
Changes to legislation: Human Tissue Act 2004 is up to date with all changes known to be in force on or before 03 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

SCHEDULES

SCHEDULE 1 **E+W+N.I.**

Section 1

SCHEDULED PURPOSES

PART 1 **E+W+N.I.**

PURPOSES REQUIRING CONSENT: GENERAL

1 Anatomical examination.

.....
Commencement Information

I1 Sch. 1 para. 1 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

2 Determining the cause of death.

.....
Commencement Information

I2 Sch. 1 para. 2 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

3 Establishing after a person's death the efficacy of any drug or other treatment administered to him.

.....
Commencement Information

I3 Sch. 1 para. 3 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

4 Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).

.....
Commencement Information

I4 Sch. 1 para. 4 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

5 Public display.

.....
Commencement Information

I5 Sch. 1 para. 5 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

6 Research in connection with disorders, or the functioning, of the human body.

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Commencement Information

I6 Sch. 1 para. 6 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

7 Transplantation.

Commencement Information

I7 Sch. 1 para. 7 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

PART 2 E+W+N.I.

PURPOSES REQUIRING CONSENT: DECEASED PERSONS

8 Clinical audit.

Commencement Information

I8 Sch. 1 para. 8 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

9 Education or training relating to human health.

Commencement Information

I9 Sch. 1 para. 9 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

10 Performance assessment.

Commencement Information

I10 Sch. 1 para. 10 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

11 Public health monitoring.

Commencement Information

I11 Sch. 1 para. 11 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

12 Quality assurance.

Commencement Information

I12 Sch. 1 para. 12 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

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SCHEDULE 2 **E+W+N.I.**

Section 13

THE HUMAN TISSUE AUTHORITY

Membership

- ^{F1} (1) The Authority shall consist of—
- (a) a chairman appointed by the Secretary of State,
 - (b) such number of other members appointed by the Secretary of State as the Secretary of State thinks fit,
 - (c) a member appointed by the [^{F2}Welsh Ministers], and
 - (d) a member appointed by the relevant Northern Ireland department.
- (2) The Secretary of State shall exercise his power to appoint members of the Authority to secure that at all times not less than half of the members are persons who do not have, and have not had, a professional interest in any of the kinds of activity within the remit of the Authority.
- [^{F1}(3) The Scottish Ministers may nominate a person who is a member of the Authority to make representations about the carrying out of its functions in Scotland.]

Textual Amendments

- F1** Sch. 2 para. 1(3) 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(6)**
- F2** Words in Sch. 2 para. 1(1)(c) substituted (E.W.) (1.12.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), **ss. 16(11)(a), 21(1)** (with s. 14); S.I. 2015/1679, art. 3(e)

Commencement Information

- I13** Sch. 2 para. 1 in force at 1.4.2005 by [S.I. 2005/919](#), art. 3, **Sch.** (with art. 2)

Disqualification

- 2 A person is disqualified for being appointed as chairman of the Authority if he has, or has had, a professional interest in any of the kinds of activity within the remit of the Authority.

Commencement Information

- I14** Sch. 2 para. 2 in force at 1.4.2005 by [S.I. 2005/919](#), art. 3, **Sch.** (with art. 2)

- 3 (1) A person is disqualified for being appointed as chairman or other member of the Authority if—
- (a) he is the subject of a bankruptcy restrictions order [^{F3}or an interim bankruptcy restrictions order, or a debt relief restrictions order or interim debt relief restrictions order under Schedule 4ZB of the Insolvency Act 1986],
 - (b) a bankruptcy order has been made against him by a court in Northern Ireland, his estate has been sequestrated by a court in Scotland or, under the law of Northern Ireland or Scotland, he has made a composition or arrangement with, or granted a trust deed for, his creditors, or

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- (c) in the last five years he has been convicted in the United Kingdom, the Channel Islands or the Isle of Man of an offence and has had a qualifying sentence passed on him.
- (2) Where a person is disqualified under sub-paragraph (1)(b) because a bankruptcy order has been made against him or his estate has been sequestered, the disqualification shall cease—
 - (a) on his obtaining a discharge, or
 - (b) if the bankruptcy order is annulled or the sequestration of his estate is recalled or reduced, on the date of that event.
- (3) Where a person is disqualified under sub-paragraph (1)(b) because of his having made a composition or arrangement with, or granted a trust deed for, his creditors, the disqualification shall cease—
 - (a) at the end of the period of five years beginning with the date on which the terms of the deed of composition or arrangement or trust deed are fulfilled, or
 - (b) if, before then, he pays his debts in full, on the date on which the payment is completed.
- (4) For the purposes of sub-paragraph (1)(c), the date of conviction shall be taken to be the ordinary date on which the period allowed for making an appeal or application expires or, if an appeal or application is made, the date on which the appeal or application is finally disposed of or abandoned or fails by reason of its non-prosecution.
- (5) In sub-paragraph (1)(c), the reference to a qualifying sentence is to a sentence of imprisonment for a period of not less than three months (whether suspended or not) without the option of a fine.

Textual Amendments

F3 Words in [Sch. 2 para. 3\(1\)\(a\)](#) substituted (1.10.2012) by [The Tribunals, Courts and Enforcement Act 2007 \(Consequential Amendments\) Order 2012 \(S.I. 2012/2404\)](#), art. 1, [Sch. 2 para. 51](#) (with arts. 5, 6)

Commencement Information

I15 Sch. 2 para. 3 in force at 1.4.2005 by [S.I. 2005/919](#), art. 3, [Sch.](#) (with art. 2)

Tenure of office

- 4 Subject to the following provisions of this Schedule, the chairman and other members of the Authority shall hold and vacate office in accordance with the terms of their respective appointments.

Commencement Information

I16 Sch. 2 para. 4 in force at 1.4.2005 by [S.I. 2005/919](#), art. 3, [Sch.](#) (with art. 2)

- 5 (1) The terms of appointment of the chairman and other members of the Authority shall be such as the Secretary of State may determine, subject to sub-paragraph (2).
- (2) Appointment as chairman or other member shall be for a term not exceeding three years.

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Commencement Information

I17 Sch. 2 para. 5 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

- 6 Previous service as chairman or other member of the Authority does not affect a person’s eligibility for appointment to either office.

Commencement Information

I18 Sch. 2 para. 6 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

- 7 A person holding office as chairman or other member of the Authority may resign that office by giving notice in writing to the person who appointed him.

Commencement Information

I19 Sch. 2 para. 7 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

- 8 A person holding office as chairman or other member of the Authority shall cease to hold that office if he ceases to be qualified for appointment to it.

Commencement Information

I20 Sch. 2 para. 8 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

- 9 A person may be removed from office as chairman or other member of the Authority by the person who appointed him if that person is satisfied that he—
- (a) has been absent from meetings of the Authority for six consecutive months, or longer, without the permission of the Authority, or
 - (b) is unable or unfit to carry out his functions as chairman or other member.

Commencement Information

I21 Sch. 2 para. 9 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

- [^{F4}9A** The appointing authority may suspend a person from office as chairman or other member of the Authority if it appears to the appointing authority that one of the conditions in paragraph 9 is or may be satisfied in relation to the person.

