



Human Tissue Act 2004

2004 CHAPTER 30

PART 2

REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE

The Human Tissue Authority

13 The Human Tissue Authority

- (1) There shall be a body corporate to be known as the Human Tissue Authority (referred to in this Act as “the Authority”).
- (2) Schedule 2 (which makes further provision about the Authority) has effect.

Commencement Information

- II [S. 13](#) in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

14 Remit

- (1) The following are the activities within the remit of the Authority—
 - (a) 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;
 - (b) the use, for a scheduled purpose, of—
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body;
 - (c) the storage of an anatomical specimen or former anatomical specimen;
 - (d) the storage (in any case not falling within paragraph (c)) 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;

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- (e) the import or 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;
 - (f) the disposal of the body of a deceased person which has been—
 - (i) imported for use,
 - (ii) stored for use, or
 - (iii) used,
 for a scheduled purpose;
 - (g) the disposal of relevant material which—
 - (i) has been removed from a person’s body for the purposes of his medical treatment,
 - (ii) has been removed from the body of a deceased person for the purposes of an anatomical, or post-mortem, examination,
 - (iii) has been removed from a human body (otherwise than as mentioned in sub-paragraph (ii)) for use for a scheduled purpose,
 - (iv) has come from a human body and been imported for use for a scheduled purpose, or
 - (v) has come from the body of a deceased person which has been imported for use for a scheduled purpose.
 - [^{F1}(h) the procurement, processing, preservation, testing, storage, distribution, import or export of tissue or cells, in so far as those activities are activities to which regulation 7(1) or (2) of the 2007 Regulations applies and are not within the remit of the Authority by virtue of paragraphs (a) to (g).]
 - [^{F2}(i) the donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of human organs, in so far as those activities are activities to which regulation 5(1) of the 2012 Regulations applies and are not within the remit of the Authority by virtue of paragraphs (a) to (h).]
- (2) Without prejudice to the generality of subsection (1)(a) and (b), the activities within the remit of the Authority include, in particular—
- (a) the carrying-out of an anatomical examination, and
 - (b) the making of a post-mortem examination.
- [^{F3}(2ZA) The activities within the remit of the Authority do not include the use, for a scheduled purpose, of relevant material where the use of the material requires consent under paragraph 6(1) or 12(1) of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (use of human cells to create an embryo or a human admixed embryo) or would require such consent but for paragraphs 16 and 20 of that Schedule.]
- [^{F4}(2A) Expressions used in paragraph (h) of subsection (1) and in the 2007 Regulations have the same meaning in that paragraph as in those Regulations; and the reference to activities to which regulation 7(1) or (2) of those Regulations applies is to be read subject to regulation 2(3) of those Regulations.]
- [^{F5}(2B) Expressions used in paragraph (i) of subsection (1) and in the 2012 Regulations have the same meaning in that paragraph as in those Regulations.]
- (3) An activity is excluded from the remit of the Authority if—

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- (a) it relates to the body of a person who died before the day on which this section comes into force or to material which has come from the body of such a person, and
 - (b) at least one hundred years have elapsed since the date of the person's death.
- (4) The Secretary of State may by order amend this section for the purpose of adding to the activities within the remit of the Authority.
- (5) In this section, “relevant material”, in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood.

Textual Amendments

- F1** S. 14(1)(h) inserted (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)**30(2)**
- F2** S. 14(1)(i) inserted (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3)**25(2)(a)**
- F3** S. 14(2ZA) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), s. 68(2), [Sch. 7 para. 23](#); S.I. 2009/2232, art. 2(y)
- F4** S. 14(2A) inserted (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)**30(3)**
- F5** S. 14(2B) inserted (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3)**25(2)(b)**

Commencement Information

- I2** S. 14 in force at 1.4.2005 by [S.I. 2005/919](#), art. 3, [Sch.](#) (with art. 2)

15 General functions

The Authority shall have the following general functions—

- (a) maintaining a statement of the general principles which it considers should be followed—
 - (i) in the carrying-on of activities within its remit, and
 - (ii) in the carrying-out of its functions in relation to such activities;
- (b) providing in relation to activities within its remit such general oversight and guidance as it considers appropriate;
- (c) superintending, in relation to activities within its remit, compliance with—
 - (i) requirements imposed by or under Part 1 or this Part [^{F6}or under the Human Transplantation (Wales) Act 2013], and
 - (ii) codes of practice under this Act;
- (d) providing to the public, and to persons carrying on activities within its remit, such information and advice as it considers appropriate about the nature and purpose of such activities;
- (e) monitoring developments relating to activities within its remit and advising the Secretary of State, the [^{F7}Welsh Ministers] and the relevant Northern Ireland department on issues relating to such developments;

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- (f) advising the Secretary of State, the [^{F8}Welsh Ministers] or the relevant Northern Ireland department on such other issues relating to activities within its remit as he, the [^{F8}Ministers] or the department may require.

