
STATUTORY INSTRUMENTS

2006 No. 1997

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

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;
- (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(1), 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(2), or article 6(1) of the Anatomy (Northern Ireland) Order 1992(3) (“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.

(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,

(1) S.I.2005/404.

(2) 1984 (c. 14).

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

(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(4), or
 - (ii) regulation 2 of the Human Organ Transplants (Unrelated Persons) Regulations (Northern Ireland) 1990(5), 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(6),
- (b) the Human Organ Transplants (Unrelated Persons) Regulations 1989,
- (c) the Human Organ Transplants (Establishment of Relationship) Regulations 1998(7),
- (d) articles 1, 2, 4 and 6 of the Human Organ Transplants (Northern Ireland) Order 1989(8)
- (e) the Human Organ Transplants (Unrelated Persons) Regulations (Northern Ireland) 1990,
- (f) the Human Organ Transplants (Establishment of Relationship) Regulations (Northern Ireland) 1998(9).

(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

20th July 2006

Rosie Winterton
Minister of State
Department of Health

(4) S.I. 1989/2480.
(5) S.R. 1990/357.
(6) 1989 (c. 31).
(7) S.I. 1998/1428.
(8) S.I. 1989/2408 (N.I. 21).
(9) S.R. 1998/389.