

Human Organ Transplants Act 1989

1989 CHAPTER 31

An Act to prohibit commercial dealings in human organs intended for transplanting; to restrict the transplanting of such organs between persons who are not genetically related; and for supplementary purposes connected with those matters. [27th July 1989]

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

1.—(1) A person is guilty of an offence if in Great Britain he—

Prohibition of commercial dealings in human organs.

- (a) makes or receives any payment for the supply of, or for an offer to supply, an organ which has been or is to be removed from a dead or living person and is intended to be transplanted into another person whether in Great Britain or elsewhere;
- (b) seeks to find a person willing to supply for payment such an organ as is mentioned in paragraph (a) above or offers to supply such an organ for payment;
- (c) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, such an organ; or
- (d) takes part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.

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(2) Without prejudice to paragraph (b) of subsection (1) above, a person is guilty of an offence if he causes to be published or distributed, or knowingly publishes or distributes, in Great Britain an advertisement—

- (a) inviting persons to supply for payment any such organs as are mentioned in paragraph (a) of that subsection or offering to supply any such organs for payment; or
- (b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned in paragraph (c) of that subsection.

(3) In this section "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing—

- (a) the cost of removing, transporting or preserving the organ to be supplied; or
- (b) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying an organ from his body.

(4) In this section "advertisement" includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons.

(5) A person guilty of an offence under subsection (1) above is liable on summary conviction to imprisonment for a term not exceeding three months or a fine not exceeding level 5 on the standard scale or both; and a person guilty of an offence under subsection (2) above is liable on summary conviction to a fine not exceeding level 5 on that scale.

Restriction on transplants between persons not genetically related.

2.—(1) Subject to subsection (3) below, a person is guilty of an offence if in Great Britain he—

- (a) removes from a living person an organ intended to be transplanted into another person; or
- (b) transplants an organ removed from a living person into another person,

unless the person into whom the organ is to be or, as the case may be, is transplanted is genetically related to the person from whom the organ is removed.

(2) For the purposes of this section a person is genetically related to—

- (a) his natural parents and children;
- (b) his brothers and sisters of the whole or half blood;

(c) the brothers and sisters of the whole or half blood of either of his natural parents; and

(d) the natural children of his brothers and sisters of the whole or half blood or of the brothers and sisters of the whole or half blood of either of his natural parents; but persons shall not in any particular case be treated as related in any of those ways unless the fact of the relationship has been established by such means as are specified by regulations made by the Secretary of State.

(3) The Secretary of State may by regulations provide that the prohibition in subsection (1) above shall not apply in cases where—

(a) such authority as is specified in or constituted by the regulations is satisfied—

- (i) that no payment has been or is to be made in contravention of section 1 above; and
- (ii) that such other conditions as are specified in the regulations are satisfied; and

(b) such other requirements as may be specified in the regulations are complied with.

(4) The expenses of any such authority shall be defrayed by the Secretary of State out of money provided by Parliament.

(5) A person guilty of an offence under this section is liable on summary conviction to imprisonment for a term not exceeding three months or a fine not exceeding level 5 on the standard scale or both.

(6) The power to make regulations under this section shall be exercisable by statutory instrument.

(7) Regulations under subsection (2) above shall be subject to annulment in pursuance of a resolution of either House of Parliament; and no regulations shall be made under subsection (3) above unless a draft of them has been laid before and approved by a resolution of each House of Parliament.

3.—(1) The Secretary of State may make regulations requiring such persons as are specified in the regulations to supply to such authority as is so specified such information as may be so specified with respect to transplants that have been or are proposed to be carried out in Great Britain using organs removed from dead or living persons.

Information about transplant operations.

(2) Any such authority shall keep a record of information supplied to it in pursuance of the regulations made under this section.

(3) Any person who without reasonable excuse fails to comply with those regulations is guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale; and any person who, in purported compliance with those regulations, knowingly or recklessly supplies information which is false or misleading in a material respect is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(4) The power to make regulations under this section shall be exercisable by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

Offences by
bodies
corporate.