Textual Amendments

- F6** Words in s. 15(c)(i) inserted (E.W.) (1.12.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), [ss. 16\(5\)\(a\), 21\(1\)](#) (with s. 14); [S.I. 2015/1679](#), art. 3(e)
- F7** Words in s. 15(e) substituted (E.W.) (1.12.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), [ss. 16\(5\)\(b\), 21\(1\)](#) (with s. 14); [S.I. 2015/1679](#), art. 3(e)
- F8** Words in s. 15(f) substituted (E.W.) (1.12.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), [ss. 16\(5\)\(c\), 21\(1\)](#) (with s. 14); [S.I. 2015/1679](#), art. 3(e)

Modifications etc. (not altering text)

- C1** S. 15(a) extended (Scotland) (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), [regs. 1\(2\)\(3\), 7\(1\)\(b\)\(2\)](#)
- C2** S. 15(b) extended (Scotland) (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), [regs. 1\(2\)\(3\), 7\(1\)\(b\)\(2\)](#)
- C3** S. 15(a)(b)(c)(ii)(d)(e)(f) 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 \(S.I. 2007/1523\)](#), [regs. 1\(2\)\(3\), 9](#) (with reg. 2(3))
- C4** S. 15(d) extended (Scotland) (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), [regs. 1\(2\)\(3\), 7\(1\)\(b\)\(2\)](#)
- C5** S. 15(e) extended (Scotland) (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), [regs. 1\(2\)\(3\), 7\(1\)\(b\)\(2\)](#)
- C6** S. 15(f) extended (Scotland) (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), [regs. 1\(2\)\(3\), 7\(1\)\(b\)\(2\)](#)

Commencement Information

- I3** S. 15 in force at 1.4.2005 by [S.I. 2005/919](#), art. 3, [Sch.](#) (with art. 2)

Licensing

^{F9}16 Licence requirement

- (1) No person shall do an activity to which this section applies otherwise than under the authority of a licence granted for the purposes of this section.
- (2) This section applies to the following activities—
- the carrying-out of an anatomical examination;
 - the making of a post-mortem examination;
 - the removal from the body of a deceased person (otherwise than in the course of an activity mentioned in paragraph (a) or (b)) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;
 - the storage of an anatomical specimen;

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- (e) the storage (in any case not falling within paragraph (d)) 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;
- (f) the use, for the purpose of public display, of—
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from the body of a deceased person.

[^{F9}(2A) This section does not apply to the procurement, testing, processing, preservation, storage, distribution, import or export of tissue and cells intended for human application in so far as those activities are activities to which regulation 7(1) or (2) of the 2007 Regulations applies.

(2B) Expressions used in subsection (2A) and in the 2007 Regulations have the same meaning in that subsection as in those Regulations; and the reference to activities to which regulation 7(1) or (2) of those Regulations applies is to be read subject to regulation 2(3) of those Regulations.]

- (3) The Secretary of State may by regulations specify circumstances in which storage of relevant material by a person who intends to use it for a scheduled purpose is excepted from subsection (2)(e)(ii).
- (4) An activity is excluded from subsection (2) if—
 - (a) it relates to the body of a person who died before the day on which this section comes into force or to material which has come from the body of such a person, and
 - (b) at least one hundred years have elapsed since the date of the person’s death.
- (5) The Secretary of State may by regulations amend this section for the purpose of—
 - (a) adding to the activities to which this section applies,
 - (b) removing an activity from the activities to which this section applies, or
 - (c) altering the description of an activity to which this section applies.
- (6) Schedule 3 (which makes provision about licences for the purposes of this section) has effect.
- (7) In subsection (2)—
 - (a) references to storage do not include storage which is incidental to transportation, and
 - (b) “relevant material”, in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood.

Textual Amendments

- F9** S. 16(2A)(2B) inserted (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)**31(2)**

Commencement Information

- I4** S. 16 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I5** S. 16 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), **art. 2**, **Sch.** (with **art. 4**)

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- I6** S. 16 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)
- I7** S. 16(1)(2)(e)(ii) in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(2)(4)** (with art. 4)
- I8** S. 16(1)(2)(e)(ii) in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(2)** (with arts. 4-6)

17 Persons to whom licence applies

The authority conferred by a licence extends to—

- (a) the designated individual,
- (b) any person who is designated as a person to whom the licence applies by a notice given to the Authority by the designated individual, and
- (c) any person acting under the direction of—
 - (i) the designated individual, or
 - (ii) a person designated as mentioned in paragraph (b).

Modifications etc. (not altering text)

- C7** S. 17 applied (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)8(2)(a)** (with **reg. 2(3)**)

Commencement Information

- I9** S. 17 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I10** S. 17 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I11** S. 17 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
- I12** S. 17 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, **art. 2**, **Sch.** (with art. 4)
- I13** S. 17 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

18 Duty of the designated individual

It shall be the duty of the individual designated in a licence as the person under whose supervision the licensed activity is authorised to be carried on to secure—

- (a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity,
- (b) that suitable practices are used in the course of carrying on that activity, and
- (c) that the conditions of the licence are complied with.

