



Human Tissue Act 2004

2004 CHAPTER 30

PART 1

REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

1 Authorisation of activities for scheduled purposes

- (1) The following activities shall be lawful if done with appropriate consent—
- (a) the storage of the body of a deceased person for use for a purpose specified in Schedule 1, other than anatomical examination;
 - (b) the use of the body of a deceased person for a purpose so specified, other than anatomical examination;
 - (c) the removal from the body of a deceased person, for use for a purpose specified in Schedule 1, of any relevant material of which the body consists or which it contains;
 - (d) the storage for use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;
 - (e) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a deceased person;
 - (f) the use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;
 - (g) the use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a deceased person.
- (2) The storage of the body of a deceased person for use for the purpose of anatomical examination shall be lawful if done—
- (a) with appropriate consent, and
 - (b) after the signing of a certificate—
 - (i) under section 22(1) of the Births and Deaths Registration Act [1953 \(c. 20\)](#), or
 - (ii) under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 ([S.I. 1976/1041 \(N.I. 14\)](#)),

of the cause of death of the person.

- (3) The use of the body of a deceased person for the purpose of anatomical examination shall be lawful if done—
- (a) with appropriate consent, and
 - (b) after the death of the person has been registered—
 - (i) under section 15 of the Births and Deaths Registration Act 1953, or
 - (ii) under Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.
- (4) Subsections (1) to (3) do not apply to an activity of a kind mentioned there if it is done in relation to—
- (a) a body to which subsection (5) applies, or
 - (b) relevant material to which subsection (6) applies.
- (5) This subsection applies to a body if—
- (a) it has been imported, or
 - (b) it is the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.
- (6) This subsection applies to relevant material if—
- (a) it has been imported,
 - (b) it has come from a body which has been imported, or
 - (c) it is material which has come from the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.
- (7) Subsection (1)(d) does not apply to the storage of relevant material for use for the purpose of research in connection with disorders, or the functioning, of the human body if—
- (a) the material has come from the body of a living person, and
 - (b) the research falls within subsection (9).
- (8) Subsection (1)(f) does not apply to the use of relevant material for the purpose of research in connection with disorders, or the functioning, of the human body if—
- (a) the material has come from the body of a living person, and
 - (b) the research falls within subsection (9).
- (9) Research falls within this subsection if—
- (a) it is ethically approved in accordance with regulations made by the Secretary of State, and
 - (b) it is to be, or is, carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the person from whose body the material has come can be identified.
- (10) The following activities shall be lawful—
- (a) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a living person;
 - (b) the use for such a purpose of any relevant material which has come from the body of a living person;

- (c) an activity in relation to which subsection (4), (7) or (8) has effect.
- (11) The Secretary of State may by order—
- (a) vary or omit any of the purposes specified in Part 1 or 2 of Schedule 1, or
 - (b) add to the purposes specified in Part 1 or 2 of that Schedule.
- (12) Nothing in this section applies to—
- (a) the use of relevant material in connection with a device to which Directive [98/79/EC](#) of the European Parliament and of the Council on *in vitro* diagnostic medical devices applies, where the use falls within the Directive, or
 - (b) the storage of relevant material for use falling within paragraph (a).
- (13) In this section, the references to a body or material which has been imported do not include a body or material which has been imported after having been exported with a view to its subsequently being re-imported.

2 “Appropriate consent”: children

- (1) This section makes provision for the interpretation of “appropriate consent” in section 1 in relation to an activity involving the body, or material from the body, of a person who is a child or has died a child (“the child concerned”).
- (2) Subject to subsection (3), where the child concerned is alive, “appropriate consent” means his consent.
- (3) Where—
- (a) the child concerned is alive,
 - (b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, and
 - (c) either he is not competent to deal with the issue of consent in relation to the activity or, though he is competent to deal with that issue, he fails to do so,
- “appropriate consent” means the consent of a person who has parental responsibility for him.
- (4) Where the child concerned has died and the activity is one to which subsection (5) applies, “appropriate consent” means his consent in writing.
- (5) This subsection applies to an activity involving storage for use, or use, for the purpose of—
- (a) public display, or
 - (b) where the subject-matter of the activity is not excepted material, anatomical examination.
- (6) Consent in writing for the purposes of subsection (4) is only valid if—
- (a) it is signed by the child concerned in the presence of at least one witness who attests the signature, or
 - (b) it is signed at the direction of the child concerned, in his presence and in the presence of at least one witness who attests the signature.
- (7) Where the child concerned has died and the activity is not one to which subsection (5) applies, “appropriate consent” means —
- (a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;

- (b) if paragraph (a) does not apply—
 - (i) the consent of a person who had parental responsibility for him immediately before he died, or
 - (ii) where no person had parental responsibility for him immediately before he died, the consent of a person who stood in a qualifying relationship to him at that time.