4.—(1) Where an offence under this Act committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or any person who was purporting to act in any such capacity, he as well as the body corporate is guilty of the offence and is liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, subsection (1) above shall apply to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

Prosecutions.

5. No proceedings for an offence under section 1 or 2 above shall be instituted in England and Wales except by or with the consent of the Director of Public Prosecutions.

Northern
Ireland.
1974 c. 28.

6. An Order in Council under paragraph 1(1)(b) of Schedule 1 to the Northern Ireland Act 1974 (legislation for Northern Ireland in the interim period) which contains a statement that it is made only for purposes corresponding to the purposes of this Act—

- (a) shall not be subject to paragraph 1(4) and (5) of that Schedule (affirmative resolution of both Houses of Parliament); but
- (b) shall be subject to annulment in pursuance of a resolution of either House of Parliament.

7.—(1) This Act may be cited as the Human Organ Transplants Act 1989. Short title,
interpretation,
commence-
ment and
extent.

(2) In this Act "organ" means any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body.

(3) Section 1 above shall not come into force until the day after that on which this Act is passed and section 2(1) above shall not come into force until such day as the Secretary of State may appoint by an order made by statutory instrument.

(4) Except for section 6 this Act does not extend to Northern Ireland.

 STATUTORY INSTRUMENTS

1991 No. 1645

**MEDICAL PROFESSION
 NATIONAL HEALTH SERVICE,
 ENGLAND AND WALES**
**The Human Organ Transplants
 and the United Kingdom Transplant Support
 Service Authority (Miscellaneous Amendments)
 Regulations 1991**

<i>Made</i> - - - -	<i>18th July 1991</i>
<i>Laid before Parliament</i>	<i>24th July 1991</i>
<i>Coming into force</i>	<i>1st September 1991</i>

In exercise of powers conferred by sections 13, 18(1) and 128(1) of the National Health Service Act 1977(a) and by section 3(1) of the Human Organ Transplants Act 1989(b) and of all other powers enabling me in that behalf I hereby make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Human Organ Transplants and the United Kingdom Transplant Support Service Authority (Miscellaneous Amendments) Regulations 1991 and shall come into force on 1st September 1991.

Amendment of 1989 Regulations

2.—(1) The Human Organ Transplants (Supply of Information) Regulation 1989(c) shall be amended in accordance with the following paragraphs of this regulation.

(2) In regulation 1(2) there shall be inserted after the definition of "health service hospital" the following definition—

""NHS trust" means a National Health Service trust, in relation to England and Wales, established in pursuance of section 5 of the National Health Service and Community Care Act 1990(d) and, in relation to Scotland, established in pursuance of section 12A of the National Health Service (Scotland) Act 1978(e);"

(3) The following sub-paragraph shall be substituted for sub-paragraphs (a) and (b) of regulation 2(1)—

(a) 1977 c.49. Sections 13 and 18 were amended by the Health Services Act 1980 (c.53), Schedule 1, paragraph 33 and paragraphs 38 and 92 respectively, and section 18 was modified by the Family Practitioner Committees (Consequential Modifications) Order 1985 (S.I. 1985/39), article 7(2); section 128(1), which is cited for the definition of "regulations", was amended by the National Health Service and Community Care Act 1990, section 26(2);

(b) 1989 c.31.

(c) S.I. 1989/2108, as amended by S.I. 1991/408.

(d) 1990 c.19.

(e) 1978 c.29. Section 12A was inserted by section 31 of the National Health Service and Community Care Act 1990.

- “(a) Where the removal of the relevant organ was carried out in England or Wales—
- (i) except where the removal was carried out in a hospital managed by a special health authority or an NHS trust, to the District Health Authority for the district in which the removal of the relevant organ was carried out,
 - (ii) where the removal was carried out in a hospital managed by a special health authority or an NHS trust, to that authority or trust;
- (b) where the removal of the relevant organ was carried out in Scotland—
- (i) except where the removal was carried out in a hospital managed by an NHS trust, to the Health Board for the area in which the removal of the relevant organ was carried out, or
 - (ii) where the removal was carried out in a hospital managed by an NHS trust, to that trust.”