Commencement Information

- I14** S. 18 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I15** S. 18 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I16** S. 18 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
- I17** S. 18 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, **art. 2**, **Sch.** (with art. 4)
- I18** S. 18 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

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19 Right to reconsideration of licensing decisions

- (1) If an application for the grant, revocation or variation of a licence is refused, the applicant may require the Authority to reconsider the decision.
- (2) If a licence is—
 - (a) revoked under paragraph 7(2) of Schedule 3, or
 - (b) varied under paragraph 8(3) or (5) of that Schedule,the holder of the licence, or the designated individual, may require the Authority to reconsider the decision.
- (3) If an application for the grant, or revocation, of permission for the purposes of an authorisation condition is refused, the applicant may require the Authority to reconsider the decision.
- (4) If permission for the purposes of an authorisation condition is revoked under paragraph 12(4)(b) of Schedule 3, any of—
 - (a) the individual concerned,
 - (b) the holder of the licence, and
 - (c) the designated individual,may require the Authority to reconsider the decision.
- (5) The right under subsection (1) or (2) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under paragraph 11 of Schedule 3.
- (6) The right under subsection (3) or (4) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under paragraph 12 of Schedule 3.
- (7) Subsections (1) to (4) do not apply to a decision on reconsideration.
- (8) In this section, “authorisation condition” means a condition of a licence where—
 - (a) the licence is one to which paragraph 3 of Schedule 3 applies, and
 - (b) the condition is the one required in the licence by sub-paragraph (2) of that paragraph.

Modifications etc. (not altering text)

- C8** S. 19(1)(2) applied (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), **8(2)(b)** (with reg. 2(3))
- C9** S. 19(1) applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C10** S. 19(1) amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**
- C11** S. 19(2) applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C12** S. 19(2) amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

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- C13** S. 19(5)(7) applied (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), **8(2)(b)** (with reg. 2(3))
- C14** S. 19(5) applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C15** S. 19(5) amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**
- C16** S. 19(7) applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C17** S. 19(7) amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

Commencement Information

- I19** S. 19 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I20** S. 19 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), art. 2(3)(4), **Sch.** (with arts. 4-6)
- I21** S. 19 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), art. 3(3), **Sch.** (with arts. 4-6)
- I22** S. 19 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, **Sch.** (with art. 4)
- I23** S. 19 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with arts. 4, 7, 8)

20 Appeals committees

- (1) The Authority shall maintain one or more committees to carry out its functions in pursuance of notices under section 19.
- (2) A committee under subsection (1) is referred to in this Part as an appeals committee.
- (3) An appeals committee shall consist of not less than five members of the Authority.
- (4) The quorum for an appeals committee shall be three.

Modifications etc. (not altering text)

- C18** Ss. 20-24 applied (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)**8(2)(c)8(4)** (with reg. 2(3))
- C19** Ss. 20-24 applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C20** Ss. 20-24 amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

Commencement Information

- I24** S. 20 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I25** S. 20 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), art. 2(3)(4), **Sch.** (with arts. 4-6)
- I26** S. 20 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), art. 3(3), **Sch.** (with arts. 4-6)
- I27** S. 20 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, **Sch.** (with art. 4)

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I28 S. 20 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997, art. 3\(2\)](#) (with arts. 4, 7, 8)

21 Procedure on reconsideration

- (1) Reconsideration shall be by way of fresh decision.
- (2) On reconsideration—
 - (a) the person by whom reconsideration is required (“the appellant”) shall be entitled to require that he or his representative be given an opportunity to appear before and be heard by the appeals committee dealing with the matter,
 - (b) at any meeting at which such an opportunity is given, the person who made the decision which is the subject of reconsideration shall be entitled to appear and be heard in person or by a representative, and
 - (c) the appeals committee dealing with the matter shall consider any written representations received from the appellant or the person who made the decision which is the subject of reconsideration.
- (3) The appeals committee by which a decision is reconsidered in pursuance of a notice under section 19 shall give the appellant notice of its decision.
- (4) If on reconsideration an appeals committee upholds the previous decision, the notice under subsection (3) shall include a statement of the reasons for the appeals committee’s decision.
- (5) The Authority may by regulations make such other provision about procedure in relation to reconsideration as it thinks fit.
- (6) Where reconsideration of a decision—
 - (a) is required under section 19(2) or (4) by only one of two persons by whom it could have been required, or
 - (b) is required under section 19(4) by only one or two of three persons by whom it could have been required,it shall be treated for the purposes of this section as required by both or (as the case may be) all of them.
- (7) In this section, “reconsideration” means reconsideration in pursuance of a notice under section 19.

