

2006 No. 1997 (C. 68)

HUMAN TISSUE

The Human Tissue Act 2004 (Commencement No. 5 and Transitional Provisions) Order 2006

Made - - - -

20th July 2006

The Secretary of State for Health, makes this Order in exercise of the powers conferred upon her by sections 58(3) and (4) and 60(2) of the Human Tissue Act 2004(a). In accordance with sections 58(5) to (7) and 60(3) to (5) of that Act she has consulted the National Assembly for Wales, the relevant Northern Ireland Department(b) and the Scottish Ministers before exercising these powers.

Citation and interpretation

1.—(1) This Order may be cited as the Human Tissue Act 2004 (Commencement No.5 and Transitional Provisions) Order 2006.

(2) In this Order—

“the Act” means the Human Tissue Act 2004.

Appointed Day

2.—(1) This article is subject to article 4.

(2) The provisions of the Act listed in the Schedule, so far as not already in force and so far as they apply for the purposes set out in paragraph (3), shall come into force on 31st July 2006.

(3) The purposes mentioned in paragraph (2) are—

- (a) to enable the Authority to grant or refuse licences;
- (b) to require that applications for licences are accompanied by such fee as the Authority may determine in accordance with paragraph 13(2) of Schedule 3 to the Act;
- (c) to enable the Authority to impose conditions on licences;
- (d) to enable the Authority to vary, revoke or suspend licences;
- (e) to enable the Authority to give directions under sections 23 and 24 of the Act and under paragraph 2(4) of Schedule 3 to the Act;
- (f) to require the Authority to give notice of its decision in accordance with paragraphs 10 and 11 of Schedule 3 to the Act;
- (g) to enable a person to whom a notice is given in accordance with paragraph 10 of Schedule 3 to the Act to require the Authority to give him an opportunity to make representations in accordance with that paragraph;

(a) 2004 (c..30).

(b) See section 54(1), which defines “relevant Northern Ireland Department” as the Department of Health, Social Services and Public Safety.

- (h) to enable applicants to require the Authority to reconsider decisions to revoke or vary licences;
- (i) to enable the Authority to reconsider decisions to revoke or vary licences;
- (j) to enable persons aggrieved by a decision on reconsideration to appeal on a point of law to the High Court.

3.—(1) This article is subject to articles 4 and 7.

(2) Subject to paragraph (3), the Act shall come into force on 1st September 2006 so far as not already in force on that date.

(3) Sections 5 and 8 (prohibition of activities without consent etc., restriction of activities in relation to donated material), shall come into force on 1st December 2006.

Transitional arrangements: pending applications

4.—(1) Subject to paragraph (4), a licence shall be deemed to have been granted in relation to an application where—

- (a) a licence is required for the purposes of the activities listed in section 16(2) of the Act,
- (b) an application for such a licence is received by the Authority on or before 31st August 2006, and
- (c) an application fee is received by the Authority on or before 31st August 2006 in relation to that application.

(2) For the purposes of paragraph (1) “application fee” means such fee (if any) as the Authority determines under paragraph 13(2) of Schedule 3 to the Act.

(3) A licence deemed to have been granted under paragraph (1) shall have effect from 1st September 2006 and shall continue to have effect until either a licence is granted on the application or the application is refused.

(4) This article does not apply in relation to an application for a licence if a licence would have been deemed to have been granted, by virtue of article 5(1) of the Human Tissue Act 2005 (Commencement No. 4) Order 2006(a), if the application had been received by the Authority by 31st March 2006.

(5) Subject to paragraphs (6) and (7), the provisions of the Act in force or brought into force by this Order apply to a licence deemed to have been granted under paragraph (1) to the same extent as they would apply to a licence granted under the Act.

(6) Paragraphs 2(2), 3(2)(b), 6 and 12 of Schedule 3 to the Act shall not apply in relation to a licence deemed to have been granted under paragraph (1).

(7) For the purposes of a licence deemed to have been granted under paragraph (1) references in Schedule 3 to the Act to—

- (a) “the premises specified in the licence” shall mean the premises specified in the application form to which the licence relates; and
- (b) “the individual designated in the licence” and “the designated individual” shall mean the person specified in the application form to which the licence relates as the proposed designated individual.

Transitional arrangements: existing consent to use body or parts of body for anatomical examination

5.—(1) Paragraph (2) applies where, before section 1 of the Act comes into force—

- (a) a person (“P”) expressed a request in accordance with section 4(1) of the Anatomy Act 1984(b), or article 6(1) of the Anatomy (Northern Ireland) Order 1992(c) (“the Northern Ireland Order”), that his body be used for anatomical examination, and
- (b) P dies following the coming into force of section 1 of the Act.