(4) The following sub-paragraph shall be substituted for sub-paragraphs (a) and (b) of regulation 2(2)—

- “(a) where the relevant organ was received in England or Wales—
- (i) except where the organ was received in a hospital managed by a special health authority or an NHS trust, to the District Health Authority for the district in which the relevant organ was received, or
 - (ii) where the organ was received in a hospital managed by a special health authority or an NHS trust, to that authority or trust;
- (b) where the relevant organ was received in Scotland—
- (i) except where the organ was received in a hospital managed by an NHS trust, to the Health Board for the area in which the organ was received, or
 - (ii) where the organ was received in a hospital managed by an NHS trust, to that trust.”

(5) In paragraph 1 of Part I and of Part II to the Schedule there shall be inserted in each case—

- (a) after the word “authority” the words “or NHS trust”;
- (b) after the word “or”, in the second place where it appears, the words “the name of the authority”.

(6) In paragraph 5(c) of Part I of the Schedule after the word “number” insert “, if any,”.

(7) In Part I of the Schedule there shall be added after paragraph 7:

“8. The date and time of the removal of the organ.”

(8) For paragraph 5 of Part II of the Schedule there shall be substituted the following paragraph:

“5. The full names and the hospital case note number of the recipient, and the date and time of carrying out the transplant.”.

(9) In paragraph 6(c) of Part II of the Schedule after the word “number” insert “, if any,”.

Amendment of 1991 Regulations

3. In regulation 2(1) of the United Kingdom Transplant Support Service Authority Regulations 1991(a) for the words “the provisions of the Act” there shall be substituted “the enactments”.

Revocation of regulation 10(2)(b) of the 1991 Regulations

4. Regulation 10(2)(b) of the United Kingdom Transplant Support Service Authority Regulations 1991 is hereby revoked.

18th July 1991

William Waldegrave
One of Her Majesty's Principal Secretaries of State

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make two minor corrections to the United Kingdom Transplant Support Service Authority Regulations 1991, and make various amendments to the Human Organ Transplants (Supply of Information) Regulations 1989. In the case of the 1989 Regulations these are mainly consequential upon the establishment of National Health Service trusts but include minor corrections to the details of information to be supplied by practitioners about transplant operations and add requirements to provide the date and time of the removal of an organ the time when a transplant was carried out and the hospital case-note number of the recipient.

STATUTORY INSTRUMENTS

1989 No. 2106 (C. 65)

MEDICAL PROFESSION

**The Human Organ Transplants Act 1989
(Commencement) Order 1989**

Made - - - - 14th November 1989.

In exercise of powers conferred by section 7(3) of the Human Organ Transplants Act 1989(a) and of all other powers enabling me in that behalf, I hereby make the following Order:—

Appointed day

1. The day appointed for the coming into force of section 2(1) of the Human Organ Transplants Act 1989 shall be 1st April 1990.

Citation

2. This Order may be cited as the Human Organ Transplants Act 1989 (Commencement) Order 1989.

14th November 1989

Kenneth Clarke
One of Her Majesty's Principal
Secretaries of State

EXPLANATORY NOTE

(This note is not part of the Order)

Section 2(1) of the Human Organ Transplants Act 1989 prohibits the transplant of organs from, and to, living persons who are not genetically related; and this Order appoints 1st April 1990 for it to come into force.

 STATUTORY INSTRUMENTS

~~1989 No. 2107~~ Superseded by Statutory
Instrument 1998 No. 1428

MEDICAL PROFESSION

The Human Organ Transplants (Establishment of Relationship) Regulations 1989

<i>Made</i>	<i>14th November 1989</i>
<i>Laid before Parliament</i>	<i>15th November 1989</i>
<i>Coming into force</i>	<i>1st April 1990</i>

In exercise of powers conferred by section 2(2) of the Human Organ Transplants Act 1989 (a) and of all other powers enabling me in that behalf, I hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Organ Transplants (Establishment of Relationship) Regulations 1989 and shall come into force on 1st April 1990.