Textual Amendments

F4 [Sch. 2 paras. 9A-9C](#) inserted (19.1.2010) by [Health Act 2009 \(c. 21\)](#), s. 40(1), [Sch. 3 para. 7](#) (with [Sch. 3 para. 19](#)); [S.I. 2010/30](#), [art. 2\(d\)](#)

- 9B (1) This paragraph applies where the appointing authority decides to suspend a person under paragraph 9A.
- (2) The appointing authority must give notice to the person of the decision and the suspension takes effect on receipt by the person of the notice.
- (3) A notice under subsection (2) may be—

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- (a) delivered in person, in which case the person is treated as receiving it when it is delivered, or
 - (b) sent by first class post to the person's last known address, in which case the person is treated as receiving it on the third day after the day on which it was posted.
- (4) The initial period of suspension must not exceed 6 months.
- (5) The appointing authority may review the person's suspension at any time.
- (6) The appointing authority must review the person's suspension if requested in writing by the person to do so, but need not carry out a review less than 3 months after the beginning of the initial period of suspension.
- (7) Following a review the appointing authority may—
- (a) revoke the suspension, or
 - (b) suspend the person for another period of not more than 6 months from the expiry of the current period.
- (8) The appointing authority must revoke the suspension if at any time—
- (a) it decides that neither of the conditions mentioned in paragraph 9 is satisfied, or
 - (b) it decides that either of those conditions is satisfied but does not remove the person from office as chairman or other member of the Authority.
- (9) A person who is suspended under paragraph 9A is to be disregarded at any time during the suspension for the purposes of paragraph 1(1)(c) or (d).
- (10) In this paragraph “the appointing authority”, in relation to a person appointed as chairman or other member of the Authority, means the person who appointed him.

Textual Amendments

F4 Sch. 2 paras. 9A-9C inserted (19.1.2010) by Health Act 2009 (c. 21), s. 40(1), Sch. 3 para. 7 (with Sch. 3 para. 19); S.I. 2010/30, art. 2(d)

- 9C (1) This paragraph applies where a person is suspended from office as chairman under paragraph 9A.
- (2) The Secretary of State may appoint a member of the Authority as the interim chairman to exercise the chairman's functions.
- (3) The Secretary of State may only appoint a member as the interim chairman if the member is not disqualified for being appointed as chairman by virtue of paragraph 2.
- (4) Subject to the following provisions of this paragraph, the interim chairman shall hold and vacate office in accordance with the terms of his appointment.
- (5) Appointment as interim chairman shall be for a term not exceeding the shorter of—
- (a) the period ending with either—
 - (i) the appointment of a new chairman, or
 - (ii) the revocation or expiry of the existing chairman's suspension; and
 - (b) the remainder of the interim chairman's term as a member of the Authority.

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- (6) Previous service as chairman or interim chairman of the Authority does not affect a person's eligibility for appointment as interim chairman.
- (7) A person holding office as interim chairman of the Authority may resign that office by giving notice in writing to the Secretary of State.
- (8) The Secretary of State may remove a person from office as interim chairman if he is satisfied that it would be in the best interests of the Authority for another member to be the interim chairman.]

Textual Amendments

- F4** Sch. 2 paras. 9A-9C inserted (19.1.2010) by Health Act 2009 (c. 21), s. 40(1), Sch. 3 para. 7 (with Sch. 3 para. 19); S.I. 2010/30, art. 2(d)

Remuneration and pensions of members

- 10 (1) The Authority may pay to the chairman or any of the other members of the Authority such remuneration as the Secretary of State may determine.
- (2) The Authority may pay, or make provision for paying, to or in respect of the chairman or any of the other members of the Authority such pensions, allowances, fees, expenses or gratuities as the Secretary of State may determine.
- (3) The Authority may make a payment to a person who ceases to hold office as chairman or other member of the Authority otherwise than on the expiry of his term of office if it appears to the Secretary of State that there are special circumstances which make it right for that person to receive compensation.
- (4) A payment under sub-paragraph (3) shall be of such amount as the Secretary of State may determine.

Commencement Information

- I22** Sch. 2 para. 10 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

Staff

- 11 The Authority may appoint such staff as it considers appropriate, on such terms and conditions as it may determine.

Commencement Information

- I23** Sch. 2 para. 11 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

Proceedings

- 12 Subject to any provision of this Act, the Authority may regulate its own procedure (including quorum).

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Commencement Information

I24 Sch. 2 para. 12 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

- 13 The validity of any proceedings of the Authority shall not be affected by—
- (a) any vacancy in the office of—
 - (i) chairman,
 - (ii) member appointed by the [^{F5}Welsh Ministers], or
 - (iii) member appointed by the relevant Northern Ireland department,
 - (b) any defect in a person's appointment as chairman or other member, or
 - (c) the composition for the time being of the membership of the Authority.

Textual Amendments

F5 Words in [Sch. 2 para. 13\(a\)\(ii\)](#) substituted (E.W.) (1.12.2015) by [Human Transplantation \(Wales\) Act 2013 \(anaw 5\)](#), [ss. 16\(1\)\(b\)](#), [21\(1\)](#) (with [s. 14](#)); [S.I. 2015/1679](#), [art. 3\(e\)](#)

Commencement Information

I25 Sch. 2 para. 13 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

Members' interests

- 14 (1) The Authority shall establish and maintain a system for the declaration and registration of private interests of its members.
- (2) The Authority shall publish entries recorded in the register of members' interests.

Commencement Information

I26 Sch. 2 para. 14 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

Finance

- 15 The Secretary of State may out of money provided by Parliament make payments to the Authority of such amounts, at such times and on such conditions (if any) as he considers appropriate.

Commencement Information

I27 Sch. 2 para. 15 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

Accounts and audit

- 16 (1) The Authority shall keep proper accounts and proper records in relation to its accounts.
- (2) The Authority shall prepare a statement of accounts in respect of each of its financial years.

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- (3) Any such statement of accounts must comply with any directions given by the Secretary of State with the approval of the Treasury as to—
- the information to be contained in it,
 - the manner in which that information is to be presented, and
 - the methods and principles according to which the statement is to be prepared.
- (4) The Authority shall send a copy of each statement of accounts required by sub-paragraph (2) to—
- the Secretary of State,
 - the [^{F6}Welsh Ministers],
 - the relevant Northern Ireland department, and
 - the Comptroller and Auditor General,
- before the end of such period after the end of the financial year to which the statement relates as the Secretary of State may specify by notice given to the Authority.
- (5) The relevant Northern Ireland department shall lay before the Northern Ireland Assembly each statement of accounts received by it under sub-paragraph (4).
- [^{F7}(5A) The Welsh Ministers shall lay before the National Assembly for Wales each statement of accounts received by them under sub-paragraph (4).]
- (6) The Comptroller and Auditor General shall—
- examine, certify and report on each statement of accounts received by him under sub-paragraph (4), and
 - lay a copy of each such statement of accounts, and of his report on it, before each House of Parliament.
- (7) The power under sub-paragraph (3) to give directions includes power to vary or revoke directions given in previous exercise of the power.
- (8) In this paragraph, “financial year” means—
- the period beginning with the date on which the Authority is established and ending with the next 31st March, and
 - each successive period of 12 months ending with 31st March.

Textual Amendments

- F6** Words in Sch. 2 para. 16(4)(b) substituted (E.W.) (1.12.2015) by Human Transplantation (Wales) Act 2013 (anaw 5), ss. 16(11)(c), 21(1) (with s. 14); S.I. 2015/1679, art. 3(e)
- F7** Sch. 2 para. 16(5A) inserted (E.W.) (1.12.2015) by Human Transplantation (Wales) Act 2013 (anaw 5), ss. 16(11)(d), 21(1) (with s. 14); S.I. 2015/1679, art. 3(e)
-

Commencement Information

- I28** Sch. 2 para. 16 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

Instruments

- 17 The application of the seal of the Authority shall be authenticated by the signature of any member of the Authority or of any other person who has been authorised for the purpose by the Authority, whether generally or specially.

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Commencement Information

I29 Sch. 2 para. 17 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

- 18 A document purporting—
- (a) to be duly executed under the seal of the Authority, or
 - (b) to be signed on its behalf,
- shall be received in evidence and be taken, without further proof, to be so executed or signed unless the contrary is shown.

Commencement Information

I30 Sch. 2 para. 18 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

Status

- 19 (1) The Authority is not to be regarded as the servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown.
- (2) The property of the Authority is not to be regarded as property of, or property held on behalf of, the Crown.

