

Status: Point in time view as at 31/10/2009.

Changes to legislation: Human Tissue Act 2004, SCHEDULE 4 is up to date with all changes known to be in force on or before 31 July 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)

SCHEDULES

SCHEDULE 4

Section 45

SECTION 45: SUPPLEMENTARY

PART 1

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

- I1** Sch. 4 para. 1 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I2 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—
- (a) the person is a child,
 - (b) neither a decision of his to consent, nor a decision of his not to consent, is in force, and
 - (c) 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—
- (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, 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

- I3** Sch. 4 para. 2 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I4** 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

- I5** Sch. 4 para. 3 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I6** 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

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

- I7** Sch. 4 para. 4 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

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- 18** 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
 - ^{F1}(c) constitutes one or more [^{F1}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

- F1** 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)

- C1** 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

- I9** Sch. 4 para. 5 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I10 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

- I11** Sch. 4 para. 6 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I12 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

- I13** Sch. 4 para. 7 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I14 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

I15 Sch. 4 para. 8 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)

I16 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

I17 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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I18 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

- I19** Sch. 4 para. 10 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I20 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

- I21** Sch. 4 para. 11 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I22 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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- I23** Sch. 4 para. 12 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I24 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

- I25** Sch. 4 para. 13 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
I26 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)

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