

HUMAN TISSUE ACT 2004

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 2 - Regulation of Activities Involving Human Tissue

The Human Tissue Authority

Section 13: The Human Tissue Authority

31. This section establishes the HTA as a body corporate and gives effect to Schedule 2 (which includes provision about the membership of the Authority, its organisation and financial matters).

Section 14: Remit

32. *Subsection (1)* lists the activities within the HTA's remit. The activities include disposal of bodies and relevant material stored or used for scheduled purposes. *Subsection (3)* excludes from the remit of the HTA activities done in relation to material from bodies, or bodies, where the person died before the Act comes into force and has been dead for at least 100 years. *Subsection (4)* provides that the Secretary of State may by order add to the activities within the remit of the HTA. *Subsection (5)* defines 'relevant material' in this section as excluding blood or anything derived from blood for the purpose of transplantation. Blood and blood products for transfusion will be regulated upon implementation of Directive [2002/98/EC](#) setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

Licensing

Section 16: Licence Requirements

33. *Subsection (1)* prohibits the carrying on of activities to which the section applies without a licence. *Subsection (2)* sets out the activities to which the licence requirement applies. *Subsection (3)* provides that the Secretary of State may by regulations specify circumstances in which storage of relevant material by a person who intends to use it for a scheduled purpose is exempted from the licence requirement. This will allow distinction to be made between tissue banks, for example, and individuals using tissue in research projects, who will not then require to be licensed. *Subsection (4)* excludes from the licensing requirement activities done in relation to material from bodies, or bodies, where the person died before the Act comes into force and has been dead for at least 100 years. *Subsection (5)* provides that the Secretary of State may by regulations add, remove or alter the description of an activity listed in the section. *Subsection (7)* excludes from the licence requirement storage incidental to transportation. It also excludes use of blood or blood products for transplantation, and storage of blood or blood products for use for that purpose. Schedule 3 contains the detailed procedures for granting, varying, revoking and suspending licences. Licensing functions under the Schedule are conferred on the HTA.

Section 17: Persons to whom licence applies

34. This section defines who is permitted to act under the authority conferred by a licence: the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on (the 'designated individual'), any other person notified to the HTA by the designated individual as a person to whom the licence applies, and any person acting under the direction of either of the first two.

Section 18: Duty of the designated individual

35. This section provides that the individual designated in the licence is responsible for securing that the other persons to whom the licence applies are suitable to participate in the licensed activity, that suitable practices are used and that all licence conditions are complied with.

Section 19: Right to reconsideration of licensing decisions

36. This section provides that an applicant may require the HTA to reconsider licensing decisions in respect of a refusal of an application to grant, revoke or vary a licence, or a licence holder or designated person may require the HTA to reconsider a decision to revoke or vary a licence. *Subsection (3)* provides that notice of exercise of the right to reconsideration must be given to the HTA by the appellant within 28 days of the HTA giving notice of the decision.

Section 20: Appeals Committee

37. This section requires the HTA to maintain one or more appeals committees composed of not less than 5 (with a quorum of 3) members of the HTA. The appeals committee will be responsible for dealing with requests for reconsideration of HTA decisions under section 19.

Section 21: Procedure on reconsideration

38. This section sets out the procedure for reconsideration of licensing decisions, which will be by way of fresh decision. *Subsection (5)* provides that the HTA may by regulations make other provision in relation to the procedure on reconsideration as it thinks fit.

Section 23: Conduct of licensed activities

39. This section provides that directions issued by the HTA may impose particular requirements relating to the conduct of activities authorised by a licence. *Subsection (2)* says directions may be general, applicable to particular kinds of licence or to an individual licence. *Subsection (3)* makes it a statutory requirement that they are complied with by those to whom they apply.

Section 24: Changes of licence circumstance

40. *Subsections (1) to (3)* provide that directions may be made for the purpose of dealing with a situation in consequence of the variation of a licence or the ceasing of a licence to have effect, and identify the persons on whom requirements may be imposed. *Subsection (5)* provides that in the event of the death or dissolution of a licence holder, anything done before directions are given will be treated as authorised, provided it would have been authorised by the licence holder's licence (were it still in force).

Section 25: Breach of licence requirement

41. This section establishes the offence of carrying on a licensed activity otherwise than under the authority of a licence granted under section 16(1), unless the person carrying on the activity reasonably believes the activity is not licensable or that he acts under the authority of a licence. *Subsection (2)* sets out penalties for the offence.

Codes of Practice

Section 26: Preparation of codes

42. *Subsection (1)* provides that the HTA may prepare and issue codes of practice giving guidance and setting standards in relation to activities within its remit. *Subsections (2)* and *(3)* list the matters which must be dealt with in the codes of practice prepared by the HTA.

Section 27: Provision with respect to consent

43. *Subsection (1)* provides that in a code of practice dealing with consent the HTA must lay down standards relating to obtaining consent from a person in a qualifying relationship. *Subsection (3)* provides that the HTA may lay down different standards for obtaining consent in exceptional cases, for example, a blood relative lower down the hierarchy than a partner or spouse may have a greater interest in obtaining information about their deceased relative's health where this may be relevant to their own health. *Subsection (4)* sets out the hierarchy of people close to a deceased person who are eligible to give 'appropriate consent' to the activities listed in section 1(1) to (3) (other than for the purposes of anatomical examinations or public display). If there is more than one person in an eligible class who is competent to give consent, the consent of any one of them would suffice. *Subsection (9)* provides that the Secretary of State may amend the hierarchy by order.