Commencement Information

I31 Sch. 2 para. 19 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

Supplementary powers

- 20 The Authority may do anything which is calculated to facilitate, or is conducive or incidental to, the carrying-out of its functions, but may not borrow money.

Commencement Information

I32 Sch. 2 para. 20 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

- 21 The Authority may delegate any of its functions (to such extent as it may determine)
- (a) to any member of the Authority,
 - (b) to any member of the staff of the Authority, or
 - (c) to a committee consisting of persons each of whom is—
 - (i) a member of the Authority, or
 - (ii) a member of the staff of the Authority.

Commencement Information

I33 Sch. 2 para. 21 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

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Application of Statutory Instruments Act 1946

- 22 The Statutory Instruments Act 1946 (c. 36) shall apply to any power to make orders or regulations conferred by an Act on the Authority as if the Authority were a Minister of the Crown.

Commencement Information

I34 Sch. 2 para. 22 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

Public records

- 23 In Schedule 1 to the Public Records Act 1958 (c. 51) (definition of public records), in Part 2 of the Table at the end of paragraph 3 the following entry is inserted at the appropriate place— “ Human Tissue Authority. ”

Commencement Information

I35 Sch. 2 para. 23 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

Investigation by Parliamentary Commissioner

- 24 In Schedule 2 to the Parliamentary Commissioner Act 1967 (c. 13) (departments and authorities subject to investigation), the following entry is inserted at the appropriate place— “ Human Tissue Authority. ”

Commencement Information

I36 Sch. 2 para. 24 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

House of Commons Disqualification

- 25 In Part 2 of Schedule 1 to the House of Commons Disqualification Act 1975 (c. 24) (bodies of which all members are disqualified), the following entry is inserted at the appropriate place— “ The Human Tissue Authority. ”

Commencement Information

I37 Sch. 2 para. 25 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

Northern Ireland Assembly Disqualification

- 26 In Part 2 of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 (c. 25) (bodies of which all members are disqualified), the following entry is inserted at the appropriate place— “ The Human Tissue Authority. ”

Commencement Information

I38 Sch. 2 para. 26 in force at 1.4.2005 by [S.I. 2005/919](#), [art. 3](#), [Sch.](#) (with [art. 2](#))

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Freedom of information

- 27 In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (c. 36) (public authorities), the following entry is inserted at the appropriate place— “ The Human Tissue Authority. ”

Commencement Information

I39 Sch. 2 para. 27 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

SCHEDULE 3 **E+W+N.I.**

Section 16

LICENCES FOR THE PURPOSES OF SECTION 16

Power to grant licence

- 1 The Authority may on application grant a licence for the purposes of section 16.

Commencement Information

- I40** Sch. 3 para. 1 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I41 Sch. 3 para. 1 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
I42 Sch. 3 para. 1 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
I43 Sch. 3 para. 1 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, Sch. (with art. 4)
I44 Sch. 3 para. 1 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)

Characteristics of licence

- 2 (1) A licence shall not authorise the carrying-on of more than one activity to which section 16 applies.
- (2) A licence shall—
- (a) specify the premises where the licensed activity is authorised to be carried on, and
 - (b) designate an individual as the person under whose supervision the licensed activity is authorised to be carried on.
- (3) A licence shall not authorise the licensed activity to be carried on—
- (a) on premises at different places, or
 - (b) under the supervision of more than one individual.
- (4) It shall be a condition of a licence—
- (a) that the licensed activity shall be carried on only on the premises specified in the licence;
 - (b) that the licensed activity shall be carried on only under the supervision of the individual designated in the licence as the person under whose supervision it is authorised to be carried on;

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- (c) that such information about such matters relating to the carrying-on of the licensed activity as may be specified in directions shall be recorded in such form as may be so specified;
 - (d) that any record made for the purposes of the condition in paragraph (c) shall be kept until the end of such period as may be specified in directions;
 - (e) that there shall be provided to such person and at such intervals as may be specified in directions—
 - (i) such copies of, or extracts from, any record to which the condition in paragraph (d) relates, and
 - (ii) such other information,as may be so specified;
 - (f) that there shall be paid to the Authority at such times as may be specified in directions sums of such amount as may be so specified in respect of its costs in connection with superintending compliance with the terms of licences.
- (5) Directions for the purposes of sub-paragraph (4) may be given in relation to licences generally, licences of a particular description or a particular licence.

Modifications etc. (not altering text)

- C1** Sch. 3 para. 2(4)(c)-(f) 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)(e)(6)(7)** (with reg. 2(3))
- C2** Sch. 3 para. 2(4)(c)-(f) applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C3** Sch. 3 para. 2(4)(c)-(f) 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**
- C4** Sch. 3 para. 2(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)(e)(6)(7)** (with reg. 2(3))
- C5** Sch. 3 para. 2(5) applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C6** Sch. 3 para. 2(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

- I45** Sch. 3 para. 2 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I46** Sch. 3 para. 2 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I47** Sch. 3 para. 2 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), **art. 3(3)**, **Sch.** (with arts. 4-6)
- I48** Sch. 3 para. 2 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), **art. 2**, **Sch.** (with art. 4)
- I49** Sch. 3 para. 2 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)

- 3 (1) This paragraph applies to a licence authorising the storage of anatomical specimens.
- (2) It shall be a condition of a licence to which this paragraph applies that storage at the premises specified in the licence of the body of a deceased person for use for the

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purpose of anatomical examination shall not begin before that body's storage there for use for that purpose has been authorised in writing by—

- (a) the designated individual, or
- (b) an individual who has the Authority's permission to give such authorisation (see paragraph 12).

- (3) It shall be a condition of a licence to which this paragraph applies that any anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the designated individual to have the specimen in his possession.
- (4) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give authority for the purposes of the condition in sub-paragraph (3) only if he is satisfied—
 - (a) that the person to whom authority is given is a suitable person to have the specimen in his possession, and
 - (b) that that person intends to use the specimen only for the purpose of education, training or research.
- (5) It shall be a condition of a licence to which this paragraph applies that any authority given for the purposes of the condition in sub-paragraph (3) shall specify—
 - (a) the person to whom the authority is given,
 - (b) the specimen to which the authority relates,
 - (c) the purpose for which the specimen may be used, and
 - (d) the duration of the authority.
- (6) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give such notice of any authorisation for the purposes of the condition in sub-paragraph (3) as may be specified in directions.
- (7) It shall be a condition of a licence to which this paragraph applies that such information about authorisations for the purposes of the condition in sub-paragraph (3) as may be specified in directions shall be recorded in such form as may be so specified.

Commencement Information

- I50** Sch. 3 para. 3 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I51** Sch. 3 para. 3 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
- I52** Sch. 3 para. 3 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
- I53** Sch. 3 para. 3 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, Sch. (with art. 4)
- I54** Sch. 3 para. 3 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)

- 4 (1) This paragraph applies to a licence authorising the activity mentioned in section 16(2)(e).
- (2) It shall be a condition of a licence to which this paragraph applies that any former anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the designated individual to have the specimen in his possession.

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- (3) The condition in sub-paragraph (2) does not apply to the release from storage of a specimen for the purpose of its decent disposal.
- (4) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give authority for the purposes of the condition in sub-paragraph (2) only if he is satisfied—
 - (a) that the person to whom authority is given is a suitable person to have the specimen in his possession, and
 - (b) that that person intends to use the specimen only for the purpose of education, training or research.
- (5) It shall be a condition of a licence to which this paragraph applies that any authority given for the purposes of the condition in sub-paragraph (2) shall specify—
 - (a) the person to whom the authority is given,
 - (b) the specimen to which the authority relates,
 - (c) the purpose for which the specimen may be used, and
 - (d) the duration of the authority.
- (6) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give such notice of any authorisation for the purposes of the condition in sub-paragraph (2) as may be specified in directions.
- (7) It shall be a condition of a licence to which this paragraph applies that such information about authorisations for the purposes of the condition in sub-paragraph (2) as may be specified in directions shall be recorded in such form as may be so specified.

