

Part 2 amends the Human Tissue (Scotland) Act 2006 (“the 2006 Act”) to make provision about duties of the Scottish Ministers in relation to transplantation and pre-death procedures and in relation to the register,

Part 3 amends the 2006 Act to make provision about the authorisation of removal and use of part of the body of a deceased person,

Part 4 contains general and final provisions.

## PART 2

### DUTIES OF THE SCOTTISH MINISTERS

#### 2 Information and awareness about authorisation of transplantation and about pre-death procedures

(1) In section 1 of the 2006 Act, at the end of paragraph (c), insert “;

(d) promote information and awareness about how transplantation may be authorised (including, in particular, how authorisation of transplantation may be deemed to be given);

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- (e) promote information and awareness about the nature of pre-death procedures, when they may be carried out and how they may be authorised”.
- (2) The text of section 1 so amended becomes subsection (1).
- (3) After subsection (1) so formed, insert—
  - “(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).”.

### **3 Establishment and maintenance of register**

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

*“Establishment and maintenance of register*

#### **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—

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- (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.”.
- (3) In section 59(3) (regulations subject to affirmative procedure), after paragraph (a) insert—
  - “(aa) regulations under section 2D(1);”.

## **PART 3**

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

#### **CHAPTER 1**

##### TIMING OF AUTHORISATION

#### **4 Timing of authorisation**

- (1) The 2006 Act is amended as follows.
- (2) In section 7—
  - (a) in subsection (1), for “immediately before an adult’s death no authorisation by the” substitute “at the relevant time no authorisation by an”,
  - (b) in subsections (2) and (3), for “immediately before an adult’s death authorisation by the” substitute “at the relevant time authorisation by an”,
  - (c) in subsections (1), (2) and (3), the word “deceased” is repealed.
- (3) In section 9—
  - (a) before subsection (1), insert—

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- “(A1) Subsections (1) to (3) apply in relation to a child who is 12 years of age or over at the relevant time.”,
- (b) in subsections (1) and (2), for “immediately before the death of a child who died 12 years of age or over” substitute “at the relevant time”,
  - (c) in subsections (1), (2) and (3), for “immediately before the death, had” substitute “at the relevant time, has”,
  - (d) in subsection (3), for “immediately before the child’s death” substitute “at the relevant time”.
- (4) The title of section 9 becomes “**Authorisation by person with parental rights and responsibilities: child 12 years of age or over**”.
- (5) In section 10—
- (a) before subsection (1), insert—

“(A1) Subsection (1) applies in relation to a child who is under 12 years of age at the relevant time.”,
  - (b) in subsection (1), for “immediately before the death of a child who died under 12 years of age had” substitute “at the relevant time has”.
- (6) The title of section 10 becomes “**Authorisation by person with parental rights and responsibilities: child under 12 years of age**”.
- (7) In section 11(5)—
- (a) in paragraphs (d)(iii), (e)(iii), (f)(iii), (g)(iii), (h)(iii) and (i)(iii), the word “deceased” is repealed,
  - (b) in paragraphs (l)(i), (m)(i), (n)(i), (o)(i), (p)(i), (q)(i), (r)(i) and (s)(i), for the word “died” substitute “at the relevant time was”,
  - (c) in paragraphs (l)(iii), (m)(iii), (n)(iii), (o)(iii), (p)(iii), (q)(iii), (r)(iii) and (s)(iii), for “immediately before the child’s death” substitute “at the relevant time”.
- (8) In section 22—
- (a) in subsection (1), for “immediately before an adult’s death authorisation by the” substitute “at the relevant time authorisation by an”,
  - (b) in subsection (2), for “immediately before the death of a child who died twelve years of age or over authorisation by the” substitute “at the relevant time authorisation by a”,
  - (c) in subsection (3)—
    - (i) in the opening words, for “a deceased” substitute “an”,
    - (ii) in paragraph (a), for “immediately before the adult’s death” substitute “at the relevant time”,
  - (d) in subsection (4)—
    - (i) in the opening words, the word “deceased” is repealed,
    - (ii) in paragraph (a), for “immediately before the child’s death” substitute “at the relevant time”.
- (9) In section 50—
- (a) in subsections (1) and (2), for “sections 7 and 30” substitute “Part 1 and section 30”,
  - (b) in subsection (1)—

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- (i) in the opening words, for “is the person who immediately before the adult’s death was” substitute “in relation to an adult is the person who, at the time mentioned in subsection (1A), is”,
- (ii) in paragraph (b), for “was in hospital immediately before death” substitute “is in hospital at the time mentioned in subsection (1A)”,
- (c) after subsection (1), insert—
  - “(1A) The time is—
    - (a) in relation to Part 1, the relevant time, and
    - (b) in relation to section 30, immediately before the adult’s death.”.

## 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
  - (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—

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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, 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).”.

## **6 Opt-out declaration by adult**

After section 6A of the 2006 Act insert—

### **“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,

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- (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—
  - (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).”.