3 “Appropriate consent”: adults

- (1) This section makes provision for the interpretation of “appropriate consent” in section 1 in relation to an activity involving the body, or material from the body, of a person who is an adult or has died an adult (“the person concerned”).
- (2) Where the person concerned is alive, “appropriate consent” means his consent.
- (3) Where the person concerned has died and the activity is one to which subsection (4) applies, “appropriate consent” means his consent in writing.
- (4) This subsection applies to an activity involving storage for use, or use, for the purpose of—
 - (a) public display, or
 - (b) where the subject-matter of the activity is not excepted material, anatomical examination.
- (5) Consent in writing for the purposes of subsection (3) is only valid if—
 - (a) it is signed by the person concerned in the presence of at least one witness who attests the signature,
 - (b) it is signed at the direction of the person concerned, in his presence and in the presence of at least one witness who attests the signature, or
 - (c) it is contained in a will of the person concerned made in accordance with the requirements of—
 - (i) section 9 of the Wills Act 1837 (c. 26), or
 - (ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).
- (6) Where the person concerned has died and the activity is not one to which subsection (4) applies, “appropriate consent” means—
 - (a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;
 - (b) if—
 - (i) paragraph (a) does not apply, and
 - (ii) he has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity, consent given under the appointment;
 - (c) if neither paragraph (a) nor paragraph (b) applies, the consent of a person who stood in a qualifying relationship to him immediately before he died.
- (7) Where the person concerned has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity, the appointment shall be disregarded for the purposes of subsection (6) if no one is able to give consent under it.

- (8) If it is not reasonably practicable to communicate with a person appointed under section 4 within the time available if consent in relation to the activity is to be acted on, he shall be treated for the purposes of subsection (7) as not able to give consent under the appointment in relation to it.

4 Nominated representatives

- (1) An adult may appoint one or more persons to represent him after his death in relation to consent for the purposes of section 1.
- (2) An appointment under this section may be general or limited to consent in relation to such one or more activities as may be specified in the appointment.
- (3) An appointment under this section may be made orally or in writing.
- (4) An oral appointment under this section is only valid if made in the presence of at least two witnesses present at the same time.
- (5) A written appointment under this section is only valid if—
- (a) it is signed by the person making it in the presence of at least one witness who attests the signature,
 - (b) it is signed at the direction of the person making it, in his presence and in the presence of at least one witness who attests the signature, or
 - (c) it is contained in a will of the person making it, being a will which is made in accordance with the requirements of—
 - (i) section 9 of the Wills Act 1837 (c. 26), or
 - (ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).
- (6) Where a person appoints two or more persons under this section in relation to the same activity, they shall be regarded as appointed to act jointly and severally unless the appointment provides that they are appointed to act jointly.
- (7) An appointment under this section may be revoked at any time.
- (8) Subsections (3) to (5) apply to the revocation of an appointment under this section as they apply to the making of such an appointment.
- (9) A person appointed under this section may at any time renounce his appointment.
- (10) A person may not act under an appointment under this section if—
- (a) he is not an adult, or
 - (b) he is of a description prescribed for the purposes of this provision by regulations made by the Secretary of State.

5 Prohibition of activities without consent etc.

- (1) A person commits an offence if, without appropriate consent, he does an activity to which subsection (1), (2) or (3) of section 1 applies, unless he reasonably believes—
- (a) that he does the activity with appropriate consent, or
 - (b) that what he does is not an activity to which the subsection applies.
- (2) A person commits an offence if—

