



Human Tissue Act 2004

2004 CHAPTER 30

PART 2

REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE

Codes of practice

26 Preparation of codes

- (1) The Authority may prepare and issue codes of practice for the purpose of—
 - (a) giving practical guidance to persons carrying on activities within its remit, and
 - (b) laying down the standards expected in relation to the carrying-on of such activities.
- (2) The Authority shall deal under subsection (1) with the following matters—
 - (a) the carrying-out of anatomical examinations;
 - (b) the storage of anatomical specimens;
 - (c) the storage and disposal of former anatomical specimens;
 - (d) the definition of death for the purposes of this Act^{F1} and the Human Transplantation (Wales) Act 2013];
 - (e) communication with the family of the deceased in relation to the making of a post-mortem examination;
 - (f) the making of post-mortem examinations;
 - (g) communication with the family of the deceased in relation to the removal from the body of the deceased, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
 - (h) the removal from a human body, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
 - (i) the storage for use for a scheduled purpose, and the use for such a purpose, of—
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body;

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- (j) the storage for use for a scheduled purpose, and the use for such a purpose, of an existing holding within the meaning of section 9;
 - (k) the import, and the export, of—
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body, for use for a scheduled purpose;
 - (l) the disposal of relevant material which—
 - (i) has been removed from a human body for use for a scheduled purpose, or
 - (ii) has come from a human body and is an existing holding for the purposes of section 9.
- (3) In dealing under subsection (1) with the matters mentioned in subsection (2)(h) and (i), the Authority shall, in particular, deal with consent^[F2](including consent for the purposes of the Human Transplantation (Wales) Act 2013).]
- (4) The Authority shall—
- (a) keep any code of practice under this section under review, and
 - (b) prepare a revised code of practice when appropriate.
- (5) Before preparing a code of practice under this section, the Authority shall—
- (a) consult such persons as it considers appropriate,
 - (b) if the code of practice relates to Wales, consult the ^[F3]National Assembly for Wales^[F3]Welsh Ministers]], and
 - (c) if the code of practice relates to Northern Ireland, consult the relevant Northern Ireland department.
- (6) The Authority shall publish a code of practice issued under this section in such way as, in its opinion, is likely to bring it to the attention of those interested.
- (7) A code of practice issued under this section shall come into effect on such day as may be appointed by directions.
- (8) Codes of practice under this section may make different provision in relation to England, Wales and Northern Ireland respectively.

Textual Amendments

- F1** Words in s. 26(2)(d) inserted (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(2)(a), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)
- F2** Words in s. 26(3) added (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(2)(b), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)
- F3** Words in s. 26(5)(b) substituted (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(2)(c), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)

Modifications etc. (not altering text)

- C1** S. 26(1) extended (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), **reg. 1(2)(3)9** (with **reg. 2(3)**)
- C2** S. 26(4)-(8) extended (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), **reg. 1(2)(3)9** (with **reg. 2(3)**)

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Commencement Information

II S. 26 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

27 Provision with respect to consent

(1) The duty under section 26(3) shall have effect, in particular, to require the Authority to lay down the standards expected in relation to the obtaining of consent where consent falls by virtue of [^{F4}section 2(7)(b)(ii) or 3(6)(c)]^{F4}a provision listed in subsection (1A)] to be obtained from a person in a qualifying relationship.

[^{F5}(1A) Those provisions are—

- (a) section 2(7)(b)(ii) or 3(6)(c) of this Act;
- (b) section 4(3), 5(4), 6(3) or 7 of the Human Transplantation (Wales) Act 2013.]

(2) Subject to subsection (3), the standards required to be laid down by subsection (1) shall include provision to the effect set out in subsections (4) to (8).

(3) The standards required to be laid down by subsection (1) may include provision to different effect in relation to cases which appear to the Authority to be exceptional.

(4) The qualifying relationships for the purpose of [^{F6}sections 2(7)(b)(ii) and 3(6)(c)]^{F6}a provision listed in subsection (1A)] should be ranked in the following order—

- (a) spouse^{F7}, civil partner] or partner;
- (b) parent or child;
- (c) brother or sister;
- (d) grandparent or grandchild;
- (e) child of a person falling within paragraph (c);
- (f) stepfather or stepmother;
- (g) half-brother or half-sister;
- (h) friend of longstanding.

(5) Relationships in the same paragraph of subsection (4) should be accorded equal ranking.

(6) Consent should be obtained from the person whose relationship to the person concerned is accorded the highest ranking in accordance with subsections (4) and (5).

(7) If the relationship of each of two or more persons to the person concerned is accorded equal highest ranking in accordance with subsections (4) and (5), it is sufficient to obtain the consent of any of them.

(8) In applying the principles set out above, a person's relationship shall be left out of account if—

- (a) he does not wish to deal with the issue of consent,
- (b) he is not able to deal with that issue, or
- (c) having regard to the activity in relation to which consent is sought, it is not reasonably practicable to communicate with him within the time available if consent in relation to the activity is to be acted on.

[^{F8}(8ZA) The duty under section 26(3) shall also have effect, in particular, to require the Authority to give practical guidance on the circumstances in which the person concerned is to be deemed to have consented under section 3(6)(ba).