Commencement Information

- I55** Sch. 3 para. 4 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I56** Sch. 3 para. 4 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
- I57** Sch. 3 para. 4 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
- I58** Sch. 3 para. 4 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, Sch. (with art. 4)
- I59** Sch. 3 para. 4 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)

Power to impose conditions

- 5 The Authority may grant a licence subject to such further conditions as it thinks fit.

Modifications etc. (not altering text)

- C7** Sch. 3 para. 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), regs. 1(2)(3), 8(2)(e)(6)(7) (with reg. 2(3))
- C8** Sch. 3 para. 5 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (S.I. 2012/1501), regs. 1(2)(3), 6 (as amended (14.7.2014) by S.I. 2014/1459, reg. 4)

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- C9** Sch. 3 para. 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

- I60** Sch. 3 para. 5 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I61 Sch. 3 para. 5 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
I62 Sch. 3 para. 5 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
I63 Sch. 3 para. 5 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, Sch. (with art. 4)
I64 Sch. 3 para. 5 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)

Pre-conditions to grant of licence

- 6 (1) The Authority may not grant a licence in pursuance of an application unless the following requirements are met.
- (2) The proposed designated individual must—
- (a) be the applicant for the licence, or
 - (b) consent to the application for the licence.
- (3) The Authority must be satisfied that the proposed designated individual—
- (a) is a suitable person to supervise the activity to be authorised by the licence, and
 - (b) will perform the duty under section 18.
- (4) Where the applicant for the licence is not the proposed designated individual, the Authority must be satisfied that the applicant is a suitable person to be the holder of the licence.
- (5) The Authority must be satisfied that the premises in respect of which the licence is to be granted are suitable for the activity to be authorised by the licence.
- (6) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by—
- (a) the applicant for the licence, and
 - (b) where different, the proposed designated individual.
- (7) In this paragraph, references to the proposed designated individual are to the individual whom the application proposes the licence designate as the person under whose supervision the activity to be authorised by the licence is to be carried on.

Commencement Information

- I65** Sch. 3 para. 6 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I66 Sch. 3 para. 6 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
I67 Sch. 3 para. 6 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
I68 Sch. 3 para. 6 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, Sch. (with art. 4)
I69 Sch. 3 para. 6 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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Power to revoke licence

- 7 (1) The Authority may revoke a licence on application by—
- (a) the holder of the licence, or
 - (b) the designated individual.
- (2) The Authority may revoke a licence otherwise than on an application under sub-paragraph (1) if—
- (a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading,
 - (b) it is satisfied that the designated individual has failed to discharge, or is unable because of incapacity to discharge, the duty under section 18,
 - (c) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,
 - (d) it ceases to be satisfied that the person to whom the licence is granted is a suitable person to be the holder of the licence,
 - (e) it ceases to be satisfied that the designated individual is a suitable person to supervise the licensed activity,
 - (f) the designated individual dies, ^{F8} ...
 - (g) it is satisfied that there has been any other material change of circumstances since the licence was granted [^{F9} or
 - (h) it is not satisfied that any third country premises are suitable for carrying out activities in a manner which secures that tissues or cells imported from a third country by an importing licence holder meet standards of quality and safety equivalent to those laid down in the 2007 Regulations].

[^{F10}(3) For the purposes of sub-paragraph (2)(h), “importing licence holder”, “third country” and “third country premises” have the same meaning as in the 2007 Regulations.]

Textual Amendments

- F8** Word in Sch. 3 para. 7(2)(f) omitted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by virtue of [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), reg. 1(2)(3), **9(4)(a)**
- F9** Sch. 3 para. 7(2)(h) and word inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), reg. 1(2)(3), **9(4)(b)**
- F10** Sch. 3 para. 7(3) inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), reg. 1(2)(3), **9(5)**

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 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)(e)(6)(7)** (with reg. 2(3))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C12** Sch. 3 paras. 7-11 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**

Changes to legislation: Human Tissue Act 2004 is up to date with all changes known to be in force on or before 03 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Commencement Information

- I70** Sch. 3 para. 7 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I71** Sch. 3 para. 7 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), **art. 2(3)(4)**, **Sch.** (with [arts. 4-6](#))
- I72** Sch. 3 para. 7 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), **art. 3(3)**, **Sch.** (with [arts. 4-6](#))
- I73** Sch. 3 para. 7 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), **art. 2**, **Sch.** (with [art. 4](#))
- I74** Sch. 3 para. 7 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](#))

Power to vary licence

- 8 (1) The Authority may on application by the holder of a licence vary the licence so as to substitute another individual for the designated individual if—
- (a) the application is made with the consent of the other individual, and
 - (b) the authority is satisfied that the other individual is a suitable person to supervise the licensed activity.
- (2) The Authority may vary a licence on application by—
- (a) the holder of the licence, or
 - (b) the designated individual.
- (3) The Authority may vary a licence without an application under sub-paragraph (2) if it has power to revoke the licence under paragraph 7(2).
- (4) The powers under sub-paragraphs (2) and (3) do not extend to making the kind of variation mentioned in sub-paragraph (1).
- (5) The Authority may vary a licence without an application under sub-paragraph (2) by—
- (a) removing or varying a condition of the licence, or
 - (b) adding a condition to the licence.
- (6) The powers conferred by this paragraph do not extend to the conditions required by paragraphs 2(4), 3 and 4.

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 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)(e)(6)(7)** (with [reg. 2\(3\)](#))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), **reg. 1(2)(3)**, **6**
- C12** Sch. 3 paras. 7-11 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

- I75** Sch. 3 para. 8 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I76** Sch. 3 para. 8 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), **art. 2(3)(4)**, **Sch.** (with [arts. 4-6](#))
- I77** Sch. 3 para. 8 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), **art. 3(3)**, **Sch.** (with [arts. 4-6](#))

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- I78** Sch. 3 para. 8 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, **Sch.** (with art. 4)
I79 Sch. 3 para. 8 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)

Power to suspend licence

- 9 (1) Where the Authority—
- (a) has reasonable grounds to suspect that there are grounds for revoking a licence, and
 - (b) is of the opinion that the licence should immediately be suspended,
- it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.
- (2) The Authority may continue suspension under sub-paragraph (1) by giving a further notice under that sub-paragraph.
- (3) Notice under sub-paragraph (1) shall be given to the designated individual or, where the designated individual has died or appears to the Authority to be unable because of incapacity to discharge the duty under section 18—
- (a) to the holder of the licence, or
 - (b) to some other person to whom the licence applies.
- (4) Subject to sub-paragraph (5), a licence shall be of no effect while a notice under sub-paragraph (1) is in force.
- (5) An application may be made under paragraph 7(1) or 8(1) or (2) notwithstanding the fact that a notice under sub-paragraph (1) is in force.

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 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)(e)(6)(7)** (with reg. 2(3))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (S.I. 2012/1501), reg. 1(2)(3), **6**
- C12** Sch. 3 paras. 7-11 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

- I80** Sch. 3 para. 9 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I81** Sch. 3 para. 9 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), **Sch.** (with arts. 4-6)
- I82** Sch. 3 para. 9 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), **Sch.** (with arts. 4-6)
- I83** Sch. 3 para. 9 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, **Sch.** (with art. 4)
- I84** Sch. 3 para. 9 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)

Procedure in relation to licensing decisions

- 10 (1) Before making a decision—

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- (a) to refuse an application for the grant, revocation or variation of a licence, or
 - (b) to grant an application for a licence subject to a condition under paragraph 5,
- the Authority shall give the applicant notice of the proposed decision and of the reasons for it.
- (2) Before making a decision under paragraph 7(2) or 8(3) or (5), the Authority shall give notice of the proposed decision and of the reasons for it to—
- (a) the holder of the licence, and
 - (b) where different, the designated individual.
- (3) A person to whom notice under sub-paragraph (1) or (2) is given has the right to require the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely—
- (a) oral representations by him, or a person acting on his behalf;
 - (b) written representations by him.
- (4) The right under sub-paragraph (3) 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 the notice under sub-paragraph (1) or (2) was given.
- (5) The Authority may by regulations make such additional provision about procedure in relation to the carrying-out of functions under this Schedule as it thinks fit.

