STATUTORY INSTRUMENTS

2006 No. 1260

HUMAN TISSUE, ENGLAND AND WALES

HUMAN TISSUE, NORTHERN IRELAND

The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006

Made - - - -	*25th April 2006*
Laid before Parliament	*10th May 2006*
Coming into force - -	*1st September 2006*

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred upon her by sections 1(9), 16(3), 34(1) and 52(1) of, and paragraph 10(b) of Schedule 4 and paragraph 4(5) of Schedule 5 to, the Human Tissue Act 2004(**a**).

In accordance with section 52(8) and (10) of that Act she has consulted with the National Assembly for Wales, the relevant Northern Ireland Department(**b**) and the Scottish Ministers on the proposal to make the Regulations.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 and shall come into force on 1st September 2006.

(2) In these Regulations—

"the Act" means the Human Tissue Act 2004;

"donor" and "recipient" have the meaning given by regulation 4; and

"research ethics authority" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004(**c**), or

(b) any other committee established or person appointed—

(i) to advise on, or on matters which include, the ethics of research investigations on relevant material which has come from a human body, and

(ii) recognised for that purpose by, or on behalf of, the—

(**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.
(**c**) S.I. 2004/1031.

(aa) Secretary of State,

(bb) National Assembly of Wales, or

(cc) Department of Health, Social Services and Public Safety;

"transplantable material" has the meaning given in regulation 9 of the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006(**a**).

Ethical approval of research

2. Research is ethically approved for the purposes of section 1(9)(a) and paragraph 10(b) of Schedule 4 to the Act where it is approved by a research ethics authority.

Exceptions from licensing requirement

3.—(1) The storage of relevant material by a person who intends to use it for a scheduled purpose is excepted from section 16(2)(e)(ii) of the Act (storage of relevant material which has come from a human body) in the circumstances set out in paragraphs (2) to (4).

(2) Storage of relevant material which has come from the body of a living person is excepted where the person storing it is intending to use it for—

(a) any purpose specified in paragraphs 2 to 5 or 8 to 12 of Part 1 of Schedule 1 to the Act (determining the cause of death, establishing after a person's death the efficacy of any drug or treatment administered to him, obtaining information which may be relevant to another person, public display, clinical audit, education or training relating to human health, performance assessment, public health monitoring, quality assurance); or

(b) the purpose of qualifying research.

(3) Storage of relevant material which has come from a human body is excepted where the person storing it is intending to use it for the purpose of transplantation and—

(a) the material is an organ or part of an organ if it is to be used for the same purpose as the entire organ in the human body; or

(b) the storage is for a period of less than 48 hours.

(4) Storage of relevant material which has come from the body of a deceased person is excepted where—

(a) the person storing it is intending to use it for the purpose of qualifying research; or

(b) the relevant material—

(i) has come from premises in respect of which a license under section 16(2) is in force,

(ii) is stored by a person intending to use it for the sole purpose of analysis for a scheduled purpose other than research, and

(iii) will be returned to premises in respect of which a license under section 16(2) is in force when the analysis is completed.

(5) In this regulation—

(a) "organ" means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

(b) "qualifying research" means—

(i) research which is ethically approved for the purposes of section 1(9)(a) of the Act; or

(ii) a specific research project for which such ethical approval is pending;

(c) an application for ethical approval is pending from when it has been submitted to a research ethics authority until the decision of the authority has been communicated to the applicant.

(**a**) S.I. 2006/[ ].

Information about transplant operations

Information to be supplied by medical practitioner who removes transplantable material

4. A person who has removed transplantable material from a human body ("the donor") which is proposed to be transplanted to another person ("the recipient") shall supply to NHS Blood and Transplant(**a**) the information specified in Schedule 1 to these Regulations.

Information to be supplied by medical practitioner who receives transplantable material

5. A person who has received transplantable material which is proposed to be transplanted to a recipient shall supply to NHS Blood and Transplant the information specified in Schedule 2 to these Regulations.

Rosie Winterton,
Minister of State,
Department of Health

25th April 2006

SCHEDULE 1

Regulation 4

REMOVAL OF TRANSPLANTABLE MATERIAL

Information about removal

1. Name and address of the hospital or other place at which the transplantable material was removed from the donor.

2. Full name of registered medical practitioner or person who removed the transplantable material, the appointment he holds and the place at which he holds it.

3. In any case where the transplantable material is considered unsuitable for transplanting after removal, a statement of—

(a) the reason for the unsuitability, and

(b) the manner of disposal of the material.