Section 28: Effect of codes

44. This section provides that, while failure to observe a provision of a code of practice will not itself make a person liable to any proceedings, the HTA may take account of observance or failure to observe a provision of a code of practice dealing with a matter that is subject to a licence requirement when carrying out its licensing functions.

Section 29: Approval of codes

45. This section provides that draft codes of practice dealing with matters that are subject to a licence requirement must be approved by the Secretary of State and laid before Parliament by him. The code may not be issued by the HTA until it has been before Parliament for 40 days with no resolution not to approve it having been made by either House.

Anatomy

Section 30: Possession of anatomical specimens away from licensed premises

46. This section and the following one transpose provisions of the Anatomy Act 1984 relating to control of possession of anatomical specimens. This section makes it an offence to keep anatomical specimens away from licensed premises. Exceptions are provided for possession authorised by a designated individual for authorised purposes, for persons in lawful possession of bodies immediately after death and for possession for the purpose of transport to licensed premises or premises where the specimen is to be used for the purpose of education, training or research. These exceptions are intended, for example, to allow an anatomy teacher to take a specimen away from a dissecting room to a lecture theatre for teaching purposes, and to allow undertakers to deliver bodies to the medical school. An exception is also provided where the person has possession for the purposes of functions of or under the authority of a coroner.

Section 31: Possession of former anatomical specimens away from licensed premises

47. This section makes it an offence for a person to have a former anatomical specimen in his possession away from licensed storage premises. As under the preceding section,

exceptions are provided for possession authorised by a designated individual for authorised purposes, for possession for the purposes of transport to licensed premises or premises where the former specimen is to be used for the purpose of education, training or research. There are also exceptions where the person has possession for the purposes of decent disposal or where he has possession for the purposes of functions of, or under, the authority of a coroner.

Trafficking

Section 32: Prohibition of commercial dealings in human material for transplantation

48. This section transposes the existing prohibition on buying or selling organs from the Human Organ Transplants Act 1989, and extends the prohibition to cover all human material (subject to certain exceptions) intended to be used for transplantation. Advertising for suppliers of material for reward is also prohibited. *Subsection (3)* allows the HTA to designate a person who may lawfully engage in trade in human material (for example, the National Blood Service will continue to be allowed to purchase blood from abroad). *Subsection (7)* provides that reimbursement for expenses connected with transporting, removing, preparing, preserving or storing the body of a deceased person or relevant human material is not prohibited. *Subsection (6)* allows for the possibility of commercial tissue banks by allowing licence-holders to receive more than just expenses in relation to these activities. *Subsection (7)* also provides that it is not an offence to provide expenses or recompense for loss of earnings given to an individual supplying human material, and allows for costs incurred by others to be passed along a chain of suppliers. *Subsection (9)* makes clear that the material covered by the prohibition excludes gametes and embryos (as defined in, and regulated by, the Human Fertilisation and Embryology Act 1990), and material which has become property by reason of the application of human skill. Cell lines are excluded from the section by virtue of section 54(7).

Transplants

Section 33: Restriction on transplants involving a live donor

Section 34: Information about transplant operations

49. These sections are transposed from the Human Organ Transplants Act 1989. Section 33 sets out the offence and penalties related to the removal and transplantation of organs and other material from living donors in circumstances other than those provided for in regulations made under this section. These include circumstances where the HTA is satisfied that no reward has been given in relation to the transplant. Section 34 replicates the existing requirement for information about organ transplants to be supplied to the specified authority (UK Transplant). Failure to supply information, or the supply of false information, is an offence under this section.

General

Section 35: Agency arrangements and provision of services

50. This section enables the HTA to make arrangements with other public bodies for the carrying out of any of the HTA's functions by the other body or its staff or for the other body to provide administrative, professional or technical services to the HTA.

Section 36: Annual Report

51. This section requires the HTA to prepare an annual report to be submitted to the Secretary of State, the National Assembly for Wales and the relevant Northern Ireland department, and for the Secretary of State and the relevant Northern Ireland Department

*These notes refer to the Human Tissue Act 2004 (c.30)
which received Royal Assent on 15 November 2004*

to lay a copy before each House of Parliament and before the Northern Ireland Assembly respectively.

Section 37: Directions

52. This section makes provision with respect to the giving of directions by the HTA under Part 2, which must be in writing.

Section 38: Duties in relation to carrying out functions

53. This section sets out how the HTA must carry out its functions and the matters to which it must have regard in doing so.

Exceptions

Section 39: Criminal Justice purposes

54. This section deals with excluding activities done for criminal justice purposes from the relevant provisions of Part 2 of the Act. The intention is for all coroners' *post mortem* examinations carried out in premises to be subject to regulation, so even where these are carried out also for criminal justice purposes, they will not be excluded from Part 2 of the Act. *Subsection (2)* of the section achieves this. *Subsection (1)* excludes from the regulatory regime of Part 2 of the Act other activities done for criminal justice purposes. Examples of activities excluded from regulation by this section might be *post mortem* examinations authorised by a coroner in a criminal case to take place at the place where the police first attend a body (which would not need a licence) and disposal of material which has been removed from a body during a *post mortem* examination in a criminal case (which would not be within the HTA's remit and not subject to any code of practice on this subject).

Section 40: Religious relics

55. This section excludes the public display of religious relics and storage of such relics for the purpose of public display, from the remit of the HTA, from the requirement for a licence and from the remit of the Inspectorate of Anatomy & Pathology. It applies to relics displayed in places of public religious worship or associated places.