

HUMAN TISSUE ACT 2004

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 3 - Miscellaneous and General

Miscellaneous

Section 43: Preservation for transplantation

56. This section makes it lawful to retain the body of a dead person and preserve organs in the body which may be suitable for transplantation, while consent to use the organs is sought, provided the preservation involves the minimum steps necessary and the least invasive procedures.

Section 44: Surplus tissue

57. This section allows any human material which comes from a body during medical treatment, diagnostic testing or research, or 'relevant material' (as defined in section 53) which is no longer required for scheduled purposes, to be disposed of. *Subsection (4)* makes it clear that the reference to lawful disposals in the section is not intended to affect the lawfulness or otherwise of other disposals of human material.

Section 45: Non-consensual analysis of DNA

58. It is an offence under section 45(1) to have any bodily material (that is, any material which has come from a human body and which consists of or contains human cells) intending to analyse the DNA in it without qualifying consent, subject to certain exceptions. This offence applies to the whole of the UK. The offence does not apply if the results of the analysis are to be used for excepted purposes and these are listed in Part 2 of Schedule 4. These include general purposes such as medical treatment and criminal justice purposes, as well as more specific matters which largely reflect what may be done without consent under Part 1 of the Act, with modifications for Scotland where necessary. Paragraph 11 of Schedule 4 also has the effect that, if consent to use material has been obtained under section 1(1) of the Act, it is not necessary to obtain a separate consent where that use involves DNA analysis.
59. What constitutes qualifying consent is set out in Part 1 of Schedule 4. It may be given to analysis of DNA for any purpose. It can be given by the person from whose body the material came or someone with parental responsibility if the person is a child. Once the person has died, consent may be given by anyone who stood in a qualifying relationship (as listed in section 54(9)) with the deceased immediately before he died. The hierarchy referred to in section 27(4) does not apply to this list.
60. Certain material is outside the scope of the offence altogether and this includes material from a person who died more than 100 years ago and embryos outside the body (as these are subject to separate regulation by the Human Fertilisation & Embryology Act 1990). Also outside the scope of the offence are existing holdings of material where the identity of the person from whom it came is not known, and is not likely to become

known. There is also an exemption if the person reasonably believes the material they have to be excepted.

General

Section 47: Power to give effect to Community obligations

61. This section contains a power to amend the Act at a later date by regulations subject to the affirmative procedure in order to implement Community obligations in relation to human material. This section has in view Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, which is due to be implemented by 7 April 2006. The power in this section will allow any necessary amendments to be made to the Act by regulations.

Section 47: Power to de-accession human remains

62. This section confers a power upon the bodies listed in *subsection (1)* ('listed institutions') to de-accession human remains.
63. *Subsection (2)* enables listed institutions to transfer human remains from their collections if it appears to them appropriate to do so for any reason whether or not it relates to their other functions. The power only applies to human remains which are reasonably believed to be of a person who died less than 1,000 years before this section comes into force.
64. *Subsection (3)* provides that if it appears to a listed institution that human remains are mixed or bound up with non-human material and it is undesirable or impracticable to separate them, the power to de-accession the human remains extends also to the associated non-human material. This has the effect of enabling artefacts such as mummies (where non-human material is integral to the human remains) to be de-accessioned intact. The provision does not extend to grave chattels that are buried with but are separate from human remains found in a grave.
65. *Subsection (4)* provides that the power contained in subsection (2) does not affect any trust or condition subject to which a listed institution may hold human remains.

Section 48: Powers of inspection, entry, search and seizure

66. This section gives effect to Schedule 5, which provides a power for persons authorised by the HTA to inspect certain records, enter, search and inspect premises and seize things on the premises in connection with the HTA's regulatory functions.

Section 50: Prosecutions

67. This section specifies that proceedings regarding offences relating to appropriate consent, commercial dealing in tissue and payment for transplants will be instituted only with the consent of the Director of Public Prosecutions.

Section 58: Transition

68. This section provides for the fact that the maximum penalties in the Act reflect the provisions of the Criminal Justice Act 2003. Until such time as the relevant provisions of the 2003 Act are in force, the maximum penalties are to be read as those which apply under the law currently in force.