Modifications etc. (not altering text)

- C18** Ss. 20-24 applied (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\(2\)\(3\)8\(2\)\(c\)8\(4\)](#) (with [reg. 2\(3\)](#))
- C19** Ss. 20-24 applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), [reg. 1\(2\)\(3\)](#), [6](#)
- C20** Ss. 20-24 amendment to earlier affecting provision [S.I. 2012/1501 reg. 6 \(14.7.2014\)](#) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), [regs. 1\(1\)](#), [4](#)

Commencement Information

- I29** S. 21 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792, art. 2\(2\)\(j\)](#)

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- I30** S. 21 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), **Sch.** (with arts. 4-6)
- I31** S. 21 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), **Sch.** (with arts. 4-6)
- I32** S. 21 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, **Sch.** (with art. 4)
- I33** S. 21 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

22 Appeal on point of law

A person aggrieved by a decision on reconsideration in pursuance of a notice under section 19 may appeal to the High Court on a point of law.

Modifications etc. (not altering text)

- C18** Ss. 20-24 applied (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)**8(2)(c)8(4)** (with reg. 2(3))
- C19** Ss. 20-24 applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C20** Ss. 20-24 amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

Commencement Information

- I34** S. 22 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I35** S. 22 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), **Sch.** (with arts. 4-6)
- I36** S. 22 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), **Sch.** (with arts. 4-6)
- I37** S. 22 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, **Sch.** (with art. 4)
- I38** S. 22 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

23 Conduct of licensed activities

- (1) Directions may impose requirements in relation to the conduct of the activity which a licence authorises to be carried on.
- (2) Directions under subsection (1) may be given in relation to licences generally, licences of a particular description or a particular licence.
- (3) A person shall comply with a requirement imposed by directions under subsection (1) if it is applicable to him.

Modifications etc. (not altering text)

- C18** Ss. 20-24 applied (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)**8(2)(c)8(4)** (with reg. 2(3))
- C19** Ss. 20-24 applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**

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C20 Ss. 20-24 amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), 4

Commencement Information

- I39** S. 23 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I40** S. 23 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), **Sch.** (with arts. 4-6)
- I41** S. 23 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), **Sch.** (with arts. 4-6)
- I42** S. 23 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, **Sch.** (with art. 4)
- I43** S. 23 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

24 Changes of licence circumstance

- (1) Directions may make provision for the purpose of dealing with a situation arising in consequence of—
- the variation of a licence, or
 - a licence ceasing to have effect.
- (2) Directions under subsection (1)(a) may impose requirements—
- on the holder of the licence;
 - on a person who is the designated individual immediately before, or immediately after, the variation;
 - on any other person, if he consents.
- (3) Directions under subsection (1)(b) may impose requirements—
- on the person who is the holder of the licence immediately before the licence ceases to have effect;
 - on the person who is the designated individual at that time;
 - on any other person, if he consents.
- (4) Directions under subsection (1) may, in particular, require anything kept, or information held, in pursuance of the licence to be transferred in accordance with the directions.
- (5) Where a licence has ceased to have effect by reason of the death or dissolution of its holder, anything subsequently done by a person before directions are given under subsection (1) shall, if the licence would have been authority for doing it, be treated as authorised by a licence.

Modifications etc. (not altering text)

- C18** Ss. 20-24 applied (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)**8(2)(c)8(4)** (with reg. 2(3))
- C19** Ss. 20-24 applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), 6
- C20** Ss. 20-24 amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), 4

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Commencement Information

- I44** S. 24 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I45** S. 24 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4), Sch.** (with arts. 4-6)
- I46** S. 24 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3), Sch.** (with arts. 4-6)
- I47** S. 24 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, **art. 2, Sch.** (with art. 4)
- I48** S. 24 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

25 Breach of licence requirement

- (1) A person who contravenes section 16(1) commits an offence, unless he reasonably believes—
 - (a) that what he does is not an activity to which section 16 applies, or
 - (b) that he acts under the authority of a licence.
- (2) A person guilty of an offence under subsection (1) 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.

Commencement Information

- I49** S. 25 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I50** S. 25 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4), Sch.** (with arts. 4-6)
- I51** S. 25 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3), Sch.** (with arts. 4-6)
- I52** S. 25 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

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^{F10} 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;

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- (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;
 - (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^[F11](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 ^[F12]National Assembly for Wales^[F12]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

F10 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)

F11 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)

Status: Point in time view as at 01/12/2015.

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F12 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)

C21 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)**)

C22 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)**)

Commencement Information

I53 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 [^{F13}section 2(7)(b)(ii) or 3(6)(c)]^{F13}a provision listed in subsection (1A)] to be obtained from a person in a qualifying relationship.

[^{F14}(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 [^{F15}sections 2(7)(b)(ii) and 3(6)(c)]^{F15}a provision listed in subsection (1A)] should be ranked in the following order—

- (a) spouse^{F16}, 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.

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- (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.
- [^{F17}(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)[^{F18}, except in so far as it applies to section 4(3), 5(4), 6(3) or 7 of the Human Transplantation (Wales) Act 2013.]
- [^{F19}(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

- F13** 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)
- F14** 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)
- F15** 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)
- F16** 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)**
- F17** 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)
- F18** 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)
- F19** 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

- I54** 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.

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- (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 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

I55 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.