- (a) he falsely represents to a person whom he knows or believes is going to, or may, do an activity to which subsection (1), (2) or (3) of section 1 applies—
 - (i) that there is appropriate consent to the doing of the activity, or
 - (ii) that the activity is not one to which the subsection applies, and
 - (b) he knows that the representation is false or does not believe it to be true.
- (3) Subject to subsection (4), a person commits an offence if, when he does an activity to which section 1(2) applies, neither of the following has been signed in relation to the cause of death of the person concerned—
- (a) a certificate under section 22(1) of the Births and Deaths Registration Act 1953 (c. 20), and
 - (b) a certificate under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)).
- (4) Subsection (3) does not apply—
- (a) where the person reasonably believes—
 - (i) that a certificate under either of those provisions has been signed in relation to the cause of death of the person concerned, or
 - (ii) that what he does is not an activity to which section 1(2) applies, or
 - (b) where the person comes into lawful possession of the body immediately after death and stores it prior to its removal to a place where anatomical examination is to take place.
- (5) Subject to subsection (6), a person commits an offence if, when he does an activity to which section 1(3) applies, the death of the person concerned has not been registered under either of the following provisions—
- (a) section 15 of the Births and Deaths Registration Act 1953, and
 - (b) Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.
- (6) Subsection (5) does not apply where the person reasonably believes—
- (a) that the death of the person concerned has been registered under either of those provisions, or
 - (b) that what he does is not an activity to which section 1(3) applies.
- (7) A person guilty of an offence under this section shall be liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum;
 - (b) on conviction on indictment—
 - (i) to imprisonment for a term not exceeding 3 years, or
 - (ii) to a fine, or
 - (iii) to both.
- (8) In this section, “appropriate consent” has the same meaning as in section 1.

6 Activities involving material from adults who lack capacity to consent

Where—

- (a) an activity of a kind mentioned in section 1(1)(d) or (f) involves material from the body of a person who—
 - (i) is an adult, and
 - (ii) lacks capacity to consent to the activity, and

- (b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force,

there shall for the purposes of this Part be deemed to be consent of his to the activity if it is done in circumstances of a kind specified by regulations made by the Secretary of State.

7 Powers to dispense with need for consent

(1) If the Authority is satisfied—

- (a) that relevant material has come from the body of a living person,
- (b) that it is not reasonably possible to trace the person from whose body the material has come (“the donor”),
- (c) that it is desirable in the interests of another person (including a future person) that the material be used for the purpose of obtaining scientific or medical information about the donor, and
- (d) that there is no reason to believe—
 - (i) that the donor has died,
 - (ii) that a decision of the donor to refuse to consent to the use of the material for that purpose is in force, or
 - (iii) that the donor lacks capacity to consent to the use of the material for that purpose,

it may direct that subsection (3) apply to the material for the benefit of the other person.

(2) If the Authority is satisfied—

- (a) that relevant material has come from the body of a living person,
- (b) that it is desirable in the interests of another person (including a future person) that the material be used for the purpose of obtaining scientific or medical information about the person from whose body the material has come (“the donor”),
- (c) that reasonable efforts have been made to get the donor to decide whether to consent to the use of the material for that purpose,
- (d) that there is no reason to believe—
 - (i) that the donor has died,
 - (ii) that a decision of the donor to refuse to consent to the use of the material for that purpose is in force, or
 - (iii) that the donor lacks capacity to consent to the use of the material for that purpose, and
- (e) that the donor has been given notice of the application for the exercise of the power conferred by this subsection,

it may direct that subsection (3) apply to the material for the benefit of the other person.

(3) Where material is the subject of a direction under subsection (1) or (2), there shall for the purposes of this Part be deemed to be consent of the donor to the use of the material for the purpose of obtaining scientific or medical information about him which may be relevant to the person for whose benefit the direction is given.

(4) The Secretary of State may by regulations enable the High Court, in such circumstances as the regulations may provide, to make an order deeming there for the purposes of this Part to be appropriate consent to an activity consisting of—

- (a) the storage of the body of a deceased person for use for the purpose of research in connection with disorders, or the functioning, of the human body,
- (b) the use of the body of a deceased person for that purpose,
- (c) the removal from the body of a deceased person, for use for that purpose, of any relevant material of which the body consists or which it contains,
- (d) the storage for use for that purpose of any relevant material which has come from a human body, or
- (e) the use for that purpose of any relevant material which has come from a human body.

