
STATUTORY INSTRUMENTS

2006 No. 1260

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

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, ^{F1}... [^{F1}quality assurance, maintaining the requirements of structure and vascularisation]); 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—

- ^{F1}(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 licence 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 licence under section 16(2) is in force when the analysis is completed.

(5) In this regulation—

- (a) “organ” means a differentiated ^{F2}...part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with ^{F3}... [^{F3}a significant] level of autonomy [^{F4}, and a part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation];
- (b) “qualifying research” means—

Changes to legislation: There are currently no known outstanding effects for the *The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, Section 3.* (See end of Document for details)

- (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.

Textual Amendments

- F1** Words in reg. 3(2)(a) substituted (12.7.2012 for specified purposes, 1.10.2015 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), regs. 1(2)(3), **27(a)**
- F2** Words in reg. 3(5)(a) omitted (12.7.2012 for specified purposes, 1.10.2015 in so far as not already in force) by virtue of [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), regs. 1(2)(3), **27(b)**
- F3** Words in reg. 3(5)(a) substituted (12.7.2012 for specified purposes, 1.10.2015 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), regs. 1(2)(3), **27(b)**
- F4** Words in reg. 3(5)(a) inserted (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **11**

Changes to legislation:

There are currently no known outstanding effects for the The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, Section 3.