



# Human Tissue Act 2004

## 2004 CHAPTER 30

### PART 2

#### REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE

##### *Licensing*

#### <sup>F1</sup>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—
  - (a) the carrying-out of an anatomical examination;
  - (b) the making of a post-mortem examination;
  - (c) 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;
  - (d) the storage of an anatomical specimen;
  - (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.

[<sup>F1</sup>(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.

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- (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

- F1** 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

- I1** S. 16 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), art. 2(2)(j)
- I2** S. 16 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, Sch. (with art. 4)
- I3** 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)
- I4** 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)
- I5** 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

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(ii) a person designated as mentioned in paragraph (b).

#### Modifications etc. (not altering text)

- C1** 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

- I6** S. 17 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), [art. 2\(2\)\(j\)](#)  
**I7** 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](#))  
**I8** S. 17 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), [art. 3\(3\)](#), [Sch.](#) (with [arts. 4-6](#))  
**I9** S. 17 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), [art. 2](#), [Sch.](#) (with [art. 4](#))  
**I10** 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

- I11** S. 18 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), [art. 2\(2\)\(j\)](#)  
**I12** 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](#))  
**I13** S. 18 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), [art. 3\(3\)](#), [Sch.](#) (with [arts. 4-6](#))  
**I14** S. 18 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), [art. 2](#), [Sch.](#) (with [art. 4](#))  
**I15** 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](#))

## 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.

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- (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)

- C2** 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\(3\)](#))
- C3** 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\(3\)](#))

#### Commencement Information

- I16** S. 19 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), [art. 2\(2\)\(j\)](#)
- I17** 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)
- I18** S. 19 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), [art. 3\(3\)](#), [Sch.](#) (with arts. 4-6)
- I19** S. 19 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), [art. 2](#), [Sch.](#) (with art. 4)
- I20** 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.

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#### **Modifications etc. (not altering text)**

- C4** 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\(3\)](#))

#### **Commencement Information**

- I21** S. 20 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), [art. 2\(2\)\(j\)](#)  
**I22** 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](#))  
**I23** S. 20 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), [art. 3\(3\)](#), [Sch.](#) (with [arts. 4-6](#))  
**I24** S. 20 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), [art. 2](#), [Sch.](#) (with [art. 4](#))  
**I25** 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.

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#### Modifications etc. (not altering text)

- C4** 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\(3\)](#))

#### Commencement Information

- I26** S. 21 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), [art. 2\(2\)\(j\)](#)  
**I27** 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)  
**I28** S. 21 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), [art. 3\(3\)](#), [Sch.](#) (with arts. 4-6)  
**I29** S. 21 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), [art. 2](#), [Sch.](#) (with art. 4)  
**I30** 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)

- C4** 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\(3\)](#))

#### Commencement Information

- I31** S. 22 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), [art. 2\(2\)\(j\)](#)  
**I32** 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)  
**I33** S. 22 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), [art. 3\(3\)](#), [Sch.](#) (with arts. 4-6)  
**I34** S. 22 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), [art. 2](#), [Sch.](#) (with art. 4)  
**I35** 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)

- C4** 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\(3\)](#))

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#### Commencement Information

- I36** S. 23 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I37** 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)
- I38** S. 23 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), **Sch.** (with arts. 4-6)
- I39** S. 23 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, **Sch.** (with art. 4)
- I40** 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)

- C4** 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))

#### Commencement Information

- I41** S. 24 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I42** 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)
- I43** S. 24 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), **Sch.** (with arts. 4-6)
- I44** S. 24 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, **Sch.** (with art. 4)
- I45** 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)

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## 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

- I46** S. 25 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I47** 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)
- I48** S. 25 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
- I49** 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)



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