General Notes and Guidance on the Human Tissue Act 2004.

**Background**

The Human Tissue (HT) Act received Royal assent on the 15th November 2004. The HT Act 2004 provides the framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specified health related purposes and public display. The Human Tissue Authority (HTA) has the responsibility to regulate against the HT Act 2004.

The HTA framework offers various models of governance around three key roles, as outlined in the HT Act. These three roles are:

* Designated Individual (DI)
* Licence Holder
* Person Designated as a person to whom the licence applies

The HTA has also prepared and issued Codes of Practice for the purpose of:

* Giving practical guidance to persons carrying out activities within its remit; and
* Laying out the standards expected in relation to the carrying on of such activities.

The Royal Devon and Exeter NHS Foundation Trust has the responsibility to ensure compliance with the HT Act for licensed activities.

**Activities covered by HTA License**

The HTA License held by the RD&E and to which this policy refers, covers the following activities:

* The making of a post mortem examination and is subject to both the standard and any addition conditions set out by the HTA
* The removal from the body of a deceased person (otherwise in the course of carrying out an anatomical examination or the making of a post mortem) of relevant material of which the body consists or which it contains, for use of a scheduled purpose other than transplantation and is subject to both the standard and additional conditions set out by the HTA
* The respectful disposal of fetal tissue resulting from pregnancy loss (e.g. by miscarriage or termination) before 24 weeks gestation.
* The storage of the body of a deceased person or relevant material which has come from a human body of use for a scheduled purpose and is subject to both standard and any additional conditions set out by the HTA

**The Designated Individual – DI**

The DI in relation to the HTA license, means the person under whose supervision the licensed activity is authorised to be carried out upon. At the RD&E the DI is usually the Cellular Pathology medical head of service. The role of the DI is crucial to the successful implementation of the HTA’s licensing system.

Section 18 of the HT Act provides that it shall be the duty of the DI to secure:

* That the other persons to whom the license applies are suitable persons to participate in the carrying on of the licensed activity;
* That suitable practices are used in the course of carrying out that activity, and;
* That the conditions of the license are complied with.

The DI needs to have knowledge and understanding of the HT Act and the relevant Codes of Practice.

**License Holder**

The RD&E NHS Foundation Trust is the corporate body, which is the nominated Licence Holder. The License Holder can apply to the HTA to vary the license so as to substitute another individual for the DI should the need arise.

**Person Designated**

Persons designated do not have legal duty comparable with those set out for the DI under section 18 of the HT Act. However the role of Person Designated carries with it the ability to ‘direct’ others in relation to the HT Act.

**Codes of Practice**

The HTA has prepared the following Codes of Practice:

* Consent
* Donation of organs, tissues and cells for transplantation
* Post mortem examinations
* Anatomical examinations
* Removal/collection, retention and disposal of human organs and tissue
* Donation of allogenic bone marrow, peripheral blood stem cells and donor lymphocytes for transplantation

The Codes of Practice 1, 2, 3 and 5 are directly relevant to the license this policy refers to. The Codes of Practice contain guidance and standards and should not be treated as being equivalent to a statutory requirement. A failure on the part of any person to observe any provision of a Code of Practice shall not render the person liable to any proceedings.

HTA Codes of Practice are available on the HTA website at <http://www.hta.gov.uk>

**Consent**

The HT Act 2004 sets out a legal framework for the removal, storage and use of tissue and organs from the deceased.

All those involved in the above licensed activities should be aware of the following statutory requirements for consent:

* The storage and use of dead bodies
* The removal, storage and use of ‘relevant material’ from a dead body
* Consent is required where, after a Coroner’s post mortem, the continued storage or use of material no longer required to be kept for the Coroner’s purposes.
* Consent is required for the removal, storage and use of tissue or organs for the following scheduled purposes:
* Determining the cause of death (other than under authority of the Coroner)
* Establishing, after death, the efficiency of drug or other treatment administered
* Obtaining scientific or medical information, which may be relevant to any other person now or in the future
* Research in connection with disorders or the functioning, of the human body
* Transplantation
* Clinical audit
* Education or training relating to human health
* Performance assessment
* Quality assurance
* Consent applies to all tissue removed at post mortem, including small samples such as blocks and slides, and samples that might be kept as part of the record
* Consent is also required for the respectful disposal of fetal tissue resulting from pregnancy loss before 24 weeks gestation by any cause e.g. miscarriage, termination, ectopic pregnancy.

**Consent not required**

Consent is not needed for:

* Carrying out an investigation into the cause of death under the authority of a Coroner.
* Keeping material after a post mortem under the authority of the Coroner, for as long as the Coroner requires it.
* Keeping material in connection with a criminal investigation or following a criminal conviction (Police and Criminal Evidence Act 1984)

**Who can give consent?**

For consent to be valid it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question.