## 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”),
  - (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

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- (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);”.

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

After section 6D of the 2006 Act insert—

### **“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.

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- (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.”.

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

After section 6E of the 2006 Act insert—

### **“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.”.

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

After section 6F of the 2006 Act insert—

**“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.”.

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

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

### **“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.

**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.”.

**CHAPTER 3**

AUTHORISATION BY OR ON BEHALF OF CHILD

**13 Authorisation by child 12 years of age or over**

(1) The 2006 Act is amended as follows.

(2) After section 8(1) insert—

“(1A) An authorisation by virtue of subsection (1) must—

- (a) if it is for transplantation, be—
  - (i) in writing, or
  - (ii) given to the register organisation orally or in writing,

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*Status: This is the original version (as it was originally enacted).*

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- (b) if it is for a purpose referred to in paragraphs (b) to (d) of section 3(1), be in writing.

(1B) If there is in force immediately before a child becomes an adult an authorisation by 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.”.

(3) Section 8(2) is repealed.

(4) After section 8 insert—

**“8A 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).”.

#### 14 **Opt-out declaration by child 12 years of age or over**

After section 8A of the 2006 Act insert—

##### **“8B 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.

##### **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—



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- (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).”.

**15 Authorisation by person with parental rights and responsibilities: child 12 years of age or over**

- (1) The 2006 Act is amended as follows.
- (2) After section 8C insert—

**“8D 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—

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*Status: This is the original version (as it was originally enacted).*

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- (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.”
- (3) Section 9 is repealed.

## **16 Authorisation by person with parental rights and responsibilities: child under 12 years of age**

- (1) Section 10 of the 2006 Act is amended as follows.
- (2) In subsection (1), after “section 3(1)” insert “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—

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- (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”.

(3) After subsection (1), insert—

“(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.”.

(4) Subsection (2) is repealed.

## **17 Authorisation by other persons: children**

After section 10 of the 2006 Act insert—

### **“10A 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

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*Status: This is the original version (as it was originally enacted).*

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- (d) the person, having had regard to any evidence referred to in section 161(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 161(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.

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*Status: This is the original version (as it was originally enacted).*

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- (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.”.

## **18 Functions of local authority with parental rights and responsibilities**

- (1) The 2006 Act is amended as follows.
- (2) In section 10(1), the words “(but who is not a local authority)” are repealed.
- (3) After section 10A insert—

### **“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.

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*Status: This is the original version (as it was originally enacted).*

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- (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.”.

## CHAPTER 4

### AUTHORISATIONS: GENERAL

#### 19 Power to make provision about decisions

- (1) The 2006 Act is amended as follows.
- (2) After section 10B insert—

##### “10C 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.”.
- (3) In section 59(3) (regulations subject to affirmative procedure), after paragraph (ab) insert—
  - “(ac) regulations under section 10C(1);”.

#### 20 Withdrawal by person who is blind or unable to write

- (1) The 2006 Act is amended as follows.
- (2) After section 10C insert—

### **“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.”.
- (3) In section 6, subsections (3) to (5) are repealed.
- (4) In section 8, subsections (3) to (6) are repealed.

## **21 Removal and use of part of body for quality assurance purposes**

In section 3(1)(d) of the 2006 Act, after “audit” insert “or quality assurance”.

## **22 Removal of part of body of deceased person: further requirements**

- (1) Section 11 of the 2006 Act is amended as follows.
- (2) In subsection (1)(b), after “person” insert “(or description of person)”.
- (3) In subsection (2), after “person” insert “(or description of person)”.
- (4) In subsection (3), paragraph (b) is repealed.
- (5) In subsection (4)—

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- (a) in the opening words, the words from “(and,” to “the practitioner)” are repealed,
  - (b) at the beginning of paragraph (a), insert “if the person is a registered medical practitioner,”,
  - (c) after paragraph (a), insert—
    - “(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,”,
  - (d) in paragraph (c)—
    - (i) after “removal” insert “and use for the purpose in question”,
    - (ii) for “7, 8, 9 or, as the case may be, 10” substitute “6D, 6E, 6F, 6G, 6H, 8, 8D, 10 or, as the case may be, 10A”.
- (6) After subsection (4), insert—
- “(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—



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- (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.”.
- (7) Subsection (5) is repealed.

## CHAPTER 5

### PRE-DEATH PROCEDURES RELATING TO TRANSPLANTATION

#### 23 Pre-death procedures relating to transplantation

- (1) After section 16 of the 2006 Act insert—

#### *“Pre-death procedures relating to transplantation*

##### **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 pre-death 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 pre-death 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,

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- (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.

*Status: This is the original version (as it was originally enacted).*

- (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.”.
- (2) In section 59(3) of the 2006 Act (regulations subject to affirmative procedure), after paragraph (ac) insert—
  - “(ad) regulations under section 16B(1) or 16C(1);”.