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 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)(e)(6)(7)** (with reg. 2(3))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C12** Sch. 3 paras. 7-11 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

- I85** Sch. 3 para. 10 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I86** Sch. 3 para. 10 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), art. 2(3)(4), **Sch.** (with arts. 4-6)
- I87** Sch. 3 para. 10 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), art. 3(3), **Sch.** (with arts. 4-6)
- I88** Sch. 3 para. 10 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, **Sch.** (with art. 4)
- I89** Sch. 3 para. 10 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)

Notification of licensing decisions

- 11 (1) In the case of a decision to grant a licence, the Authority shall give notice of the decision to—
- (a) the applicant, and
 - (b) the person who is to be the designated individual.

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- (2) In the case of a decision to revoke a licence, the Authority shall give notice of the decision to—
 - (a) the holder of the licence, and
 - (b) the designated individual.
- (3) In the case of a decision to vary a licence on an application under paragraph 8(1), the Authority shall give notice of the decision to—
 - (a) the holder of the licence, and
 - (b) the person who is to be the designated individual.
- (4) In the case of any other decision to vary a licence, the Authority shall give notice of the decision to—
 - (a) the holder of the licence, and
 - (b) the designated individual.
- (5) In the case of a decision to refuse an application for the grant, revocation or variation of a licence, the Authority shall give notice of the decision to the applicant.
- (6) Subject to sub-paragraph (7), a notice under sub-paragraph (2), (4) or (5) shall include a statement of the reasons for the decision.
- (7) In the case of a notice under sub-paragraph (2) or (4), the notice is not required to include a statement of the reasons for the decision if the decision is made on an application under paragraph 7(1) or 8(2).

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 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)(e)(6)(7)** (with reg. 2(3))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C12** Sch. 3 paras. 7-11 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

- I90** Sch. 3 para. 11 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I91** Sch. 3 para. 11 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), art. 2(3)(4), **Sch.** (with arts. 4-6)
- I92** Sch. 3 para. 11 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), art. 3(3), **Sch.** (with arts. 4-6)
- I93** Sch. 3 para. 11 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, **Sch.** (with art. 4)
- I94** Sch. 3 para. 11 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)

Permission for the purposes of the licence condition required by paragraph 3(2)

- 12 (1) This paragraph applies to a licence authorising the storage of anatomical specimens.
- (2) The reference to the Authority’s permission in the condition of the licence required by paragraph 3(2) (“the authorisation condition”) is to—

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- (a) permission granted by the Authority on an application made, in conjunction with the application for the licence, by—
 - (i) the applicant for the licence, or
 - (ii) the person who, within the meaning of paragraph 6, is the proposed designated individual, or
 - (b) permission granted by the Authority on application by—
 - (i) the holder of the licence, or
 - (ii) the designated individual.
- (3) The Authority may grant permission to an individual for the purposes of the authorisation condition only if it is satisfied that the individual is a suitable person to give authorisation under that condition.
- (4) The Authority may revoke permission granted to an individual for the purposes of the authorisation condition—
- (a) on application by the individual, the designated individual or the holder of the licence, or
 - (b) if it ceases to be satisfied that the individual is a suitable person to give authorisation under that condition.
- (5) Before refusing an application for the grant or revocation of permission, the Authority shall give the applicant notice of the proposed refusal and of the reasons for it.
- (6) Before revoking permission under sub-paragraph (4)(b), the Authority shall give notice of the proposed revocation and of the reasons for it—
- (a) to the individual concerned, and
 - (b) to the designated individual and, where different, the holder of the licence.
- (7) Paragraph 10(3) and (4) shall apply in relation to notice under sub-paragraph (5) or (6) as to notice under paragraph 10(1).
- (8) In the case of a decision to refuse an application for the grant or revocation of permission, the Authority shall give notice of the decision to the applicant.
- (9) In the case of a decision to grant or revoke permission, the Authority shall give notice of the decision—
- (a) to the individual concerned, and
 - (b) to the designated individual and, where different, the holder of the licence.
- (10) Notice under sub-paragraph (8), and notice under sub-paragraph (9) of revocation under sub-paragraph (4)(b), shall include a statement of the reasons for the refusal or revocation.
- (11) Where the Authority—
- (a) has reasonable grounds to suspect that there are grounds for revoking permission granted to an individual for the purposes of the authorisation condition, and
 - (b) is of the opinion that the permission should immediately be suspended,
- it may by notice suspend the permission for such period not exceeding three months as may be specified in the notice.
- (12) The Authority may continue suspension under sub-paragraph (11) by giving a further notice under that sub-paragraph.

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- (13) Notice under sub-paragraph (11) shall be given to—
- (a) the individual concerned, and
 - (b) the designated individual and, where different, the holder of the licence.

Commencement Information

- I95** Sch. 3 para. 12 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I96** Sch. 3 para. 12 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), **Sch.** (with arts. 4-6)
- I97** Sch. 3 para. 12 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), **Sch.** (with arts. 4-6)
- I98** Sch. 3 para. 12 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, **Sch.** (with art. 4)
- I99** Sch. 3 para. 12 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)

Applications under this Schedule

- 13^{F11F12}**(1) The Authority may by regulations make provision about applications under this Schedule^{F11}[^{F12}, Schedule 1 to the 2007 Regulations and Schedule 1 to the 2012 Regulations] and may, in particular, make provision about—
- (a) the form and content of such an application,
 - (b) the information to be supplied with such an application, and
 - (c) procedure in relation to the determination of such an application.
- (2) An application under this Schedule shall be accompanied by such fee (if any) as the Authority may determine.]

Textual Amendments

- F11** Words in Sch. 3 para. 13(1) 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)**33**
- F12** Words in Sch. 3 para. 13(1) substituted (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), **25(7)**

Modifications etc. (not altering text)

- C13** Sch. 3 para. 13 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 \(S.I. 2007/1523\)](#), regs. 1(2)(3), **8(2)(e)(6)(7)** (with reg. 2(3))
- C14** Sch. 3 para. 13 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 \(S.I. 2012/1501\)](#), regs. 1(2)(3), **6** (as amended (14.7.2014) by S.I. 2014/1459, art. 4)
- C15** Sch. 3 para. 13 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

- I100** Sch. 3 para. 13 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I101** Sch. 3 para. 13 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), **Sch.** (with arts. 4-6)

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- I102** Sch. 3 para. 13 in force at 7.4.2006 for specified purposes by S.I. 2006/404 , art. 3(3) , Sch. (with arts. 4-6)
I103 Sch. 3 para. 13 in force at 31.7.2006 for specified purposes by S.I. 2006/1997 , art. 2 , Sch. (with art. 4)
I104 Sch. 3 para. 13 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)

SCHEDULE 4 U.K.

Section 45

SECTION 45: SUPPLEMENTARY

PART 1 U.K.

QUALIFYING CONSENT

Introductory

- 1 This Part of this Schedule makes provision for the interpretation of “qualifying consent” in section 45(1)(a)(i).