Persons are competent to consent if they can:

* Understand the nature and purpose of the proposed procedure
* Understand and retain information relevant to the decision
* Weigh the necessary information to arrive at a choice

Consent for post mortem, removal, storage and use of relevant material from a deceased person can be given by someone in a ‘qualifying’ relationship. Those in a qualifying relationship with the deceased person are (highest first):

* Spouse or partner (including civil or same sex partner)
* Parent or child
* Brother or sister
* Grandparent or grandchild
* Niece or nephew
* Stepfather or stepmother
* Half-brother or half-sister
* Friend of long standing

Consent should be obtained from the person ranked highest unless they do not wish to deal with the issue of consent, are not competent, or it is not practical (e.g. highest ranked cannot be found). In the case of a child appropriate consent will be that from a person with a parental responsibility for a child. If there is no person with parental responsibility then consent should be sought from someone in a qualifying relationship as detailed above.

**Fetal tissue**

Fetal tissue is regarded as mother’s tissue and consent should be obtained for the examination and disposal of fetal tissue and for its use for all scheduled purposes, regardless of gestational age.

The complete HTA Code of Practice on Consent is available on the HTA website at <http://www.hta.gov.uk> and should be used if there is any doubt when carrying out any of the licensed activities.

**Recording consent**

It is essential that the person obtaining the consent documents clearly the agreement, either through the use of a consent form (with full details in the deceased notes if necessary) or through documentation in the deceased’s notes that oral consent has been given.

**Donations of organs, tissue and cells for transplantation**

This policy only relates to the removal of relevant material from a deceased person for the purpose of transplantation. The storage and use of relevant material from a living person, other than fetal material, is not covered by this policy.

Discussions on organ donation should always be handled sensitively with the views of the deceased person paramount. An agreed position should be reached by inclusive discussion, where possible. The removal of tissue from a donor after death must be carried out by staff that are trained in tissue retrieval.

In the RD&E NHS Foundation Trust referral and removal of tissue is covered by the Tissue Donation Officers and Mortuary Staff. Obtaining consent is the first mandatory step in removing, storing and using tissue for transplantation. This is performed by NHSBT.

If an adult, while alive and competent, consented to one or more of the scheduled purpose taking place after death, then that consent is sufficient for donation to be lawful. Where the deceased has not given their consent (or refusal) and a nominated person has not been nominated then a qualifying person as outlined in the consent section may give consent. In the case of a child consent to donation should be obtained from a person with parental responsibility if possible. If this is not possible then consent should be obtained from a person in a qualifying relationship.

The Complete HTA Code of Practice on donations of organs, tissue or cells for transplantation is available on the HTA website at <http://www.hta.gov.uk> and should be used if there is any doubt when carrying out any of the licensed activities.

**Post mortem examination**

A post mortem examination (or autopsy) may take place because the Coroner considers it necessary or because it has been agreed upon by the deceased person or relative. Before the post mortem examination the person obtaining the consent should, in collaboration with the Pathologist, check that the post mortem examination and any removal, storage and use has been properly authorised. This authorisation will either come from a completed consent form or from the Coroner.

Consent to the post mortem must be separate from consent to the subsequent removal, storage and use of tissue and organs (including blocks and slides) i.e. relatives must be clear that these are two separate decisions. Specific consent must be obtained to store and or use tissue, including blocks and slides, for any of the scheduled purposes listed in the Act.

All post mortem examinations must be carried out in premises licensed by the HTA, and in accordance with the conditions of the license. It is essential the post mortem examinations are carried out by the competent, trained staff, that suitable practices are being used and that the conditions of the license are being complied with. The post mortem examination should follow the professional guidelines produced by the Royal Collage of Pathologists (RCPath).

**Coroner’s post mortem**

Although the consent of the deceased person or relatives is not required for the post mortem examination the reasons for the examination should be explained to them. They should be given information of when and where the post mortem will take place and told of their right to be represented at the post mortem by a professional person, if they so wish.

The Coroner has a duty to inform relatives or representatives of the deceased person about the retention of organs or tissue for examination. This should include the material being kept, the period for which it will be kept and the options for subsequent disposal.

There is a service level agreement between the Royal Devon and Exeter NHS Foundation Trust and the Coroners using our facilities regarding compliance with the HT Act. This includes protocols to ensure proper communication with the deceased person’s relatives.

A hospital post mortem is carried out with the prior consent of the deceased person, or with the consent of their nominated representative or a person in a qualifying relationship. The consent should cover the removal and storage of organs and tissues for purposes scheduled in the HT Act.

The complete HTA Code of Practice on post mortem examinations is available on the HTA website at <http://www.hta.gov.uk> and should be used if there is any doubt when carrying out any of the licensed activities.