## **CHAPTER 6**

### **DUTY TO INQUIRE**

#### **24 Duty to inquire**

After section 16G of the 2006 Act insert—

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**“16H 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—

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- (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.

### **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.”.

**PART 4**

## GENERAL AND FINAL PROVISIONS

**25 Meaning of “the 2006 Act”**

In this Act “the 2006 Act” means the Human Tissue (Scotland) Act 2006.

**26 Ancillary provision**

- (1) The Scottish Ministers may by regulations make any incidental, supplementary, consequential, transitional, transitory or saving provision they consider appropriate for the purposes of, in connection with or for giving full effect to this Act or any provision made under it.
- (2) Regulations under this section may—
  - (a) modify any enactment (including this Act),
  - (b) make different provision for different purposes.
- (3) Regulations under subsection (1) which contain provision adding to, replacing or omitting any part of the text of an Act are subject to the affirmative procedure.
- (4) Otherwise, regulations under subsection (1) are subject to the negative procedure.

**27 Interpretation**

- (1) The 2006 Act is amended as follows.
- (2) After section 16I insert—

**“16J 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,



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- (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.”.
- (3) In section 59(3) (regulations subject to affirmative procedure), after paragraph (ad) insert—
  - “(ae) regulations under section 16J(8);”.
- (4) After section 16J insert—

#### **“16K 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,

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“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.”.

(5) The following are repealed—

(a) section 6(6),

(b) section 8(7),

(c) section 16(2).

(6) In section 14(5), the definitions of “Health Board” and “Special Health Board” are repealed.

## **28 Minor and consequential modifications**

(1) In section 1(5) of the Anatomy Act 1984—

(a) for “or audit” in each place where it occurs substitute “, audit or quality assurance”,

(b) for “7, 8, 9 or 10” substitute “6D, 6E, 6F, 6G, 6H, 8, 8D, 10 or 10A”.

(2) The Adults with Incapacity (Scotland) Act 2000 is amended as follows—

(a) in section 16(6)—

(i) in paragraph (d), after “section 6(1),” insert “16F(1)(a)”,

(ii) after paragraph (d), insert—

“(da) withdraw an authorisation, on behalf of the granter, by virtue of section 6A(1) of that Act;

(db) make, on behalf of the granter, an opt-out declaration by virtue of section 6B(1) of that Act;

(dc) withdraw an opt-out declaration, on behalf of the granter, by virtue of section 6C(1) of that Act;”,

(b) in section 64(2)—

(i) in paragraph (d), after “section 6(1),” insert “16F(1)(a)”,

(ii) after paragraph (d), insert—

“(da) withdraw an authorisation, on behalf of the adult, by virtue of section 6A(1) of that Act;

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- (db) make, on behalf of the adult, an opt-out declaration by virtue of section 6B(1) of that Act;
  - (dc) withdraw an opt-out declaration, on behalf of the adult, by virtue of section 6C(1) of that Act;”.
- (3) The 2006 Act is amended as follows—
- (a) in section 3(2)(a), for “7, 8, 9 or, as the case may be, 10” substitute “6D, 6E, 6F, 6G, 6H, 8, 8D, 10 or, as the case may be, 10A”,
  - (b) in section 12, for “6(1), 7(1), (2) or (3), 8(1), 9(1), (2) or (3) or 10(1)” substitute “6, 6D, 6E, 6F, 6G, 8, 8D, 10 or, as the case may be, 10A”,
  - (c) in section 15(1)—
    - (i) for the words “expressed verbally” in both places where they occur substitute “given orally”,
    - (ii) for “expressed” in both places where it occurs substitute “given”,
    - (iii) for “authorisation by the adult in accordance with section 6(1)” substitute “an express authorisation by the adult”,
  - (d) in section 16(1)(a), for “7, 8, 9 or, as the case may be, 10” substitute “6D, 6E, 6F, 6G, 6H, 8, 8D, 10 or, as the case may be, 10A”,
  - (e) in section 22—
    - (i) in subsection (1), for “authorisation by an adult by virtue of section 6(1)” substitute “an express authorisation by an adult”,
    - (ii) after subsection (1), insert—

“(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).”.
    - (iii) subsection (3) is repealed,
    - (iv) in subsection (4), for “9(1), (2) or (3) or 10(1)” substitute “8D, 10 or 10A”,
  - (f) in section 49(1)(a), for “7(1), 9(1) or 10(1)” substitute “6H, 8D, 10 or 10A”,
  - (g) in section 51(1), for “6(3), 8(3)” substitute “10D”.

## 29 Commencement

- (1) This section and sections 25, 26 and 30 come into force on the day after Royal Assent.
- (2) The rest of this Act comes into force on such day as the Scottish Ministers may by regulations appoint.
- (3) Regulations under this section may appoint different days for different purposes.
- (4) Regulations under this section may—
  - (a) include transitional, transitory or saving provision,

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(b) make different provision for different purposes.

**30 Short title**

The short title of this Act is the Human Tissue (Authorisation) (Scotland) Act 2019.