(2) In these Regulations—

“donor” means a living person from whom an organ is proposed to be removed which is intended to be transplanted into another person and “recipient” means the person into whom the organ is intended to be transplanted;

“tester” means a person approved by the Secretary of State to carry out the tests described in regulation 2 of these Regulations.

The means by which genetic relationship is to be established

2.—(1) The means by which the fact of a genetic relationship is to be established for the purposes of section 2 of the Human Organ Transplants Act 1989 are the carrying out by a tester of the appropriate tests described in paragraph (2) of this regulation.

(2) The tester shall carry out on the donor and the recipient and on such relatives of each as appear to the tester to be necessary—

- (a) tests for the antigenic products of the Human Major Histocompatibility system HLA-A, HLA-B and HLA-DR, using conventional serological techniques, and
- (b) tests to establish HLA-DR beta and HLA-DQ beta gene restriction fragment length polymorphisms, and
- (c) where the tests in the preceding sub-paragraphs do not establish a genetic relationship between the donor and the recipient, tests to establish DNA polymorphisms, using at least 2 multi-locus gene probes, and
- (d) where the tests in the preceding sub-paragraphs do not establish a genetic relationship between the donor and the recipient, further tests to establish DNA polymorphisms, using at least 5 single locus polymorphic probes.

14th November 1989

Kenneth Clarke
One of Her Majesty's Principal Secretaries of State

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations provide that the genetic relationship between proposed living donors of human organs and proposed recipients is to be established in each case by persons approved for that purpose by the Secretary of State using tests specified in the Regulations.

 STATUTORY INSTRUMENTS

1989 No. 2108

MEDICAL PROFESSION

 The Human Organ Transplants (Supply of Information)
 Regulations 1989

<i>Made</i> - - - -	<i>14th November 1989</i>
<i>Laid before Parliament</i>	<i>15th November 1989</i>
<i>Coming into force</i> -	<i>1st April 1990</i>

In exercise of powers conferred by section 3(1) of the Human Organ Transplants Act 1989(a) and of all other powers enabling me in that behalf, I hereby make the following Regulations:-

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Organ Transplants (Supply of Information) Regulations 1989 and shall come into force on 1st April 1990.

(2) In these Regulations—

“the Act” means the Human Organ Transplants Act 1989;

“authority” means a District Health Authority, a special health authority or a Health Board;

“District Health Authority” means a District Health Authority within the meaning of the National Health Service Act 1977(b);

“donor” means a dead or living person from whom an organ is to be removed which is proposed to be transplanted into another person and “recipient” means a person into whom an organ is, or is proposed to be, transplanted;

“Health Board” means a Health Board within the meaning of the National Health Service (Scotland) Act 1978(c);

“health service hospital” means—

(a) in relation to England and Wales, a health service hospital within the meaning of the National Health Service Act 1977; and

(b) in relation to Scotland, a health service hospital within the meaning of the National Health Service (Scotland) Act 1978;

“relevant organ” means any of the following, namely, kidney, heart, lung, pancreas or liver;

“special health authority” means a special health authority established in pursuance of section 11 of the National Health Service Act 1977;

(a) 1989 c.31.

(b) 1977 c.49; section 128 (interpretation and construction) was amended by the Health Services Act 1980 (c.53), Schedule 1, paragraph 77.

(c) 1978 c.29; section 108 provides for interpretation and construction and was amended by the Health Services Act 1980 (c.53), Schedule 6, paragraph 6(a).

- "South Western Regional Health Authority" means the authority of that name constituted in accordance with the National Health Service (Constitution of Regional Health Authorities) Order 1975(a).