**Removal/collection, retention and disposal of human organs and tissue**

The HTA Code provides a model of good practice for all those involved in removing, storing or disposing of human tissue whether donated by living patients or removed from the body after death. It also provides a model of good practice for the respectful disposal of fetal tissue resulting from pregnancy loss before 24 weeks gestation by any cause e.g. miscarriage, termination, ectopic pregnancy. It does not deal with the legal and ethical issues relating to the use of human organs or tissue for research, education or other purposes.

**Removal**

It is an offence under the HT Act remove relevant material from a dead body for any scheduled purpose without obtaining consent other than under a Coroner’s authority or under proper authority for criminal justice purposes. Where required, consent should be given by a person in a ‘qualifying relationship’.

**Consent**

The consent requirements of the Act do not apply to the removal of relevant material from the living. Fetal tissue and products of conception are treated no differently from any other tissue taken from a living person. Clearly however there are particular sensitivities relating to the use and disposal of such tissue.

Consent is required for the storage of use of material taken during a Coroner’s post mortem for scheduled purposes once the material is no longer required by the Coroner. Consent must be sought from the deceased person’s relatives regarding storage of organs and tissues, and their method of disposal after the Coroner’s investigations have ended.

It is an offence to store and/or use material without consent after it is no longer need for the Coroner’s purposes. Consent for the storage of tissue, post mortem, should always be obtained. If the deceased person’s relatives indicate that they wish organs and tissue to be disposed of it should be done as soon as possible and certainly within six weeks of the deadline on the storage specified by the Coroner.

Where the relatives have not expressed a preference by the time the Coroner’s time limit expires, the organs or tissue may be stored for up to six weeks. The relatives should then be advised that, unless they specify otherwise, that the organs or tissue will be disposed of in a further four weeks’ time.

**Storage**

It is an offence under the Act to store relevant material taken after the death without consent for any scheduled purposes, apart from material stored for Coroner’s or Criminal justice purposes.

The HT Act does not distinguish between blocks and slides and any other form of human tissue. Whilst it may be desirable for blocks and slides to be taken and kept for clinical audit, teaching or other purposes, it should not be assumed that consent to a post mortem implies consent to removing and keeping blocks and slides.

For hospital post mortems it is made clear to relatives that consent for removal, storage and or use of organs or tissue for any scheduled purpose is a separate decision from consent to conducting a post mortem examination.

Organs and tissue are stored in line with current good practice on:

* Security
* Traceability, including information about risk. Records should detail the location of the materials
* Health and safety, including appropriate containment levels for the storage, transportation and handling of materials that may pose a risk to staff.

**Disposal**

Tissue and organs are handled in accordance with any reasonable wishes expressed by the relatives or the deceased person, as long as the method of disposal is legal.

Relatives may wish the hospital to arrange for collection of tissue or an organ, usually by a funeral director of their choice, at some specified time after the post mortem examination. They can make their own arrangements for cremation of burial.

If the deceased person has already been buried or cremated and relatives ask for the remaining tissue or organs to be returned later, these should be released:

* Preferably to funeral directors acting for those who have legitimate responsibility for the disposal of the body
* With authoritative confirmation of the identity of the tissue or organ and
* With confirmation that the cremation or burial authorities have agreed in principle to accept the remains for disposal.

There is no legal bar to releasing stored material directly to relatives but the proposed method of disposal must be lawful and safe and it may be difficult to ascertain this. The Pathologist should notify the recipient, or the burial or cremation authorities, of any hazards associated with the tissue and its fixative and obtain confirmation that they are able to handle them appropriately. Because of the potential health hazards releasing organs and tissue directly to relatives for their indefinite storage is not generally advisable.

**Surplus material from tissue samples**

The Act permits disposal as waste material that has come from a human body and ceases to be used, or stored or used, for scheduled purposes.

It is normal practice to dispose of such material by incineration. This includes:

* Tissue fragments trimmed from the tissue sample before it is processes for histology
* The tissue in the sections trimmed from a wax embedded block before the usable sections are cut and
* The unrecoverable bodily material that is washed out of the tissue during its processing into a wax block.

The complete HTA Code of Practice on Removal, Collection, Retention and Disposal of Human Organs and Tissue is available on the HTA website at <http://www.hta.gov.uk> and should be used if there is any doubt when carrying out any of the licensed activities.

**Fetal Tissue**

Guidance on disposal of fetal tissue is covered in the RD&E NHS Foundation Trust policy. This policy is applied in all cases of early pregnancy loss, including spontaneous miscarriage, termination for fetal abnormality and the termination of pregnancy requested solely by the mother.

A mother or both parents should be told that information on disposal options is available if they wish to see it. It should be clearly documented in the woman’s medical notes whether or not information has been requested and whether it has been given.