Commencement Information

- I105** Sch. 4 para. 1 in force at 20.10.2005 for specified purposes by S.I. 2005/2792 , art. 2(2)(j)
I106 Sch. 4 para. 1 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)

Qualifying consent

- 2 (1) In relation to analysis of DNA manufactured by the body of a person who is alive, “qualifying consent” means his consent, except where sub-paragraph (2) applies.
- (2) Where—
- the person is a child,
 - neither a decision of his to consent, nor a decision of his not to consent, is in force, and
 - either he is not competent to deal with the issue of consent or, though he is competent to deal with that issue, he fails to do so,
- “qualifying consent” means the consent of a person who has parental responsibility for him.
- (3) In relation to analysis of DNA manufactured by the body of a person who has died an adult, “qualifying consent” means—
- if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;
 - if paragraph (a) does not apply, the consent of a person who stood in a qualifying relationship to him immediately before he died.
- (4) In relation to analysis of DNA manufactured by the body of a person who has died a child, “qualifying consent” means—

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

Commencement Information

I107 Sch. 4 para. 2 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I108 Sch. 4 para. 2 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)

Application to Scotland

- 3
- (1) In its application to Scotland, paragraph 2 has effect with the following amendments.
 - (2) In sub-paragraphs (2) and (4)(b)(i) and (ii), for parental responsibility for there is substituted “parental responsibilities in relation to”.
 - (3) At the end there is inserted—
 - “(5) In this paragraph—
 - adult means a person who has attained the age of 16 years;
 - child means a person who has not attained the age of 16 years;
 - parental responsibilities has the meaning given by section 1(3) of the Children (Scotland) Act 1995 (c. 36).”

Commencement Information

I109 Sch. 4 para. 3 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I110 Sch. 4 para. 3 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)

PART 2 **U.K.**

USE FOR AN EXCEPTED PURPOSE

Introductory

- 4 This Part of this Schedule makes provision for the interpretation of “use for an excepted purpose” in section 45(1)(a)(ii).

Commencement Information

I111 Sch. 4 para. 4 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

Changes to legislation: Human Tissue Act 2004 is up to date with all changes known to be in force on or before 03 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

II12 Sch. 4 para. 4 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)

Purposes of general application

- 5 (1) Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose—
- (a) the medical diagnosis or treatment of the person whose body manufactured the DNA;
 - (b) purposes of functions of a coroner;
 - (c) purposes of functions of a procurator fiscal in connection with the investigation of deaths;
 - (d) the prevention or detection of crime;
 - (e) the conduct of a prosecution;
 - (f) purposes of national security;
 - (g) implementing an order or direction of a court or tribunal, including one outside the United Kingdom.
- (2) For the purposes of sub-paragraph (1)(d), detecting crime shall be taken to include—
- (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 sub-paragraph (1)(d) to the detection of crime includes any detection outside the United Kingdom of any crime or suspected crime.
- (3) In sub-paragraph (1)(e), the reference to a prosecution includes a prosecution brought in respect of a crime in a country or territory outside the United Kingdom.
- (4) In this paragraph, a reference to a crime includes 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 a country or territory outside the United Kingdom),
 - (b) is, or corresponds to, conduct which, if it all took place in any one part of the United Kingdom, would constitute one or more criminal offences, or
 - ^{F13}(c) constitutes one or more [^{F13}service offences within the meaning of the Armed Forces Act 2006.]
- (5) Sub-paragraph (1)(g) shall not be taken to confer any power to make orders or give directions.

Textual Amendments

F13 Words in Sch. 4 para. 5(4)(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. 242; 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)

C16 Sch. 4 para. 5(4)(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

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Commencement Information

- I113** Sch. 4 para. 5 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
I114 Sch. 4 para. 5 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)

Purpose of research in connection with disorders, or functioning, of the human body

- 6 (1) Use of the results of an analysis of DNA for the purpose of research in connection with disorders, or the functioning, of the human body is use for an excepted purpose if the bodily material concerned is the subject of an order under sub-paragraph (2).
(2) The Secretary of State may by regulations specify circumstances in which the High Court or the Court of Session may order that this paragraph apply to bodily material.

Commencement Information

- I115** Sch. 4 para. 6 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
I116 Sch. 4 para. 6 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)

Purposes relating to existing holdings

- 7 Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose if the bodily material concerned is an existing holding—
(a) clinical audit;
(b) determining the cause of death;
(c) education or training relating to human health;
(d) establishing after a person's death the efficacy of any drug or other treatment administered to him;
(e) obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
(f) performance assessment;
(g) public health monitoring;
(h) quality assurance;
(i) research in connection with disorders, or the functioning, of the human body;
(j) transplantation.

Commencement Information

- I117** Sch. 4 para. 7 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
I118 Sch. 4 para. 7 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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Purposes relating to material from body of a living person

8 Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose if the bodily material concerned is from the body of a living person—

- (a) clinical audit;
- (b) education or training relating to human health;
- (c) performance assessment;
- (d) public health monitoring;
- (e) quality assurance.

Commencement Information

I119 Sch. 4 para. 8 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I120 Sch. 4 para. 8 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)

9 (1) Use of the results of an analysis of DNA for the purpose of obtaining scientific or medical information about the person whose body manufactured the DNA is use for an excepted purpose if—

- (a) the bodily material concerned is the subject of a direction under sub-paragraph (2) or (3) or an order under sub-paragraph (4) or (5), and
- (b) the information may be relevant to the person for whose benefit the direction is given or order is made.

(2) If the Authority is satisfied—

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

it may direct that this paragraph apply to the material for the benefit of the other person.

(3) If the Authority is satisfied—

- (a) that bodily material has come from the body of a living person,
- (b) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the purpose of obtaining scientific or medical information about the person from whose body the material has come (“the donor”),
- (c) that reasonable efforts have been made to get the donor to decide whether to consent to the use of the material for that purpose,
- (d) that there is no reason to believe—

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- (i) that the donor has died,
 - (ii) that a decision of the donor to refuse to consent to the use of the material for that purpose is in force, or
 - (iii) that the donor lacks capacity to consent to the use of the material for that purpose, and
- (e) that the donor has been given notice of the application for the exercise of the power conferred by this sub-paragraph,

it may direct that this paragraph apply to the material for the benefit of the other person.

(4) If the Court of Session is satisfied—

- (a) that bodily material has come from the body of a living person,
- (b) that it is not reasonably possible to trace the person from whose body the material has come (“the donor”),
- (c) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the purpose of obtaining scientific or medical information about the donor, and
- (d) that there is no reason to believe—
 - (i) that the donor has died,
 - (ii) that a decision of the donor to refuse consent to the use of the material for that purpose is in force, or
 - (iii) that the donor is an incapable adult within the meaning of the Adults with Incapacity (Scotland) Act 2000 (asp 4),

it may order that this paragraph apply to the material for the benefit of the other person.

(5) If the Court of Session is satisfied—

- (a) that bodily material has come from the body of a living person,
- (b) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the purpose of obtaining scientific or medical information about the person from whose body the material has come (“the donor”),
- (c) that reasonable efforts have been made to get the donor to decide whether to consent to the use of the material for that purpose,
- (d) that there is no reason to believe—
 - (i) that the donor has died,
 - (ii) that a decision of the donor to refuse to consent to the use of the material for that purpose is in force, or
 - (iii) that the donor is an incapable adult within the meaning of the Adults with Incapacity (Scotland) Act 2000, and
- (e) that the donor has been given notice of the application for the exercise of the power conferred by this sub-paragraph,

it may order that this paragraph apply to the material for the benefit of the other person.

Commencement Information

I121 Sch. 4 para. 9 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

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I122 Sch. 4 para. 9 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)

- 10 Use of the results of an analysis of DNA for the purpose of research in connection with disorders, or the functioning, of the human body is use for an excepted purpose if—
- (a) the bodily material concerned is from the body of a living person,
 - (b) the research is ethically approved in accordance with regulations made by the Secretary of State, and
 - (c) the analysis is to be carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the individual from whose body the material has come can be identified.

Commencement Information

I123 Sch. 4 para. 10 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I124 Sch. 4 para. 10 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)

Purpose authorised under section 1

- 11 Use of the results of an analysis of DNA for a purpose specified in paragraph 7 is use for an excepted purpose if the use in England and Wales, or Northern Ireland, for that purpose of the bodily material concerned is authorised by section 1(1) or (10)(c).