^[F20](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 ^[F21]National Assembly for Wales^[F21]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 ^[F22]National Assembly for Wales^[F22]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.

^[F23](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—

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- (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
 - (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

- F20** 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)
- F21** 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)
- F22** 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)
- F23** 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

- I56** S. 29 in force at 1.4.2005 by [S.I. 2005/919](#), art. 3, **Sch.** (with art. 2)

Anatomy

30 Possession of anatomical specimens away from licensed premises

- (1) Subject to subsections (2) to (6), a person commits an offence if—
 - (a) he has possession of an anatomical specimen, and
 - (b) the specimen is not on premises in respect of which an anatomy licence is in force.
- (2) Subsection (1) does not apply where—
 - (a) the specimen has come from premises in respect of which a storage licence is in force, and
 - (b) the person—
 - (i) is authorised in writing by the designated individual to have possession of the specimen, and
 - (ii) has possession of the specimen only for a purpose for which he is so authorised to have possession of it.
- (3) Subsection (1) does not apply where—
 - (a) the specimen is the body of a deceased person which is to be used for the purpose of anatomical examination,
 - (b) the person who has possession of the body has come into lawful possession of it immediately after the deceased's death, and
 - (c) he retains possession of the body prior to its removal to premises in respect of which an anatomy licence is in force.
- (4) Subsection (1) does not apply where the person has possession of the specimen only for the purpose of transporting it to premises—

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- (a) in respect of which an anatomy licence is in force, or
 - (b) where the specimen is to be used for the purpose of education, training or research.
- (5) Subsection (1) does not apply where the person has possession of the specimen for purposes of functions of, or under the authority of, a coroner.
- (6) Subsection (1) does not apply where the person reasonably believes—
- (a) that what he has possession of is not an anatomical specimen,
 - (b) that the specimen is on premises in respect of which an anatomy licence is in force, or
 - (c) that any of subsections (2) to (5) applies.
- (7) A person guilty of an offence under subsection (1) 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—
- “anatomy licence” means a licence authorising—
 - (a) the carrying-out of an anatomical examination, or
 - (b) the storage of anatomical specimens;
 - “storage licence” means a licence authorising the storage of anatomical specimens.

Commencement Information

I57 S. 30 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I58 S. 30 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, art. 3(2) (with arts. 4, 7, 8)

31 Possession of former anatomical specimens away from licensed premises

- (1) Subject to subsections (2) to (5), a person commits an offence if—
- (a) he has possession of a former anatomical specimen, and
 - (b) the specimen is not on premises in respect of which a storage licence is in force.
- (2) Subsection (1) does not apply where—
- (a) the specimen has come from premises in respect of which a storage licence is in force, and
 - (b) the person—
 - (i) is authorised in writing by the designated individual to have possession of the specimen, and
 - (ii) has possession of the specimen only for a purpose for which he is so authorised to have possession of it.

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- (3) Subsection (1) does not apply where the person has possession of the specimen only for the purpose of transporting it to premises—
- (a) in respect of which a storage licence is in force, or
 - (b) where the specimen is to be used for the purpose of education, training or research.
- (4) Subsection (1) does not apply where the person has possession of the specimen—
- (a) only for the purpose of its decent disposal, or
 - (b) for purposes of functions of, or under the authority of, a coroner.
- (5) Subsection (1) does not apply where the person reasonably believes—
- (a) that what he has possession of is not a former anatomical specimen,
 - (b) that the specimen is on premises in respect of which a storage licence is in force, or
 - (c) that any of subsections (2) to (4) applies.
- (6) A person guilty of an offence under subsection (1) 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.
- (7) In this section, “storage licence” means a licence authorising the storage, for use for a scheduled purpose, of relevant material which has come from a human body.

Commencement Information

I59 S. 31 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I60 S. 31 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, art. 3(2) (with arts. 4, 7, 8)

Trafficking

32 Prohibition of commercial dealings in human material for transplantation

- (1) A person commits an offence if he—
- (a) gives or receives a reward for the supply of, or for an offer to supply, any controlled material;
 - (b) seeks to find a person willing to supply any controlled material for reward;
 - (c) offers to supply any controlled material for reward;
 - (d) initiates or negotiates any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any controlled material;
 - (e) takes part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.

Status: Point in time view as at 01/12/2015.