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- (8ZB) In giving practical guidance by virtue of subsection (8ZA), the Authority must, in particular, give guidance about the provision of information of the type described in section 3(6B) by a person who stood in a qualifying relationship to the person concerned immediately before death.]
- [^{F9}(8A) The duty under section 26(3) shall also have effect, in particular, to require the Authority to give practical guidance on the circumstances in which consent is deemed under section 4 (consent of adults that are not excepted) of the Human Transplantation (Wales) Act 2013.
- (8B) In giving practical guidance on the circumstances in which consent is deemed the authority must, in particular, give guidance on how a relative or friend of long standing of the deceased can object on the basis of the deceased's wishes.]
- (9) The Secretary of State may by order amend subsection (4)[^{F10}, except in so far as it applies to section 4(3), 5(4), 6(3) or 7 of the Human Transplantation (Wales) Act 2013.]
- [^{F11}(10) The Welsh Ministers may by order amend subsection (4) in so far as it applies to section 4(3), 5(4), 6(3) or 7 of the Human Transplantation (Wales) Act 2013.
- (11) Before making an order under subsection (10) the Welsh Ministers must carry out such public consultation as they consider appropriate.]

Textual Amendments

- F4** Words in s. 27(1) substituted (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(3)(a), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)
- F5** S. 27(1A) inserted (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(3)(b), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)
- F6** Words in s. 27(4) substituted (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(3)(c), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)
- F7** Words in s. 27(4)(a) inserted (5.12.2005) by [Civil Partnership Act 2004 \(Overseas Relationships and Consequential, etc. Amendments\) Order 2005 \(S.I. 2005/3129\)](#), art. 1, **Sch. 4 para. 12(2)**
- F8** S. 27(8ZA)(8ZB) inserted (6.2.2020) by [Organ Donation \(Deemed Consent\) Act 2019 \(c. 7\)](#), **ss. 2(4), 3(3)**; S.I. 2020/86, reg. 2(b)
- F9** S. 27(8A)(8B) inserted (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(3)(d), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)
- F10** Words in s. 27(9) inserted (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(3)(e), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)
- F11** S. 27(10)(11) inserted (E.W.) (12.9.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 15(3)(f), 21(1)** (with s. 14); S.I. 2015/1679, art. 2(b)

Commencement Information

- I2** S. 27 in force at 1.4.2005 by [S.I. 2005/919](#), art. 3, **Sch.** (with art. 2)

28 Effect of codes

- (1) A failure on the part of any person to observe any provision of a code of practice under section 26 shall not of itself render the person liable to any proceedings.
- (2) The Authority may, in carrying out its functions with respect to licences, take into account any relevant observance of, or failure to observe, a code of practice under

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section 26, so far as dealing with a matter mentioned in any of paragraphs (a) to (c) and (e) to (j) of subsection (2) of that section.

Commencement Information

I3 S. 28 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

29 Approval of codes

(1) The Authority may not issue a code of practice under section 26 that deals with a matter mentioned in any of paragraphs (a) to (c) and (e) to (j) of subsection (2) of that section unless—

- (a) a draft of it has been sent to and approved by the Secretary of State and laid by him before both Houses of Parliament, and
- (b) the 40-day period has elapsed without either House resolving not to approve the draft.

[^{F12}(1A) Where a code of practice to which subsection (1) applies deals with a matter relating to the carrying on in Wales of a transplantation activity (within the meaning of the Human Transplantation (Wales) Act 2013) the Authority may not issue the code unless—

- (a) a draft of it has been sent to and approved by the Welsh Ministers and laid by them before the [^{F13}National Assembly for Wales[^{F13}Welsh Ministers]], and
- (b) the National Assembly has approved the draft by resolution.]

(2) Before approving a draft code of practice sent to him under subsection (1), the Secretary of State shall—

- (a) if the code relates to Wales, consult the National Assembly for Wales, and
- (b) if the code relates to Northern Ireland, consult the relevant Northern Ireland department.

(3) If the Secretary of State approves a draft code of practice sent to him under subsection (1)—

- (a) if the code relates to Wales, he shall send a copy of it to the [^{F14}National Assembly for Wales[^{F14}Welsh Ministers]], and
- (b) if the code relates to Northern Ireland, he shall send a copy of it to the relevant Northern Ireland department.

(4) If the Secretary of State does not approve a draft sent to him under subsection (1), he shall give reasons to the Authority.

[^{F15}(4A) If the Welsh Ministers do not approve a draft sent to them under subsection (1A), they shall give reasons to the Authority.]

(5) The relevant Northern Ireland department shall lay before the Northern Ireland Assembly any document which it receives under subsection (3)(b).

(6) In subsection (1)(b), “40-day period”, in relation to the draft of a code of practice, means—

- (a) if the draft is laid before one House on a day later than the day on which it is laid before the other House, the period of 40 days beginning with the later of the two days, and

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- (b) in any other case, the period of 40 days beginning with the day on which the draft is laid before each House,
 no account being taken of any period during which Parliament is dissolved or prorogued or during which both Houses are adjourned for more than 4 days.

Textual Amendments

- F12** S. 29(1A) inserted (E.W.) (12.9.2015) by Human Transplantation (Wales) Act 2013 (anaw 5), **ss. 15(4)(a)**, 21(1) (with s. 14); S.I. 2015/1679, art. 2(b)
- F13** Words in s. 29(2)(a) substituted (E.W.) (12.9.2015) by Human Transplantation (Wales) Act 2013 (anaw 5), **ss. 15(4)(b)**, 21(1) (with s. 14); S.I. 2015/1679, art. 2(b)
- F14** Words in s. 29(3)(a) substituted (E.W.) (12.9.2015) by Human Transplantation (Wales) Act 2013 (anaw 5), **ss. 15(4)(c)**, 21(1) (with s. 14); S.I. 2015/1679, art. 2(b)
- F15** S. 29(4A) inserted (E.W.) (12.9.2015) by Human Transplantation (Wales) Act 2013 (anaw 5), **ss. 15(4)(d)**, 21(1) (with s. 14); S.I. 2015/1679, art. 2(b)

Commencement Information

- I4** S. 29 in force at 1.4.2005 by S.I. 2005/919, art. 3, **Sch.** (with art. 2)

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