Information to be supplied about transplant operations

2.—(1) A registered medical practitioner who has removed a relevant organ from a dead or living person which is proposed to be transplanted into another person shall supply the information specified in Part I of the Schedule to these Regulations to the South Western Regional Health Authority and—

- (a) where the removal of the relevant organ was carried out in England and Wales,
 - (i) to the District Health Authority for the district in which the removal of the relevant organ was carried out, or
 - (ii) where the removal was carried out in a hospital managed by a special health authority, to that authority;
- (b) where the removal was carried out in Scotland, to the Health Board for the area in which the removal of the relevant organ was carried out.

(2) A registered medical practitioner who has received a relevant organ removed from a dead or living person which is proposed to be transplanted into another person shall supply the information specified in Part II of the Schedule to these Regulations to the South Western Regional Health Authority and—

- (a) where the organ was received in England and Wales,
 - (i) to the District Health Authority for the district in which the relevant organ was received, or
 - (ii) where the organ was received in a hospital managed by a special health authority, to that authority;
- (b) where the organ was received in Scotland, to the Health Board for the area in which the organ was received.

Kenneth Clarke

14th November 1989

One of Her Majesty's Principal Secretaries of State

SCHEDULE

Regulation 2

INFORMATION TO BE SUPPLIED BY REGISTERED MEDICAL PRACTITIONERS ABOUT TRANSPLANT OPERATIONS

PART I

PARTICULARS WITH RESPECT TO RELEVANT ORGANS REMOVED FOR PROPOSED TRANSPLANTS

1. The name of the hospital or other place at which the removal of the organ was carried out, and the name of the authority which manages the hospital, in the case of a health service hospital, or with which the hospital or other place is registered under Part II of the Registered Homes Act 1984(b) or the Nursing Homes Registration (Scotland) Act 1938(c).
2. Description of the organ.
3. Whether the donor was living at the time of the removal of the organ.
4. The full names of the donor and the hospital case note number of the donor.

- (a) S.I. 1975/1100, to which there is an amendment not relevant to these Regulations.
- (b) 1984 c.23.
- (c) 1938 c.73, as amended by the Health Services Act 1980 c.53.

5. If the donor was living at the time of the removal of the organ—
 - (a) whether or not, for the purposes of section 2(2) of the Act, a genetic relationship to the recipient has been established by the means specified in the Human Organ Transplants (Establishment of Relationship) Regulations 1989(a),
 - (b) if such a genetic relationship to the recipient has been established, the name of the person who carried out the test to establish that relationship,
 - (c) where no such genetic relationship to the recipient has been established, the reference number in respect of the proposed transplant allocated by the authority specified in or constituted by regulations made under section 2(3) of the Act.
6. If, after removal, the relevant organ or any part of the organ was considered to be unsuitable for transplanting into another person, the reason why it was so considered and the manner of disposal.
7. The full names of the registered medical practitioner by whom the relevant organ was removed, the appointment held by him and the establishment at which he holds the appointment.

PART II

PARTICULARS WITH RESPECT TO ORGANS WHICH HAVE BEEN OR ARE PROPOSED TO BE TRANSPLANTED

1. The name of the hospital or other place at which the relevant organ proposed to be transplanted into another person is received, and the name of the authority which manages the hospital, in the case of a health service hospital, or with which the hospital or other place is registered under Part II of the Registered Homes Act 1984 or the Nursing Homes Registration (Scotland) Act 1938.
2. Description of the Organ.
3. The name and address of the hospital or other place at which the organ was removed.
4. If the organ was removed outside the United Kingdom, the country in which the organ was removed and the reference number allocated to that organ by the United Kingdom Transplant Service, when arrangements were made to import it.
5. The full names of the recipient, and the date on which the transplant was carried out.
6. If the donor was living at the time of the removal of the organ—
 - (a) whether or not, for the purposes of section 2(2) of the Act, a genetic relationship to the recipient has been established by the means specified in the Human Organ Transplants (Establishment of Relationship) Regulations 1989,
 - (b) if such a genetic relationship to the recipient has been established, the name of the person who carried out the test to establish that relationship,
 - (c) where no such genetic relationship to the recipient has been established, the reference number in respect of the proposed transplant allocated by the authority specified in or constituted by regulations made under section 2(3) of the Act.
7. If the transplant was carried out in a health service hospital, whether—
 - (a) the recipient was entitled to the provision of the treatment by virtue of regulations made by the Council of the European Communities under Article 51 of the Treaty establishing the European Economic Community, or
 - (b) the recipient was a national of another country, and was entitled to be provided with such treatment by virtue of an agreement entered into between that Community and that country, or
 - (c) the treatment of the recipient was provided under an arrangement for providing health care mutually agreed between the Government of the United Kingdom and the Government of a country or territory specified in Schedule 2 to the National Health Service (Charges to Overseas Visitors) Regulations 1989(b).