(a) S.I. 2005/404.

(b) 1984 (c. 14).

(c) S.I. 1992/1718 (N.I. 11).

(2) Subject to paragraph (3), during the relevant period, a request made in accordance with section 4(1) of the Anatomy Act 1984, or article 6(1) of the Northern Ireland Order, shall be treated for the purposes of section 1 of the Act as appropriate consent in relation to—

- (a) the storage of P's body, or separated parts of his body, for use for the purpose of anatomical examination,
- (b) the use of his body, or separated parts of his body, for that purpose.

(3) A request made in accordance with section 4(1) of the Anatomy Act 1984 or article 6(1) of the Northern Ireland Order, shall not be treated for the purposes of section 1 of the Act as appropriate consent where the person doing the section 1 activity has reason to believe that P has withdrawn his consent.

(4) Where for the purpose of section 1 of the Act there would not be appropriate consent in relation to an activity but for the request made under the Anatomy Act 1984 or the Northern Ireland Order being treated for those purposes as appropriate consent in relation to the activity, paragraphs (1) to (3) of section 1 do not authorise the doing of that activity otherwise than in accordance with that request.

(5) In this article and article 6, "the relevant period", in relation to a person, means whichever is the shorter of—

- (a) the period of three years beginning with the date of the person's death, and
- (b) the period beginning with that date and ending when the anatomical examination of the person's body is concluded.

Transitional arrangements: existing anatomical specimens Northern Ireland

6.—(1) This article applies where a person dies during the three years immediately preceding the coming into force of section 1.

(2) Paragraph (3) applies where—

- (a) before section 1 comes into force, authority is given under article 6(2) or (3) of the Anatomy (Northern Ireland) Order 1992 ("the Northern Ireland Order") for the person's body to be used for anatomical examination, and
- (b) section 1 comes into force before the anatomical examination of the person's body is concluded.

(3) During so much of the relevant period as falls after section 1 comes into force, that authority shall be treated for the purposes of section 1 as appropriate consent in relation to—

- (a) the storage of the person's body, or separated parts of his body, for use for the purpose of anatomical examination, and
- (b) the use of his body, or separated parts of his body, for that purpose.

(4) Paragraph (5) applies where—

- (a) before section 1 comes into force, authority is given under article 6(2) or (3) of the Northern Ireland Order for possession of parts (or any specified parts) of the person's body to be held after anatomical examination of his body is concluded, and
- (b) anatomical examination of the person's body is concluded—
 - (i) after section 1 comes into force, but
 - (ii) before the end of the period of three years beginning with the date of the person's death.

(5) With effect from the conclusion of the anatomical examination of the person's body, that authority shall be treated for the purposes of section 1 as appropriate consent in relation to—

- (a) the storage for use for a qualifying purpose of a part of the person's body which—
 - (i) is a part to which that authority relates, and
 - (ii) is such that the person cannot be recognised simply by examination of the part, and
- (b) the use for a qualifying purpose of such a part of the person's body.

(6) Where for the purposes of section 1 there would not be appropriate consent in relation to the activity but for authority given under the Northern Ireland Order being treated for those purposes as appropriate

consent in relation to the activity in question, paragraphs (1) and (3) of section 1 do not authorise the doing of the activity otherwise than in accordance with that authority.

(7) In this article “qualifying purpose” means a purpose specified in paragraph 6 or 9 of Schedule 1 to the Act (research in connection with disorder or the functioning of the human body, education or training relating to human health).

Transitional arrangements and savings: applications for organ transplants received by the Unrelated Live Transplant Regulatory Authority (“ULTRA”) before 1st September 2006

7.—(1) Paragraphs (2) to (4) apply in a case where—

- (a) a registered medical practitioner has referred a case to the Unrelated Live Transplant Authority (“ULTRA”) in accordance with—
 - (i) regulation 3 of the Human Organ Transplants (Unrelated Persons) Regulations 1989(a), or
 - (ii) regulation 2 of the Human Organ Transplants (Unrelated Persons) Regulations (Northern Ireland) 1990(b), and
- (b) ULTRA has received that reference before 1st September 2006.

(2) The provisions set out in paragraph (3) shall continue to have effect for the purposes of a case mentioned in paragraph (1) as if those provisions had not been repealed by the Act.