Commencement Information

I125 Sch. 4 para. 11 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I126 Sch. 4 para. 11 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)

Purposes relating to DNA of adults who lack capacity to consent

- 12 (1) Use of the results of an analysis of DNA for a purpose specified under subparagraph (2) is use for an excepted purpose if—
- (a) the DNA has been manufactured by the body of a person who—
 - (i) has attained the age of 18 years and, under the law of England and Wales or Northern Ireland, lacks capacity to consent to analysis of the DNA, or
 - (ii) under the law of Scotland, is an adult with incapacity within the meaning of the Adults with Incapacity (Scotland) Act 2000 (asp 4), and
 - (b) neither a decision of his to consent to analysis of the DNA for that purpose, nor a decision of his not to consent to analysis of it for that purpose, is in force.
- (2) The Secretary of State may by regulations specify for the purposes of this paragraph purposes for which DNA may be analysed.

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Commencement Information

- I127** Sch. 4 para. 12 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I128 Sch. 4 para. 12 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)

Power to amend paragraphs 5, 7 and 8

- 13 The Secretary of State may by order amend paragraph 5, 7 or 8 for the purpose of—
- (a) varying or omitting any of the purposes specified in that paragraph, or
 - (b) adding to the purposes so specified.

Commencement Information

- I129** Sch. 4 para. 13 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I130 Sch. 4 para. 13 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)

SCHEDULE 5 **E+W+N.I.**

Section 48

POWERS OF INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of statutory records

- 1 (1) A duly authorised person may require a person to produce for inspection any records which he is required to keep by, or by virtue of, this Act.
- (2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—
- (a) in a visible and legible form, or
 - (b) in a form from which they can readily be produced in a visible and legible form.
- (3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

Commencement Information

- I131** Sch. 5 para. 1 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I132 Sch. 5 para. 1 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
I133 Sch. 5 para. 1 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
I134 Sch. 5 para. 1 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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Entry and inspection of licensed premises

- 2 (1) A duly authorised person may at any reasonable time enter and inspect any premises in respect of which a licence is in force.
- (2) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences.

Commencement Information

- I135** Sch. 5 para. 2 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I136** Sch. 5 para. 2 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
- I137** Sch. 5 para. 2 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
- I138** Sch. 5 para. 2 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)

Entry and search in connection with suspected offence

- 3 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—
- (a) that an offence under Part 1 or 2 ^[F14] or under the Human Transplantation (Wales) Act 2013] is being, or has been, committed on any premises, and
- (b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,
- he may by signed warrant authorise a duly authorised person to enter the premises, if need be by force, and search them.
- (2) The conditions referred to are—
- (a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;
- (b) that the premises are unoccupied;
- (c) that the occupier is temporarily absent;
- (d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.
- (3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

Textual Amendments

- F14** Words in Sch. 5 para. 3(1)(a) inserted (E.W.) (1.12.2015) by Human Transplantation (Wales) Act 2013 (anaw 5), ss. 16(12)(a), 21(1) (with s. 14); S.I. 2015/1679, art. 3(e)

Commencement Information

- I139** Sch. 5 para. 3 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I140** Sch. 5 para. 3 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
- I141** Sch. 5 para. 3 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)

Changes to legislation: Human Tissue Act 2004 is up to date with all changes known to be in force on or before 03 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

I142 Sch. 5 para. 3 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)

Execution of warrants

- 4 (1) Entry and search under a warrant under paragraph 3 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.
- (2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.
- (3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—
- (a) produce the warrant to the occupier, and
 - (b) give him—
 - (i) a copy of the warrant, and
 - (ii) an appropriate statement.
- (4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—
- (a) produce the warrant to that other person,
 - (b) give him—
 - (i) a copy of the warrant, and
 - (ii) an appropriate statement, and
 - (c) leave a copy of the warrant in a prominent place on the premises.
- (5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.
- (6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.
- (7) Where the premises in relation to which a warrant under paragraph 3 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall, when leaving the premises, leave them as effectively secured as he found them.

Commencement Information

- I143** Sch. 5 para. 4 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I144** Sch. 5 para. 4 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
- I145** Sch. 5 para. 4 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
- I146** Sch. 5 para. 4 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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Seizure in the course of inspection or search

- 5 (1) A duly authorised person entering and inspecting premises under paragraph 2 may seize anything on the premises which he has reasonable grounds to believe may be required for purposes of the Authority’s functions relating to the grant, revocation, variation or suspension of licences.
- (2) A duly authorised person entering and searching premises under a warrant under paragraph 3 may seize anything on the premises which he has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under Part 1 or 2 [^{F15}or under the Human Transplantation (Wales) Act 2013].
- (3) Where a person has power under sub-paragraph (1) or (2) to seize anything, he may take such steps as appear to be necessary for preserving the thing or preventing interference with it.
- (4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.
- (5) Where by virtue of sub-paragraph (1) or (2) a person seizes anything, he shall leave on the premises from which the thing was seized a statement giving particulars of what he has seized and stating that he has seized it.

Textual Amendments

F15 Words in Sch. 5 para. 5(2) inserted (E.W.) (1.12.2015) by Human Transplantation (Wales) Act 2013 (anaw 5), ss. 16(12)(b), 21(1) (with s. 14); S.I. 2015/1679, art. 3(e)

Commencement Information

I147 Sch. 5 para. 5 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I148 Sch. 5 para. 5 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)

I149 Sch. 5 para. 5 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)

I150 Sch. 5 para. 5 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)

Powers: supplementary

- 6 (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.
- (2) Power under this Schedule to inspect or search any premises includes, in particular—
- (a) power to inspect any equipment found on the premises,
 - (b) power to inspect and take copies of any records found on the premises, and
 - (c) in the case of premises in respect of which a licence is in force, power to observe the carrying-on on the premises of the licensed activity.
- (3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person’s control as are necessary to enable the power of entry, inspection or search to be exercised.

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Commencement Information

- I151** Sch. 5 para. 6 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I152** Sch. 5 para. 6 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I153** Sch. 5 para. 6 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
- I154** Sch. 5 para. 6 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)

- 7 (1) A person’s right to exercise a power under this Schedule is subject to his producing evidence of his entitlement to exercise it, if required.
- (2) As soon as reasonably practicable after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—
- (a) prepare a written report of the inspection or search, and
 - (b) if requested to do so by the appropriate person, give him a copy of the report.
- (3) In sub-paragraph (2), the “appropriate person” means—
- (a) in relation to premises in respect of which a licence is in force, the designated individual (as defined in section 41);
 - (b) in relation to any other premises, the occupier.

Commencement Information

- I155** Sch. 5 para. 7 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I156** Sch. 5 para. 7 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I157** Sch. 5 para. 7 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
- I158** Sch. 5 para. 7 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)

Enforcement

- 8 (1) A person commits an offence if—
- (a) he fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 6(3), or
 - (b) he intentionally obstructs the exercise of any right under this Schedule.
- (2) A person guilty of an offence under this paragraph is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Commencement Information

- I159** Sch. 5 para. 8 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I160** Sch. 5 para. 8 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I161** Sch. 5 para. 8 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
- I162** Sch. 5 para. 8 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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Interpretation

- 9 In this Schedule, “duly authorised person”, in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision.

Commencement Information

- I163** Sch. 5 para. 9 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I164 Sch. 5 para. 9 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
I165 Sch. 5 para. 9 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
I166 Sch. 5 para. 9 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)

SCHEDULE 6 U.K.

Section 56

CONSEQUENTIAL AMENDMENTS

Wills Act 1837 (c. 26)

- 1 In section 1 of the Wills Act 1837, in the definition of “will”, after “child,” there is inserted “ and also to an appointment by will of a representative under section 4 of the Human Tissue Act 2004, ”.