(a) S.I. 1989/2107.

(b) S.I. 1989/306.

8. If the relevant organ or any part of the organ was not transplanted into another person, the reason why it was not so used and the manner of disposal.

9. The full names of the registered medical practitioner who carried out, or proposed to carry out, the transplant, the appointment held by him and the establishment at which he holds the appointment.

EXPLANATORY NOTE

(This Note is not part of the Regulations)

These Regulations require registered medical practitioners to supply specified information about transplants to the South Western Regional Health Authority and, in England and Wales, District Health Authorities or special health authorities or, in Scotland, Health Boards.

Part I of the Schedule specifies the information required about certain organs which have been removed from dead or living persons and which are proposed to be transplanted into other persons;

Part II of the Schedule specifies the information required about certain organs which have been received and which have been or are proposed to be transplanted into other persons.

 STATUTORY INSTRUMENTS

1989 No. 2480

MEDICAL PROFESSION

 The Human Organ Transplants (Unrelated Persons)
 Regulations 1989

Made - - - - - *29th December 1989*

Coming into force

regulations 1 and 2

1st January 1990

regulation 3

1st April 1990

Whereas a draft of this instrument was laid before Parliament in accordance with section 2(7) of the Human Organ Transplants Act 1989(a) and approved by a resolution of each House of Parliament:

Now therefore, in exercise of powers conferred by section 2(3) of the Human Organ Transplants Act 1989 and of all other powers enabling me in that behalf, I hereby make the following Regulations:-

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Organ Transplants (Unrelated Persons) Regulations 1989.

(2) Regulations 1 and 2 of these Regulations shall come into force on 1st January 1990 and regulation 3 on 1st April 1990.

(3) In these Regulations:-

“the Act” means the Human Organ Transplants Act 1989;

“the Authority” means the authority constituted by regulation 2 of these Regulations;

“donor” means a living person from whom it is proposed to remove an organ;

“recipient” means a person into whom it is proposed to transplant an organ.

Constitution of the Unrelated Live Transplant Regulatory Authority

2.—(1) There is hereby constituted for the purposes of section 2(3) of the Act an authority called the Unrelated Live Transplant Regulatory Authority.

(2) The Authority shall consist of a chairman appointed by the Secretary of State and of such number of other members appointed by him, not being less than 7 or more than 11, as he thinks fit.

(3) The chairman and at least 3 other members of the Authority shall be registered medical practitioners and at least 4 members of the Authority shall be persons who are not, and have not at any time been, registered medical practitioners.

(4) The tenure of office of the chairman and any other member of the Authority shall be on such terms and for such period as the Secretary of State shall specify on appointing him.

(5) The procedure of the Authority shall be such as the Authority may determine.

Transplants between persons who are not genetically related

3.—(1) The prohibition in section 2(1) of the Act (restriction on transplants between persons not genetically related) shall not apply in cases where a registered medical practitioner has caused the matter to be referred to the Authority and where the Authority is satisfied:—

- (a) that no payment has been, or is to be, made in contravention of section 1 of the Act;
- (b) that the registered medical practitioner who has caused the matter to be referred to the Authority has clinical responsibility for the donor; and
- (c) except in a case where the primary purpose of removal of an organ from a donor is the medical treatment of that donor, that the conditions specified in paragraph (2) of this regulation are satisfied.