Information about transplantable material and donor

4. Description of the transplantable material.

5. Whether the donor was living or deceased at the time of its removal.

6. Date and time of its removal.

7. Full name of the donor and, where applicable, his hospital case note number.

(**a**) NHS Blood and Transplant is a Special Health Authority established by S.I. 2005/2529.

SCHEDULE 2

Regulation 5

RECEIPT OF TRANSPLANTABLE MATERIAL

Information about receipt

1. Name and address of the hospital or other place at which the transplantable material was received.

2. Full name of registered medical practitioner who proposes to carry out the transplant (or who has carried it out), the appointment he holds and the place at which he holds it.

3. In any case where the transplantable material is not transplanted to another person, a statement of—

(a) the reason why not, and

(b) the manner of disposal of the material.

Information about transplantable material

4. Description of the transplantable material.

5. Name and address of the hospital or other place at which the transplantable material was removed from the donor.

6. If the transplantable material was removed outside the United Kingdom—

(a) the name of the country in which the material was removed, and

(b) the reference number allocated to the material by NHS Blood and Transplant when arrangements were made to import it.

Information about transplant and recipient

7. Full name of the recipient.

8. Date and time that the transplant was carried out.

9. In any case where the donor is genetically related to the recipient, a description of the relationship.

10. If the transplant was carried out in—

(a) a health service hospital (within the meaning of the National Health Service Act 1977(**a**)), or

(b) a hospital vested in the Department of Health, Social Services and Public Safety or managed by a Health and Social Services Trust (**b**),

a statement indicating (if that is the case) that—

(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 42 of the Treaty establishing the European Community(**c**), or

(b) the recipient was a national of another country who was entitled to be provided with the treatment by virtue of an agreement entered into between the European Community and that other 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

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(**a**) 1977 c.49.
(**b**) *See* the Health and Personal Social Services (Northern Ireland Order) 1991 (S.I. 1991/194 (N.I. 1)).
(**c**) The reference to the Treaty is to it as renumbered in accordance with the Treaty of Amsterdam (Cmnd. 3780).

Government of a country or territory specified in Schedule 2 to the National Health Service (Charges to Overseas Visitors) Regulations 1989(**a**) or specified in Schedule 2 to the Provision of Health Services to Persons Not Ordinarily Resident Regulations 2005(**b**).

(**a**) S.I. 1989/306. Schedule 2 was amended by S.I. 1991/438, 1994/1535 and 2000/602.
(**b**) S.R 2005/551.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision as to the definition of ethical approval for the purposes of certain provisions of the Human Tissue Act 2004 (c.30) ("the Act"). They also specify circumstances in which licensing by the Human Tissue Authority is not required for the storage of relevant material and sets out the information that must be provided to NHS Blood and Transplant in connection with transplants using certain material from a human body.

Regulation 2 defines ethical approval for research for the purposes of section 1(9)(a) of, and paragraph 10(b) of Schedule 4 to, the Act as approval by a research ethics authority.

Regulation 3 provides the following exceptions to the requirement under section 16(2)(e)(ii) of the Act to hold a license for storage of relevant material which has come from a human body:—

where the relevant material has come from a living person unless storage is for the purpose of transplantation (other than transplantation of an organ or part-organ or where the storage is for less than 48 hours) or for the purpose of research for which ethical approval has been given or sought

where the relevant material has from a human body where storage is for the purpose of transplantation of an organ or part of an organ or the storage period is for less than 48 hours

where the relevant material has come from a deceased person and storage is for the purpose of research for which ethical approval has been given or sought, or the material has been sent from licensed premises for analysis for a scheduled purpose other than research.

The information that must be provided to NHS Blood and Transplant in connection with the transplant of such material is specified in regulations 4 and 5 and in Schedules 1 and 2.

Regulation 4 and Schedule 1 prescribe the information to be supplied by a person who has removed transplantable material from a human body that is proposed to be transplanted to another person, to NHS Blood and Transplant.

Regulation 5 and Schedule 2 prescribe the information to be supplied by a person who has received transplantable material which is proposed to be transplanted, to NHS Blood and Transplant.

A Regulatory Impact Assessment was prepared for the Human Tissue Act 2004 and a copy has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment are published on the Department of Health's website (www.dh.gov.uk) and can be obtained from room 611, 6th Floor North, Wellington House, Waterloo Road, London SE1 8UG.

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