(3) The provisions mentioned in paragraph (2) are—

- (a) sections 2 and 4 to 7 of the Human Organ Transplants Act 1989(c),
- (b) the Human Organ Transplants (Unrelated Persons) Regulations 1989,
- (c) the Human Organ Transplants (Establishment of Relationship) Regulations 1998(d),
- (d) articles 1, 2, 4 and 6 of the Human Organ Transplants (Northern Ireland) Order 1989(e)
- (e) the Human Organ Transplants (Unrelated Persons) Regulations (Northern Ireland) 1990,
- (f) the Human Organ Transplants (Establishment of Relationship) Regulations (Northern Ireland) 1998(f).

(4) Section 33(1) and (2) of the Act do not have effect for the purposes of a case mentioned in paragraph (1).

Signed by authority of the Secretary of State for Health

Rosie Winterton
Minister of State
Department of Health

20th July 2006

SCHEDULE

Article 2(2)

Provisions of the Act coming into force on 31st July 2006 for the purposes of article 2 of this Order

<i>Provision of the Act</i>	<i>Subject matter</i>
Section 16	Licence requirement
Section 17	Persons to whom licence applies

- (a) S.I. 1989/2480.
- (b) S.R. 1990/357.
- (c) 1989 (c.31).
- (d) S.I. 1998/1428.
- (e) S.I. 1989/2408 (N.I. 21).
- (f) S.R 1998/389.

Section 18	Duty of the designated individual
Section 19	Right to reconsideration of licensing decision
Section 20	Appeals committee
Section 21	Procedure on reconsideration
Section 22	Appeal on a point of law
Section 23	Conduct of licensed activities
Section 24	Changes of licence circumstances
Section 37	Directions
Section 39	Criminal justice purposes
Section 40	Religious relics
Section 41	Interpretation of Part 2
Section 44	Surplus tissue
Section 52	Orders and regulations
Section 53	Relevant material
Section 54	General interpretation
Section 58	Transition
Schedule 3	Licences for the purpose of section 16

EXPLANATORY NOTE

(This note is not part of the Order)

This Order provides for the coming into force of provisions of the Human Tissue Act 2004 (c.30) (“the Act”).

Article 2 provides for the coming into force on 31st July 2006 of the provisions listed in the Schedule to the extent necessary to enable the Human Tissue Authority (“the Authority”) to deal with applications for licences which will be required under section 16(1) and (2) of the Act from 1st September 2006.

Article 3 provides, subject to Articles 4 and 7, for the coming into force on 1st September 2006 of the rest of the provisions of the Act so far as they have not already been brought into force by this Order and previous orders and for the coming into force of sections 5 and 8 of the Act (offences relating to carrying out section 1 activities without consent etc. and the restriction of activities in relation to donated material).

The two main themes of the provisions being brought into force are that after 1st September 2006 it will be necessary, with some exceptions, to:

- (a) obtain consent from a person before it is lawful to remove relevant material or to store or use their body, or relevant material from their body, for the purposes listed in the Schedule 1 to the Act, and
- (b) obtain a licence in order to use or store relevant material for the purposes specified in Schedule 1 to the Act.

Other provisions being brought into force also make it an offence not to comply with these requirements and make it an offence in certain circumstances to possess anatomical specimens and former anatomical specimens away from licensed premises (section 30 and 31), to remove transplantable material from a live person or to use such material in certain circumstances (section 33) or to possess bodily material with the intention of performing DNA analysis on it or using the results of such analysis.

Articles 4 to 7 make transitional arrangements.

Article 4 provides that where an application for a licence under section 16 is made on or before 31st August 2006 then a licence will be deemed to have been granted on that application until the Authority grants or refuses a licence on the application. This does not apply in relation to the types of licence which have been required since 7 April 2006, under provisions of the Act which were brought into force by the previous commencement order.

Article 5 provides that existing requests made under the Anatomy Act 1984 or the corresponding Northern Ireland provisions before 1st September 2006 are to be treated as appropriate consent for the purpose of the Human Tissue Act.

Article 6 provides that authority given under the Anatomy (Northern Ireland) Order 1992 before 1st September 2006 in relation to a person who died in the three years before the Act comes into force shall be treated as appropriate consent for the purpose of the Human Tissue Act in certain circumstances.

Article 7 provides that where a registered medical practitioner has referred a matter to the Unrelated Live Transplants Regulatory Authority (“ULTRA”) in accordance with the Human Organ Transplants (Unrelated Persons) Regulations 1989, or the corresponding Northern Ireland legislation, and ULTRA has received it before 1st September 2006, then certain provisions of the Human Organ Transplant Act and legislation made under that Act, or the corresponding Northern Ireland legislation, will apply to that case and section 33(1) and (2) will not apply.