(2) The conditions referred to in paragraph (1)(c) of this regulation are:—

- (a) that a registered medical practitioner has given the donor an explanation of the nature of the medical procedure for, and the risk involved in, the removal of the organ in question;
- (b) that the donor understands the nature of the medical procedure and the risks, as explained by the registered medical practitioner, and consents to the removal of the organ in question;
- (c) that the donor's consent to the removal of the organ in question was not obtained by coercion or the offer of an inducement;
- (d) that the donor understands that he is entitled to withdraw his consent if he wishes, but has not done so;
- (e) that the donor and the recipient have both been interviewed by a person who appears to the Authority to have been suitably qualified to conduct such interviews and who has reported to the Authority on the conditions contained in sub-paragraphs (a) to (d) above and has included in his report an account of any difficulties of communication with the donor or the recipient and an explanation of how those difficulties were overcome.

29th December 1989

K. Clarke
One of Her Majesty's Principal Secretaries of State

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for cases in which the prohibition of transplants between living persons who are not genetically related in section 2(1) of the Human Organ Transplants Act 1989 does not apply.

Regulation 2 provides for the establishment and constitution of the Unrelated Live Transplant Regulatory Authority for the purposes of section 2(3) of the Act.

Regulation 3 specifies the conditions which are required to be satisfied in cases to which the Regulations apply. These include the Authority being satisfied that no payment has been or is to be made for a human organ in contravention of section 1 of the Act.

Statutory Instrument 1998 No. 1428

The Human Organ Transplants (Establishment of Relationship) Regulations 1998

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STATUTORY INSTRUMENTS

1998 No. 1428

MEDICAL PROFESSION

The Human Organ Transplants (Establishment of Relationship) Regulations 1998

<i>Made</i>	<i>8th June 1998</i>
<i>Laid before Parliament</i>	<i>29th June 1998</i>
<i>Coming into force</i>	<i>8th August 1998</i>

In exercise of the powers conferred by section 2(2) of the **Human Organ Transplants Act 1989**[1] and of all other powers enabling him in that behalf, the Secretary of State hereby makes the following Regulations:

Citation, commencement and interpretation

1. - (1) These Regulations may be cited as the **Human Organ Transplants (Establishment of Relationship) Regulations 1998** and shall come into force on 8th August 1998.

(2) In these Regulations -

"the Act" means the **Human Organ Transplants Act 1989**;

"donor" means the living person from who it is proposed to remove an organ with the intention that it be transplanted into another person and "recipient" means that other person;

"genetic tests" means tests based on DNA variations;

"tester" means a person who has been approved by the Secretary of State as competent both to specify and to interpret the results of genetic tests.

Establishment of genetic relationship

2. - (1) For the purposes of section 2 of the Act, the means by which the fact of a genetic relationship between the donor and the recipient is to be established are genetic tests, subject to the conditions specified in paragraph (2) of this regulation.

(2) The conditions are that a tester shall -

(a) specify the genetic tests to be carried out on the donor and the recipient, and on such relatives of each of them as are available and willing to be tested and whom in the opinion of the tester it is necessary to test,

(b) interpret the results of all such genetic tests as are carried out, and

(c) state in writing whether or not he is satisfied that the claimed genetic relationship between the donor and the recipient is established.

Revocation

3. The **Human Organ Transplants (Establishment of Relationship) Regulations 1989[2]** are hereby revoked.

Signed by authority of the Secretary of State for Health

Jay
Minister of State, Department of Health

8th June 1998

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations replace the **Human Organ Transplants (Establishment of Relationship) Regulations 1989**, which are revoked. These Regulations provide that the genetic relationship between the proposed living donor of an organ and the proposed recipient is to be established by means of genetic tests based on DNA variations. The tests are to be specified and their results interpreted by a person approved by the Secretary of State as competent to do so and that person is then to state in writing whether he is satisfied that the claimed genetic relationship between the donor and the recipient is established.

Notes:

[1] 1989 c.31.[back](#)

[2] S.I. 1989/2107.[back](#)

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