8 Restriction of activities in relation to donated material

- (1) Subject to subsection (2), a person commits an offence if he—
 - (a) uses donated material for a purpose which is not a qualifying purpose, or
 - (b) stores donated material for use for a purpose which is not a qualifying purpose.
- (2) Subsection (1) does not apply where the person reasonably believes that what he uses, or stores, is not donated material.
- (3) A person guilty of an offence under this section shall be liable—
 - (a) on summary conviction to a fine not exceeding the statutory maximum;
 - (b) on conviction on indictment—
 - (i) to imprisonment for a term not exceeding 3 years, or
 - (ii) to a fine, or
 - (iii) to both.
- (4) In subsection (1), references to a qualifying purpose are to—
 - (a) a purpose specified in Schedule 1,
 - (b) the purpose of medical diagnosis or treatment,
 - (c) the purpose of decent disposal, or
 - (d) a purpose specified in regulations made by the Secretary of State.
- (5) In this section, references to donated material are to—
 - (a) the body of a deceased person, or
 - (b) relevant material which has come from a human body, which is, or has been, the subject of donation.
- (6) For the purposes of subsection (5), a body, or material, is the subject of donation if authority under section 1(1) to (3) exists in relation to it.

9 Existing holdings

- (1) In its application to the following activities, section 1(1) shall have effect with the omission of the words “if done with appropriate consent”—
 - (a) the storage of an existing holding for use for a purpose specified in Schedule 1;
 - (b) the use of an existing holding for a purpose so specified.
- (2) Subsection (1) does not apply where the existing holding is a body, or separated part of a body, in relation to which section 10(3) or (5) has effect.

- (3) Section 5(1) and (2) shall have effect as if the activities mentioned in subsection (1) were not activities to which section 1(1) applies.
- (4) In this section, “existing holding” means—
- (a) the body of a deceased person, or
 - (b) relevant material which has come from a human body,
- held, immediately before the day on which section 1(1) comes into force, for use for a purpose specified in Schedule 1.

10 Existing anatomical specimens

- (1) This section applies where a person dies during the three years immediately preceding the coming into force of section 1.
- (2) Subsection (3) applies where—
- (a) before section 1 comes into force, authority is given under section 4(2) or (3) of the Anatomy Act 1984 (c. 14) for the person’s body to be used for anatomical examination, and
 - (b) section 1 comes into force before anatomical examination of the person’s body is concluded.
- (3) During so much of the relevant period as falls after section 1 comes into force, that authority shall be treated for the purposes of section 1 as appropriate consent in relation to—
- (a) the storage of the person’s body, or separated parts of his body, for use for the purpose of anatomical examination, and
 - (b) the use of his body, or separated parts of his body, for that purpose.
- (4) Subsection (5) applies where—
- (a) before section 1 comes into force, authority is given under section 6(2) or (3) of the Anatomy Act 1984 for possession of parts (or any specified parts) of the person’s body to be held after anatomical examination of his body is concluded, and
 - (b) anatomical examination of the person’s body is concluded—
 - (i) after section 1 comes into force, but
 - (ii) before the end of the period of three years beginning with the date of the person’s death.
- (5) With effect from the conclusion of the anatomical examination of the person’s body, that authority shall be treated for the purposes of section 1 as appropriate consent in relation to—
- (a) the storage for use for a qualifying purpose of a part of the person’s body which—
 - (i) is a part to which that authority relates, and
 - (ii) is such that the person cannot be recognised simply by examination of the part, and
 - (b) the use for a qualifying purpose of such a part of the person’s body.
- (6) Where for the purposes of section 1 there would not be appropriate consent in relation to an activity but for authority given under the Anatomy Act 1984 (c. 14) being treated for those purposes as appropriate consent in relation to the activity, section 1(1) to

- (3) do not authorise the doing of the activity otherwise than in accordance with that authority.
- (7) In subsection (3), “the relevant period”, in relation to a person, means whichever is the shorter of—
- (a) the period of three years beginning with the date of the person’s death, and
 - (b) the period beginning with that date and ending when anatomical examination of the person’s body is concluded.
- (8) In subsection (5), “qualifying purpose” means a purpose specified in paragraph 6 or 9 of Schedule 1.
- (9) The Secretary of State may by order amend subsection (8).

11 Coroners

- (1) Nothing in this Part applies to anything done for purposes of functions of a coroner or under the authority of a coroner.
- (2) Where a person knows, or has reason to believe, that—
- (a) the body of a deceased person, or
 - (b) relevant material which has come from the body of a deceased person,
- is, or may be, required for purposes of functions of a coroner, he shall not act on authority under section 1 in relation to the body, or material, except with the consent of the coroner.

12 Interpretation of Part 1

In this Part, “excepted material” means material which has—

- (a) come from the body of a living person, or
- (b) come from the body of a deceased person otherwise than in the course of use of the body for the purpose of anatomical examination.