NOTE AS TO EARLIER COMMENCEMENT ORDERS

(This note is not part of the Order)

<i>Provision</i>	<i>Date of Commencement</i>	<i>S.I. No.</i>
Section 1(9) (partially)	20 October 2005	2005/2792
Section 1(11) (partially)	20 October 2005	2005/2792
Section 4(10) (partially)	20 October 2005	2005/2792
Section 6 (partially)	20 October 2005	2005/2792
Section 7(4)	20 October 2005	2005/2792
Section 10(9)	20 October 2005	2005/2792
Section 13	1 April 2005	2005/919
Section 14	1 April 2005	2005/919
Section 15	1 April 2005	2005/919
Section 16 (partially)	19 February 2006	2006/404
Section 16(3) and (5)	20 October 2005	2005/2792
Section 16(6) (partially)	20 October 2005	2005/2792
Section 17 (partially)	19 February 2006	2006/404
Section 18 (partially)	19 February 2006	2006/404
Section 19 (partially)	19 February 2006	2006/404
Section 20 (partially)	19 February 2006	2006/404
Section 21(5)	19 February 2006	2006/404
Section 21 (partially)	19 February 2006	2006/404
Section 22 (partially)	19 February 2006	2006/404
Section 23 (partially)	19 February 2006	2006/404
Section 24 (partially)	19 February 2006	2006/404
Section 25 (partially)	19 February 2006	2006/404
Section 26 (partially)	1 April 2005	2005/919
Section 27	1 April 2005	2005/919
Section 28	1 April 2005	2005/919
Section 29 (partially)	1 April 2005	2005/919
Section 32	20 October 2005	2005/2792
Section 33(3) and (4)	20 October 2005	2005/2792
Section 34(1)	1 April 2005	2005/919
Section 35	1 April 2005	2005/919
Section 36	1 April 2005	2005/919
Section 37	19 February 2006	2006/404
Section 38	1 April 2005	2005/919
Section 39 (partially)	1 April 2005	2005/919
Section 39 (partially)	19 February 2006	2006/404
Section 40 (partially)	1 April 2005	2005/919
Section 41 (partially)	1 April 2005	2005/919
Section 41 (partially)	19 February 2006	2006/404
Section 42	1 April 2005	2005/919
Section 44	19 February 2006	2006/404
Section 45 (partially)	20 October 2005	2005/2792
Section 46	20 October 2005	2005/2792
Section 47	3 October 2005	2005/2632
Section 48 (partially)	20 October 2005	2005/2792
Section 48 (partially)	19 February 2006	2006/404
Section 49 (partially)	19 February 2006	2006/404
Section 50 (partially)	19 February 2006	2006/404
Section 51 (partially)	20 October 2005	2005/2792

Section 51 (partially)	19 February 2006	2006/404
Section 52 (partially)	20 October 2005	2005/2792
Section 52 (partially)	19 February 2006	2006/404
Section 53 (partially)	1 April 2005	2005/919
Section 53 (partially)	19 February 2006	2006/404
Section 54 (partially)	1 April 2005	2005/919
Section 54 (10)	20 October 2005	2005/2792
Section 54 (partially)	20 October 2005	2005/2792
Section 54 (partially)	19 February 2006	2006/404
Section 55	1 April 2005	2005/919
Section 56	19 February 2006	2006/404
Section 57 (partially)	20 October 2005	2005/2792
Section 58(1) and (2)	19 February 2006	2006/404
Schedule 1 to the Act	1 April 2005	2005/919
Schedule 2 to the Act	1 April 2005	2005/919
Schedule 3 to the Act, paragraph 10(5)	20 October 2005	2005/2792
Schedule 3 to the Act, paragraph 13(1)	20 October 2005	2005/2792
Schedule 3 to the Act (partially)	19 February 2006	2006/404
Schedule 4 to the Act, paragraph 6(2)	20 October 2005	2005/2792
Schedule 4 to the Act, paragraph 10(b)	20 October 2005	2005/2792
Schedule 4 to the Act, paragraph 12(2)	20 October 2005	2005/2792
Schedule 4 to the Act, paragraph 13	20 October 2005	2005/2792
Schedule 5 to the Act, paragraph 4(5)	20 October 2005	2005/2792
Schedule 5 to the Act (partially)	19 February 2006	2006/404
Schedule 6 to the Act, paragraph 6	1 April 2005	2005/919
Schedule 6 to the Act (partially)	19 February 2006	2006/404
Schedule 7 to the Act, paragraph 1 (partially)	20 October 2005	2005/2792

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