

Research and the Human Tissue Act 2004 Disposal

Produced in
consultation with
the Human Tissue
Authority

Terms are defined
on page 3

The Human Tissue Act 2004¹ (HT Act) sets out a legal framework for regulating the storage and use of human tissue from the living, and removal, storage and use of human tissue from the deceased, for purposes including '*research in connection with disorders, or the functioning of, the human body*'. It was fully implemented on 1st September 2006 in England, Wales and Northern Ireland; with Section 45 implemented UK wide (including Scotland). The Human Tissue Authority² (HTA) has also produced Codes of Practice and Standards³. **This document summarises both good practice and legal requirements relating to the disposal of human tissue, stored or used for research.**

Disposal of human tissue, stored or used for research

Before disposing of human tissue you should consider options for maximising use, in line with donors' expectations⁴. There will be times when disposal is the most appropriate option i.e. following the terms of consent or where samples are no longer fit for purpose. In these cases the HT Act and Codes of Practice aim to ensure the respectful disposal of 'relevant material' in accordance with the wishes of donors or their relatives.

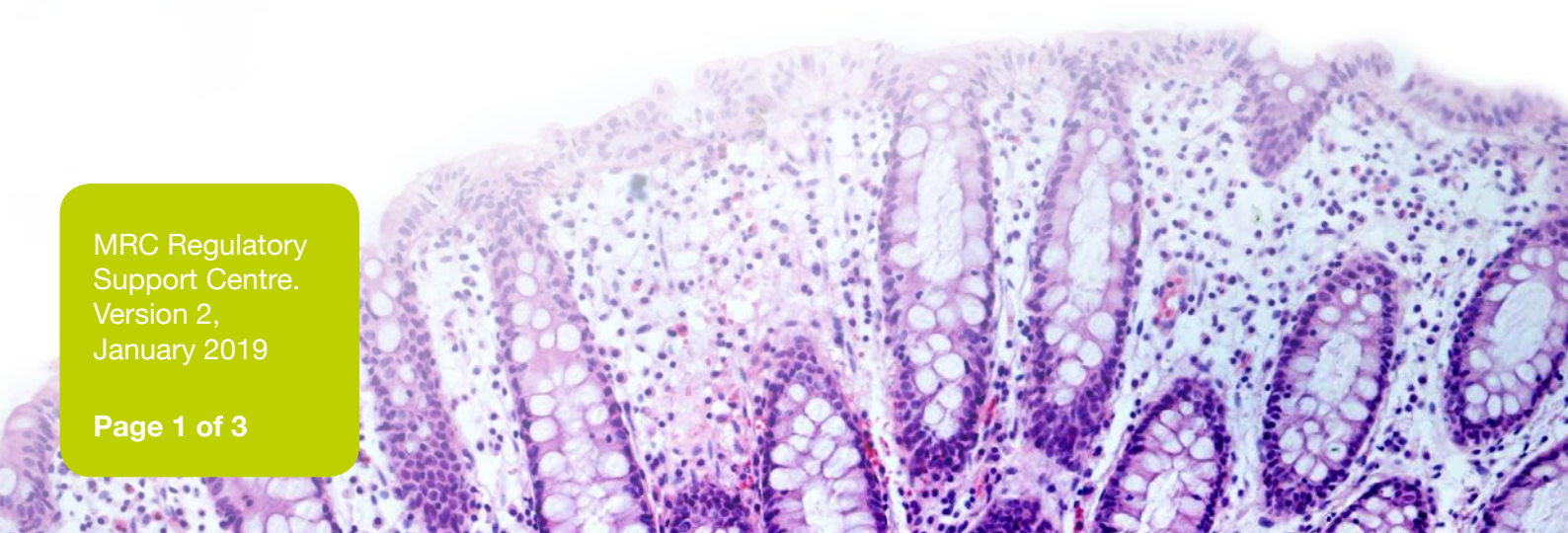
All human tissue should be disposed of with due regard to the nature of the material being handled, the sensitivity and feelings of any bereaved people and the need for clarity when providing information.

Development of disposal policy

Establishments should develop a clear and sensitive policy for disposal. It should describe when disposal is appropriate; how it should be done (including how any specific donor's wishes will be taken into consideration). Disposal should be carried out in line with the HTA Codes of Practice³.

Establishments should carefully document disposal:

- Date, reason and method for disposal should be recorded,
- Supporting Standard Operating Procedures (SOPs) should detail how disposal should be recorded and how tissue should be tracked from donation to disposal,
- To ensure disposal arrangements reflect (where applicable) consent given and any specified wishes.



Disposal of human tissue from the living

Most tissue from the living can be disposed of by incineration to local/national policy and procedures⁵.

This applies to surplus tissue which is 'relevant material' taken whilst receiving medical treatment, undergoing diagnostic testing or participating in research. Surplus tissue includes:

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

Due to the particular sensitivities around disposal of tissue following pregnancy loss, there is separate guidance⁶.

