

The Human Tissue Act 2004<sup>1</sup> (HT Act) establishes the Human Tissue Authority<sup>2</sup> (HTA) as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos).

The remit of the HTA includes regulating disposal of human tissue (excluding gametes and embryos), including imported tissue, following its use for a scheduled purpose. The HTA have issued a Code of Practice on the 'removal, storage and disposal of human organs and tissue'<sup>3</sup>, to provide a model of good practice for all those involved in removing, storing and disposing of human organs or tissue, whether donated by living patients or removed from the body after death. **The following summarises the disposal requirements for tissue, which has been stored or used for research.**

### Disposal of organs/tissue removed from a living person

The HT Act makes it lawful to treat as 'waste' any relevant material which has come from a person who was:

- Participating in research,
- In the course of receiving medical treatment, or
- Undergoing diagnostic testing.

And material that:

- Has been removed from a living human body, and
- Ceases to be used, or stored for use, for scheduled purposes (see definition overleaf).

### Disposal options

- Material taken from the living should normally be disposed of by incineration in accordance with current guidelines on Safe Disposal of Clinical Waste (1999)<sup>4</sup>.
- Specific guidance has been provided on disposal of fetal tissue in the Code of Practice<sup>3</sup> (see summary overleaf).
- Requests by patients to retain tissue samples or arrange disposal themselves should be considered on a case-by-case basis, taking account of any risk to the patient and others.

### Disposal of organs/tissues removed from a deceased person

Tissue and organs should be handled in accordance with any reasonable wishes expressed by relatives or the deceased person, as long as the method of disposal is legal. The time, place and method of disposal should be recorded.

Researchers should be familiar with local arrangements and options for disposal, and provide written information if requested.

If practical, the hospital may offer to store the body until the organ or tissue can be returned to it.

If the deceased person has been buried or cremated, relatives may ask for remaining tissues or organs to be returned later. Guidelines for these cases are outlined in sections 76 -78 of the code of practice<sup>3</sup>.

### DEFINITION

**RELEVANT MATERIAL:** Material other than gametes, which consists of or includes human cells (does not include embryos). The HTA has released more information on relevant material on their website<sup>5</sup>.

### Surplus material from tissue samples

The HT Act allows disposal as 'waste' of surplus tissue (see definitions) if the material has:

- a) Come from a human body in the course of receiving medical treatment, undergoing diagnostic research or participating in research; *and*
- b) Ceases to be used, or stored for use, for a scheduled purpose such as research.

The above includes:

- tissue fragments from histology samples,
- tissue in the sections trimmed from a wax-embedded block before usable sections are cut, and
- unrecoverable bodily material washed out of the tissue during processing into a wax block.

If the donor has since died:

Surplus material from tissue samples from persons who have since died, should be disposed of with respect. As a minimum, this material should be disposed of separately from other clinical waste.

**Disposal of fetal tissue (up to 24 weeks gestation)**

Researchers should follow the relevant NHS organisation's disposal policy for pregnancy loss before 24 weeks gestation. This policy should reflect the guidance in the HTA Code of Practice<sup>3</sup> Appendix B, which is summarised below:

**Disposal options**

- A woman or couple should be told that information on disposal options is available if they wish to see it, and it should be clearly documented in the women's medical notes if information was requested and given.
- Any personal, religious or cultural needs should be met wherever possible and documented in medical notes.
- A woman or couple may wish to arrange disposal themselves and are free to do so.

**Burial**

- Fetal tissue can be buried providing there has been consultation with the woman / couple.
- A woman or couple can bury fetal tissue at home if they wish, in consultation with local authorities (paragraph B16 of the HTA Code of Practice<sup>3</sup>).

**Cremation**

- Fetal tissue can be cremated providing there has been consultation with the woman / couple where appropriate.

**Incineration**

- Fetal tissue from a pregnancy lost before 24 weeks may be incinerated although how appropriate this is depends on individual circumstances. Disposal by maceration / sluicing is not permitted.
- Incineration should be carried out in accordance with Department of Health guidance<sup>6</sup>.

**Embryos created in vitro**

The above guidance does not apply to embryos created in vitro which have not been transferred into a woman; in this case disposal should be in accordance with the Human Fertilisation and Embryology Authority's Code of Practice<sup>7</sup>.

**Stillbirths and neonatal deaths**

The above guidance does not apply to stillbirths and neonatal deaths. Any baby that is born alive and then dies immediately afterwards is considered a live birth and neonatal death (irrespective of gestational age). If unidentifiable stillbirths have been stored for research, please consult Appendix A of the disposal Code of Practice<sup>3</sup>.

**HTA guidelines for disposal of tissue used for research purposes**

1. Develop a clear and sensitive policy for disposing of human body parts and tissues which is:
  - documented, and
  - complies with health & safety recommendations.
 (This may simply refer to a local NHS policy).
2. Carefully document the reasons for disposal and methods used, by:
  - developing standard operating procedures for tracking the disposal of tissue, and
  - ensuring disposal arrangements reflect (where applicable) the consent given for disposal.

(Adapted from the Human Tissue Authority Research Compliance Report<sup>8</sup>).

**DEFINITIONS**

**SCHEDULED PURPOSES:** The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

**RESIDUAL TISSUE:** Material left over from a diagnostic or therapeutic intervention.

**SURPLUS TISSUE:** Relevant material which has come from a body in the course of receiving treatment, diagnostic testing or participating in research.

Further definitions are available in the Code of Practice<sup>3</sup>.

**References**

1. Human Tissue Act 2004, [www.opsi.gov.uk/acts/acts2004/20040030.htm](http://www.opsi.gov.uk/acts/acts2004/20040030.htm)
2. Human Tissue Authority website [www.hta.gov.uk](http://www.hta.gov.uk)
3. Human Tissue Authority Code of Practice: The removal, storage and disposal of human organs and tissue [www.hta.gov.uk](http://www.hta.gov.uk)
4. Safe Disposal of Clinical Waste, 2nd edition, HSE books, 1999
5. Human Tissue Authority guidance on relevant material [http://www.hta.gov.uk/guidance/licensing\\_guidance/definition\\_of\\_relevant\\_material.cfm](http://www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm)
6. Health Services guidelines (91)19 – Disposal of Fetal Tissue, 12 November 1991.
7. Human Fertilisation and Embryology Authority, Code of Practice – disposal of embryos, 6th edition, 2003 [www.hfea.gov.uk](http://www.hfea.gov.uk)
8. Human Tissue Authority Research Compliance Report [www.hta.gov.uk/licensing/guide\\_to\\_licensing\\_and\\_application/compliance\\_report\\_licence\\_application.cfm](http://www.hta.gov.uk/licensing/guide_to_licensing_and_application/compliance_report_licence_application.cfm)