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- (2) Without prejudice to subsection (1)(b) and (c), a person commits an offence if he causes to be published or distributed, or knowingly publishes or distributes, an advertisement—
- (a) inviting persons to supply, or offering to supply, any controlled material for reward, or
 - (b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned in subsection (1)(d).
- (3) A person who engages in an activity to which subsection (1) or (2) applies does not commit an offence under that subsection if he is designated by the Authority as a person who may lawfully engage in the activity.
- [^{F24}(3A) The Authority may not designate a person under subsection (3) if doing so could result in the United Kingdom being in breach of—
- (a) Article 12 of [Directive 2004/23/EC](#) of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, or
 - (b) Article 13 of [Directive 2010/53/EU](#) of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation .]
- (4) A person guilty of an offence under subsection (1) shall be liable—
- (a) on summary conviction—
 - (i) to imprisonment for a term not exceeding 12 months, or
 - (ii) to a fine not exceeding the statutory maximum, or
 - (iii) to both;
 - (b) on conviction on indictment—
 - (i) to imprisonment for a term not exceeding 3 years, or
 - (ii) to a fine, or
 - (iii) to both.
- (5) A person guilty of an offence under subsection (2) shall be liable on summary conviction—
- (a) to imprisonment for a term not exceeding 51 weeks, or
 - (b) to a fine not exceeding level 5 on the standard scale, or
 - (c) to both.
- (6) For the purposes of subsections (1) and (2), payment in money or money's worth to the holder of a licence shall be treated as not being a reward where—
- (a) it is in consideration for transporting, removing, preparing, preserving or storing controlled material, and
 - (b) its receipt by the holder of the licence is not expressly prohibited by the terms of the licence.
- (7) References in subsections (1) and (2) to reward, in relation to the supply of any controlled material, do not include payment in money or money's worth for defraying or reimbursing—
- (a) any expenses incurred in, or in connection with, transporting, removing, preparing, preserving or storing the material,
 - (b) any liability incurred in respect of—

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- (i) expenses incurred by a third party in, or in connection with, any of the activities mentioned in paragraph (a), or
 - (ii) a payment in relation to which subsection (6) has effect, or
 - (c) any expenses or loss of earnings incurred by the person from whose body the material comes so far as reasonably and directly attributable to his supplying the material from his body.
- (8) For the purposes of this section, controlled material is any material which—
- (a) consists of or includes human cells,
 - (b) is, or is intended to be removed, from a human body,
 - (c) is intended to be used for the purpose of transplantation, and
 - (d) is not of a kind excepted under subsection (9).
- (9) The following kinds of material are excepted—
- (a) gametes,
 - (b) embryos, and
 - (c) material which is the subject of property because of an application of human skill.
- (10) Where the body of a deceased person is intended to be used to provide material which—
- (a) consists of or includes human cells, and
 - (b) is not of a kind excepted under subsection (9),
- for use for the purpose of transplantation, the body shall be treated as controlled material for the purposes of this section.
- (11) In this section—
- “ advertisement ” includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons;
 - “ reward ” means any description of financial or other material advantage.

Textual Amendments

F24 S. 32(3A) substituted (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#) , regs. 1(1) , **12**

Commencement Information

I61 S. 32 in force at 20.10.2005 by [S.I. 2005/2792](#) , **art. 2(2)(a)**

Transplants

33 Restriction on transplants involving a live donor

- (1) Subject to subsections (3) and (5), a person commits an offence if—
- (a) he removes any transplantable material from the body of a living person intending that the material be used for the purpose of transplantation, and
 - (b) when he removes the material, he knows, or might reasonably be expected to know, that the person from whose body he removes the material is alive.
- (2) Subject to subsections (3) and (5), a person commits an offence if—

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- (a) he uses for the purpose of transplantation any transplantable material which has come from the body of a living person, and
 - (b) when he does so, he knows, or might reasonably be expected to know, that the transplantable material has come from the body of a living person.
- (3) The Secretary of State may by regulations provide that subsection (1) or (2) shall not apply in a case where—
- (a) the Authority is satisfied—
 - (i) that no reward has been or is to be given in contravention of section 32, and
 - (ii) that such other conditions as are specified in the regulations are satisfied, and
 - (b) such other requirements as are specified in the regulations are complied with.
- (4) Regulations under subsection (3) shall include provision for decisions of the Authority in relation to matters which fall to be decided by it under the regulations to be subject, in such circumstances as the regulations may provide, to reconsideration in accordance with such procedure as the regulations may provide.
- (5) Where under subsection (3) an exception from subsection (1) or (2) is in force, a person does not commit an offence under that subsection if he reasonably believes that the exception applies.
- (6) A person guilty of an offence under this section is liable on summary conviction—
- (a) to imprisonment for a term not exceeding 51 weeks, or
 - (b) to a fine not exceeding level 5 on the standard scale, or
 - (c) to both.
- (7) In this section—
- “reward” has the same meaning as in section 32;
 - “transplantable material” means material of a description specified by regulations made by the Secretary of State.

Modifications etc. (not altering text)

C23 S. 33(1)(2) excluded (1.9.2006) by [Human Tissue Act 2004 \(Persons who Lack Capacity to Consent and Transplants\) Regulations 2006 \(S.I. 2006/1659\)](#), regs. 1(2), **11**

Commencement Information

I62 S. 33 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)** (with [art. 3](#))

I63 S. 33 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with [arts. 4, 7, 8](#))

34 Information about transplant operations

- (1) The Secretary of State may make regulations requiring such persons as may be specified in the regulations to supply to such authority as may be so specified such information as may be so specified with respect to transplants that have been or are proposed to be carried out using transplantable material removed from a human body.
- (2) Any such authority shall keep a record of information supplied to it in pursuance of regulations under this section.