Embryos created *in vitro*

Surplus embryos are regulated under the Human Fertilisation and Embryology Act 2008⁷.

Disposal of existing holdings

The disposal options and guidance for handling existing holdings depend on whether the tissue is identifiable (and donors have made any specific requests regarding disposal) or not. Where disposal is necessary this should be done with sensitivity and respect and the details documented.

Religion, belief and culture

The human body and its parts should be treated with respect. Researchers should be aware that there may be individual, cultural or religious differences in the meaning and significance attached to the body or specific parts of it, which may influence disposal. This is particularly important when donations are from the deceased.

As the beliefs of the donor may not be known to the researcher, due sensitivity should always be shown when approaching relatives to ask for consent (whether to discuss options for disposal or the potential to use these tissues from the deceased in future research). Since consent is being sought at a particularly stressful time, relatives should wherever possible, be given time to reflect before making their decision, and provided with written information for later reference.

Disposal of tissue removed from the deceased

Under the HT Act consent is required to remove tissue from the deceased to store or use it for research. When seeking such consent, you should discuss options for disposal. (A licence may also be required, see below).

Those giving consent may specify a preferred method of disposal and/or ask that remaining tissue be returned to them. All reasonable wishes should be adhered to, provided they are legal and don't pose a potential hazard to health e.g. releasing tissue to relatives where formalin was used as a fixative. The time, place, method of, and *reason for* disposal should be recorded.

Disposal following coroner's post-mortem

The following guidance is given on disposal of human tissue following post-mortem due to the consent and licensing implications of the HT Act.

A coroner can remove 'relevant material' from the deceased without consent, but once the coroner has released the tissue, the consent and licensing requirements of the HT Act must be met to use or store the tissue for research. When releasing tissue, the coroner must inform the relatives of the following 3 options:

- To ask that the tissue be disposed of; or
- To ask for the tissue to be returned to them; or
- To consent to the use of the tissue for research or other purposes.

If relatives agree for tissue from the deceased to be used for research, consent must be obtained in line with the HTA Code of Practice on Consent and Code of Practice on Research³, and the tissue stored under a HTA licence (unless an exemption applies). For further detail please see our consent and licensing summaries⁸.

Disposal options

These are cremation, burial or incineration. All human tissue should be disposed of respectfully and sensitively.

Where practical, 'relevant material' should be bagged separately from clinical waste, but the same incinerator can be used and each sample does not need to be individually incinerated. Please note some crematoria may not accept tissue blocks or glass slides for health and safety reasons.

If the deceased has been buried or cremated, relatives may ask that remaining tissues / organs be returned later.

Research in Scotland

There are some legal differences to consider in Scotland (to learn more please see our Scotland Summary⁸). However, there is an expectation that a disposal policy is in place to ensure disposal conforms to good practice.

Definitions

BODILY MATERIAL: Any tissue or sample that consists of human cells, this includes gametes, and hair and nails from the living or deceased. It **excludes:** embryos outside the body; cells manufactured outside of the human body (e.g. established cell lines) and/or any extracted cellular components where no whole cells remain.

EXISTING HOLDING: Material from the living or deceased that was already held for a scheduled purpose(s) when the Human Tissue Act 2004 came into force; i.e. relevant or bodily material held prior to 1st September 2006 for research.

RELEVANT MATERIAL: Any tissue or sample that contains human cells (from the living or deceased). It **excludes:** gametes, embryos outside the body, nails and hair from the living, cells manufactured outside of the human body (e.g. cell lines once established) and any sample that has been processed to render it acellular. The HTA website⁹ has more information on relevant material.

SCHEDULED PURPOSES: Defined in the HT Act, these are purposes for which consent is required by the Act, one of which is research 'in connection with disorders, or the functioning, of the human body'.

SURPLUS TISSUE: Relevant material which has come from a body in the course of receiving treatment, diagnostic testing or participating in research, or relevant material that has ceased to be stored or used for a 'scheduled purpose'.

References

1. Human Tissue Act 2004 <http://www.legislation.gov.uk/ukpga/2004/30/contents>
2. Human Tissue Authority (HTA) <https://www.hta.gov.uk/>
3. HTA Codes of Practice and Standards <https://www.hta.gov.uk/codes-practice>
In April 2017 the HTA released amended Codes of Practice. The Code on Disposal was removed and disposal requirements are now included in the HTA Code of Practice on Research.
4. UK Research Funders Vision for Human Tissue Resources <http://www.ukrcr.org/wp-content/uploads/2014/03/Vision+for+human+tissue+resources.pdf>
5. Department of Health and Social Care: Management and disposal of healthcare waste (HTM 07-01) <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste>
6. HTA Guidance on the disposal of pregnancy remains following pregnancy loss or termination https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf
7. Human Fertilisation and Embryology Act 2008 <http://www.legislation.gov.uk/ukpga/2008/22/contents>
8. MRC Human Tissue Legislation summaries: available from mrc.ukri.org/regulatorysupportcentre
9. HTA definition of relevant material <https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004>