Commencement Information

- I167** Sch. 6 para. 1 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I168 Sch. 6 para. 1 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)

Anatomy Act 1984 (c. 14)

- 2 In section 4 of the Anatomy Act 1984 (lawful examinations), in subsection (4) (which is expressed to be subject to subsections (5) to (8)), for “(5)” there is substituted “ (6) ”.

Commencement Information

- I169** Sch. 6 para. 2 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I170 Sch. 6 para. 2 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)

Coroners Act 1988 (c. 13)

- 3 (1) The Coroners Act 1988 is amended as follows.
 (2) In section 19 (post-mortem examination without inquest), after subsection (1) (which confers power to direct a person to make a post-mortem examination) there is inserted—

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“(1A) No direction under subsection (1) above shall have effect to require a person to make a post-mortem examination if the making of the examination by him would contravene section 16(1) of the Human Tissue Act 2004 (under which a person may make a post-mortem examination only under the authority of a licence under that Act).”

(3) In section 21 (which confers powers to direct a person to make a post-mortem examination in connection with an inquest), after subsection (4) there is inserted—

“(4A) No direction under this section shall have effect to require a person to make a post-mortem examination if the making of the examination by him would contravene section 16(1) of the Human Tissue Act 2004 (under which a person may make a post-mortem examination only under the authority of a licence under that Act).”

Commencement Information

I171 Sch. 6 para. 3 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I172 Sch. 6 para. 3 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)

Human Organ Transplants Act 1989 (c. 31)

4 In section 1(1)(a) of the Human Organ Transplants Act 1989, for “Great Britain” there is substituted “Scotland”.

Commencement Information

I173 Sch. 6 para. 4 in force at 20.10.2005 by S.I. 2005/2792, art. 2(2)(h)

Criminal Justice and Police Act 2001 (c. 16)

5 (1) Part 2 of the Criminal Justice and Police Act 2001 (powers of seizure) is amended as follows.

(2) In section 57 (retention of seized items), in subsection (1) (provisions in relation to which the section has effect), at the end there is inserted—

“(q) paragraph 5(4) of Schedule 5 to the Human Tissue Act 2004.”

(3) In section 66 (interpretation of Part 2), in subsection (4) (references to a search to include references to activities authorised by virtue of specified powers), at the end there is inserted—

“(n) paragraph 2 of Schedule 5 to the Human Tissue Act 2004 (entry and inspection of licensed premises).”

(4) In Schedule 1 (powers of seizure), in Part 1 (powers to which section 50 of the Act applies), after paragraph 73D there is inserted—

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“Human Tissue Act 2004 (c. 00)

- 73E Each of the powers of seizure conferred by the provisions of paragraph 5(1) (seizure of material relevant to licensing functions) and (2) (seizure of evidence of offences) of Schedule 5 to the Human Tissue Act 2004.”

Commencement Information

- I174** Sch. 6 para. 5 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I175 Sch. 6 para. 5 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
I176 Sch. 6 para. 5 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
I177 Sch. 6 para. 5 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)

Enterprise Act 2002 (c. 40)

- 6 (1) Paragraph 3(1)(b), (2) and (3) of Schedule 2 shall be taken to be within the definition of “provision” in section 268 of the Enterprise Act 2002 (c. 40) (power to remove bankruptcy disqualifications under pre-8th November 2002 provisions or extend them to, or replace them with disqualifications of, persons subject to bankruptcy restrictions regimes).
- (2) In its application by virtue of sub-paragraph (1), section 268 of the Enterprise Act 2002 (c. 40) shall have effect with the following modifications—
- (a) subsections (5)(d), (6) to (8) and (15) (power to make application of disqualification provision subject to person’s discretion) are omitted, and
- (b) for subsection (13) (order under section to be made by statutory instrument after parliamentary approval of a draft) there is substituted—
- “(13) An order under this section—
- (a) must be made by statutory instrument, and
- (b) shall be subject to annulment in pursuance of a resolution of either House of Parliament.”

Commencement Information

- I178** Sch. 6 para. 6 in force at 1.4.2005 by S.I. 2005/919, art. 3, Sch. (with art. 2)

Asylum and Immigration (Treatment of Claimants, etc.) Act 2004

- 7 ^[F16] In section 4 of the Asylum and Immigration (Treatment of Claimants, etc.) Act 2004 (trafficking people for exploitation), in subsection (4)(b), for “the Human Organ Transplants (Northern Ireland) Order 1989 (S.I. 1989 / 2408 (N.I. 21))” there is substituted “ under section 32 or 33 of the Human Tissue Act 2004 ” .]

Textual Amendments

- F16** Sch. 6 para. 7 repealed (N.I.) (26.4.2013) by Criminal Justice Act (Northern Ireland) 2013 (c. 7), s. 15(1), Sch. 4 Pt. 2

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Commencement Information

I179 Sch. 6 para. 7 in force at 20.10.2005 by S.I. 2005/2792, **art. 2(2)(i)** (with art. 3(1)(a))

SCHEDULE 7 U.K.

Section 57

REPEALS AND REVOCATIONS

PART 1 U.K.

REPEALS

Commencement Information

I180 Sch. 7 Pt. 1 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(f)(j)**

I181 Sch. 7 Pt. 1 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)

<i>Short title and chapter</i>	<i>Extent of repeal</i>
Human Tissue Act 1961 (c. 54)	The whole Act.
Human Tissue Act (Northern Ireland) 1962 (c. 19 (N.I.))	The whole Act.
Anatomy Act 1984 (c. 14)	The whole Act.
Corneal Tissue Act 1986 (c. 18)	The whole Act.
Human Organ Transplants Act 1989 (c. 31)	The whole Act.
National Health Service and Community Care Act 1990 (c. 19)	In Schedule 9, paragraph 7.
Human Fertilisation and Embryology Act 1990 (c. 37)	In Schedule 4, paragraphs 8 and 9.
Health Authorities Act 1995 (c. 17)	In Schedule 1, paragraph 92.

PART 2 U.K.

REVOCATIONS

Commencement Information

I182 Sch. 7 Pt. 2 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(g)**

I183 Sch. 7 Pt. 2 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)

Title

Extent of revocation

Changes to legislation: *Human Tissue Act 2004 is up to date with all changes known to be in force on or before 03 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Corneal Tissue (Northern Ireland) Order 1988 (S.I. 1988/1844 (N.I. 14))	The whole Order.
Human Organ Transplants (Northern Ireland) Order 1989 (S.I. 1989/2408 (N.I. 21))	The whole Order.
Health and Personal Social Services (Northern Ireland) Order 1991 (S.I. 1991/194 (N.I. 1))	In Part II of Schedule 5, the entry relating to the Human Tissue Act (Northern Ireland) 1962.
Anatomy (Northern Ireland) Order 1992 (S.I. 1992/1718 (N.I. 11))	The whole Order.

Changes to legislation:

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[View outstanding changes](#)

Changes and effects yet to be applied to :

- s. 1(1A) inserted by [2013 anaw 5 s. 16\(2\)\(a\)](#)
- s. 1(2) words substituted by [2009 c. 25 Sch. 21 para. 48](#)
- s. 5(3) words substituted by [2009 c. 25 Sch. 21 para. 49\(2\)](#)
- s. 5(4)(a)(i) words substituted by [2009 c. 25 Sch. 21 para. 49\(3\)](#)
- s. 32(3A) words inserted by [S.I. 2019/483 reg. 2\(2\)\(b\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/483, reg. 2(2) substituted immediately before IP completion day by S.I 2020/1035, reg. 3)
- s. 32(3A) words substituted by [S.I. 2019/483 reg. 2\(2\)\(a\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/483, reg. 2(2) substituted immediately before IP completion day by S.I 2020/1035, reg. 3)
- Sch. 6 para. 3 repealed by [2009 c. 25 Sch. 23 Pt. 1](#)

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- s. 29(7) inserted by [2013 anaw 5 s. 15\(4\)\(e\)](#)
- s. 43(5A) inserted by [2009 c. 25 Sch. 21 para. 50](#)