Status: Point in time view as at 01/12/2015.

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- (3) A person commits an offence if—
 - (a) he fails without reasonable excuse to comply with regulations under this section, or
 - (b) in purported compliance with such regulations, he knowingly or recklessly supplies information which is false or misleading in a material respect.
- (4) A person guilty of an offence under subsection (3)(a) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.
- (5) A person guilty of an offence under subsection (3)(b) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.
- (6) In this section, “transplantable material” has the same meaning as in section 33.

Commencement Information

I64 S. 34 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I65 S. 34 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, art. 3(2) (with arts. 4, 7, 8)

General

35 Agency arrangements and provision of services

- (1) Arrangements may be made between the Authority and a government department, a public authority or the holder of a public office (“the other authority”) for—
 - (a) any functions of the Authority to be carried out by, or by members of staff of, the other authority, or
 - (b) the provision by the other authority of administrative, professional or technical services to the Authority.
- (2) Arrangements under subsection (1)(a) shall not affect responsibility for the carrying-out of the Authority’s functions.
- (3) Subsection (1)(a) shall not apply to functions of making subordinate legislation (within the meaning of the Interpretation Act 1978 (c. 30)).

Commencement Information

I66 S. 35 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

36 Annual report

- (1) The Authority shall prepare—
 - (a) a report for the first twelve months of its existence, and
 - (b) a report for each succeeding period of twelve months.
- (2) A report under this section shall deal with the activities of the Authority in the period to which the report relates.
- (3) The Authority shall send each report under this section—

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- (a) to the Secretary of State,
 - (b) to the [^{F25}Welsh Ministers], and
 - (c) to the relevant Northern Ireland department,
- as soon as practicable after the end of the period to which the report relates.
- (4) The Secretary of State shall lay a copy of each report received by him under this section before each House of Parliament.
 - (5) The relevant Northern Ireland department shall lay a copy of each report received by it under this section before the Northern Ireland Assembly.
 - [^{F26}(5A) The Welsh Ministers shall lay a copy of each report received by them under this section before the National Assembly for Wales.]

Textual Amendments

- F25** Words in s. 36(3)(b) substituted (E.W.) (1.12.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 16(6)(a), 21(1)** (with s. 14); S.I. 2015/1679, art. 3(e)
- F26** S. 36(5A) inserted (E.W.) (1.12.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 16(6)(b), 21(1)** (with s. 14); S.I. 2015/1679, art. 3(e)

Commencement Information

- I67** S. 36 in force at 1.4.2005 by S.I. 2005/919, art. 3, **Sch.** (with art. 2)

37 Directions

- (1) The Authority may give directions for any purpose for which directions may be given under this Part.
- (2) Any power under this Part to give directions includes power to vary or revoke directions given in previous exercise of the power.
- (3) Any power under this Part to give directions is exercisable by instrument in writing.
- (4) Directions under this Part to a particular person shall be given by serving notice of the directions on the person.
- (5) Directions under this Part in respect of any licence (including one which has ceased to have effect) may be given—
 - (a) by serving notice of the directions on the person who is (or was immediately before the cessation) the designated individual or holder of the licence, or
 - (b) if it appears to the Authority that it is not practicable to give notice in that way, by publishing the directions in such way as, in its opinion, is likely to bring them to the attention of the persons to whom they are applicable.
- (6) Directions under this Part which appear to the Authority to be general directions may be given by publishing them as mentioned in subsection (5)(b).
- (7) This section does not apply to directions under Schedule 2.

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Modifications etc. (not altering text)

- C24** S. 37(1)-(5) applied (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)**8(2)(d)8(5)** (with reg. 2(3))
- C25** S. 37(1)-(5) applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C26** S. 37(1)-(5) amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

Commencement Information

- I68** S. 37 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I69** S. 37 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I70** S. 37 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), **art. 3(3)**, **Sch.** (with arts. 4-6)
- I71** S. 37 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), **art. 2**, **Sch.** (with art. 4)
- I72** S. 37 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with arts. 4, 7, 8)

38 Duties in relation to carrying out functions

- (1) The Authority must carry out its functions effectively, efficiently and economically.
- (2) In carrying out its functions, the Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

Commencement Information

- I73** S. 38 in force at 1.4.2005 by [S.I. 2005/919](#), **art. 3**, **Sch.** (with art. 2)

Exceptions

39 Criminal justice purposes

- (1) Subject to subsection (2), nothing in section 14(1) or 16(2) applies to anything done for purposes related to—
 - (a) the prevention or detection of crime, or
 - (b) the conduct of a prosecution.
- (2) Subsection (1) does not except from section 14(1) or 16(2) the carrying-out of a post-mortem examination for purposes of functions of a coroner.
- (3) The reference in subsection (2) to the carrying-out of a post-mortem examination does not include the removal of relevant material from the body of a deceased person, or from a part of the body of a deceased person, at the first place where the body or part is situated to be attended by a constable.
- (4) For the purposes of subsection (1)(a), detecting crime shall be taken to include—

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- (a) establishing by whom, for what purpose, by what means and generally in what circumstances any crime was committed, and
 - (b) the apprehension of the person by whom any crime was committed;
- and the reference in subsection (1)(a) to the detection of crime includes any detection outside the United Kingdom of any crime or suspected crime.
- (5) In subsection (1)(b), the reference to a prosecution includes a prosecution brought in respect of any crime in a country or territory outside the United Kingdom.
- (6) In this section, references to crime include a reference to any conduct which—
- (a) constitutes one or more criminal offences (whether under the law of a part of the United Kingdom or of a country or territory outside the United Kingdom),
 - (b) is, or corresponds to, any conduct which, if it all took place in any one part of the United Kingdom, would constitute one or more criminal offences, or
 - ^{F27}(c) constitutes one or more [^{F27}service offences within the meaning of the Armed Forces Act 2006.]

Textual Amendments

F27 Words in s. 39(6)(c) substituted (28.3.2009 for specified purposes, 31.10.2009 in so far as not already in force) by [Armed Forces Act 2006 \(c. 52\)](#), s. 383(2), **Sch. 16 para. 241**; S.I. 2009/812, art. 3(a)(b) (with transitional provisions in S.I. 2009/1059); S.I. 2009/1167, art. 4

Modifications etc. (not altering text)

C27 S. 39(6)(c) modified (24.4.2009 for specified purposes, 31.10.2009 in so far as not already in force) by [The Armed Forces Act 2006 \(Transitional Provisions etc\) Order 2009 \(S.I. 2009/1059\)](#), art. 1(3), **Sch. 1 para. 55**

Commencement Information

- I74** S. 39 in force at 1.4.2005 for specified purposes by [S.I. 2005/919](#), art. 3, **Sch.** (with art. 2)
- I75** S. 39 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I76** S. 39 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), art. 2(3)(4), **Sch.** (with arts. 4-6)
- I77** S. 39 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), art. 3(3), **Sch.** (with arts. 4-6)
- I78** S. 39 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, **Sch.** (with art. 4)
- I79** S. 39 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with arts. 4, 7, 8)

40 Religious relics

- (1) This section applies—
- (a) to the use of—
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body,
 for the purpose of public display at a place of public religious worship or at a place associated with such a place, and
 - (b) to the storage of—
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body,
 for use for the purpose mentioned in paragraph (a).

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- (2) An activity to which this section applies is excluded from sections 14(1) and 16(2) if there is a connection between—
- (a) the body or material to which the activity relates, and
 - (b) the religious worship which takes place at the place of public religious worship concerned.
- (3) For the purposes of this section, a place is associated with a place of public religious worship if it is used for purposes associated with the religious worship which takes place there.

Commencement Information

- I80** S. 40 in force at 1.4.2005 for specified purposes by S.I. 2005/919, art. 3, Sch. (with art. 2)
- I81** S. 40 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I82** S. 40 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, Sch. (with art. 4)
- I83** S. 40 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, art. 3(2) (with arts. 4, 7, 8)

Supplementary

^{F28}41 Interpretation of Part 2

^{F29}(1) In this Part—

[^{F28} “the 2007 Regulations ” means the Human Tissue (Quality and Safety for Human Application) Regulations 2007;]

[^{F29} “the 2012 Regulations ” means the Quality and Safety of Organs Intended for Transplantation Regulations 2012;]

“anatomical specimen” means—

- (a) the body of a deceased person to be used for the purpose of anatomical examination, or
- (b) the body of a deceased person in the course of being used for the purpose of anatomical examination (including separated parts of such a body);

“appeals committee” has the meaning given by section 20(2);

“designated individual”, in relation to a licence, means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on;

“export” means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland;

“import” means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland;

“scheduled purpose” means a purpose specified in Schedule 1.

- (2) In this Part, references to the carrying-out of an anatomical examination are to the carrying-out of a macroscopic examination by dissection for anatomical purposes of the body of a deceased person, and, where parts of the body of a deceased person are separated in the course of such an examination, include the carrying-out of a macroscopic examination by dissection of the parts for those purposes.
- (3) In this Part, references to a person to whom a licence applies are to a person to whom the authority conferred by the licence extends (as provided by section 17).

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Textual Amendments

- F28** Words in s. 41 inserted (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), **32**
- F29** Words in s. 41(1) inserted (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **25(4)**

Commencement Information

- I84** S. 41 in force at 1.4.2005 for specified purposes by [S.I. 2005/919](#), art. 3, **Sch.** (with art. 2)
- I85** S. 41 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I86** S. 41 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), art. 2(3)(4), **Sch.** (with arts. 4-6)
- I87** S. 41 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), art. 3(3), **Sch.** (with arts. 4-6)
- I88** S. 41 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, **Sch.** (with art. 4)
- I89** S. 41 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with arts. 4, 7, 8)

Status:

Point in time view as at 01/12/2015.

Changes to legislation:

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