

The Human Tissue Act 2004¹ (HT Act) sets out a legal framework for regulating the storage and use of human organs, tissue and cells from the living, and the removal, storage and use of human organs, tissue and cells from the deceased, for specified health-related purposes including 'research in connection with disorders or the functioning of the human body'.

The Human Tissue Authority² (HTA) produced a Code of Practice on the import and export of human bodies, body parts and tissue³. The Code provides guidance and practical steps for establishments (with or without a licence from HTA) that are involved in the import and export of human bodies, body parts or tissue.

This page summarises the HTA Code of Practice on import and export (the Code) in relation to use for research.

What comes under the scope of the Code?

The import and export of:

- The body of a deceased person; or
- Relevant material (see Definitions) which has come from a human body for use for a scheduled purpose.

This includes tissue from living persons for research (including paraffin blocks and slides).

Exceptions to the application of the Code are whole human bodies or parts of bodies that:

- fall outside the HT Act i.e. not relevant material,
- are from the living and only intended for diagnostic use,
- come under the jurisdiction of the coroner / procurator fiscal,
- are being brought into or removed from England, Wales and Northern Ireland for lawful disposal, or
- are historical human remains, or human remains incorporated into artefacts older than 100 years and imported by museums.

DEFINITIONS

IMPORT: Defined as import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland.

EXPORT: Defined as export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.

RELEVANT MATERIAL: Material other than gametes, which consists of or includes human cells (does not include embryos or hair and nails from the living). The HTA has released more information on relevant material on their website⁴.

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 2004 e.g. research in connection with disorders or the functioning of the human body.

What are the underlying principles of the Code?

Imported tissue:

- Imported tissue should be procured, used, handled, stored, transported and disposed in accordance with the consent which has been given, with due regard for safety considerations and the dignity and respect accorded to human bodies, body parts and tissue.
- It is the responsibility of any individual or organisation wishing to import human bodies, body parts or tissue into England, Wales or Northern Ireland to follow the guidance in the Code.
- Any persons or organisations importing tissue should be able to demonstrate that their purposes cannot be met by comparable material within their own country and justify the import in terms of accessibility, quality, timeliness of supply, cost effectiveness, etc.
- Although the consent provisions of the HT Act 2004 do not apply to imported material, it is good practice to ensure mechanisms are in place for obtaining consent in the source country.

Exported tissue:

- Exported tissue should be procured, used, handled, stored, transported and disposed, in accordance with the consent which has been given, with due regard for safety considerations and the dignity and respect accorded to human bodies, body parts and tissue.
- The recipient country is responsible for ensuring the material is handled appropriately and that the required standards of that country have been met.

Summary of Guidance provided in the Code of Practice

The guidance on import and export of human tissue is provided in two parts: guidance for individuals or establishments with an HTA licence, and guidance for those without a licence. These are summarised below.

IMPORT:

For establishments with an HTA licence, the Designated Individual is responsible for ensuring that suitable practices take place and for establishing systems to meet the requirements of the Code of Practice on import and export³.

Consent

For more information on consent, please see the MRC Research and Human Tissue Legislation Series: Consent⁵.

Licensed establishments

It is good practice to have processes for acquiring evidence of informed consent for imported tissue, demonstrated in policies, Standard Operating Procedures and Service Level Agreements where appropriate.

Non-licensed establishments

It is good practice to ensure a minimum level of consent is in place before tissue is imported, especially if then supplying tissue to licensed establishments.

Ethical approval

Licensed and non-licensed establishments

Importers should be satisfied that imported material is sourced consistently with the legal and ethical requirements in England, Wales and Northern Ireland. If possible, approval should be obtained from a Research Ethics Committee (or equivalent) in the source country, or a local form of ethics review should be set up.

Governance, Quality & Safety

Licensed establishments

Certain systems should be put in place depending on the use of imported tissue e.g. quality management, Standard Operating Procedures, coding and records to ensure audit trail, risk assessment and tissue traceability.

IMPORT Governance, Quality & Safety (continued)

Non-licensed establishments

Where there is a risk of infection from imported material, importers should minimise risks to health and safety of all persons who may come into contact with the tissue, and demonstrate expertise in handling and packaging of such material.

Disposal

Licensed and non-licensed establishments

There should be a disposal policy in place which meets the requirements of the HTA Code of Practice on the removal, storage and disposal of human tissue⁶. Specific requests from participants regarding disposal should be carried out. For a summary of requirements, please see MRC Research and Human Tissue Legislation Series: Disposal⁷.

Documentation

Licensed and non-licensed establishments

A register containing relevant details of imported tissue should be kept and retained for at least five years after disposal of the tissue.

EXPORT:

For establishments with and without an HTA licence, exported tissue should be procured, used, handled, stored, transported and disposed, in accordance with the consent which has been given, and with due regard for safety considerations and the dignity and respect accorded to human bodies, body parts and tissue.

Service Level Agreements

Licensed establishments

Service Level Agreements should be in place to ensure exported tissue is used in accordance with the consent given.

DEFINITIONS

STANDARD OPERATING PROCEDURES:

Procedures to be followed when carrying out a specific task e.g. consent or tissue collection.

Is a licence required for imported tissue?

The actual import and export of relevant material is not considered a licensable activity, but a licence may be required to store the material once it is imported if used for research (unless licensing exemptions apply e.g. storage for a project with or pending approval from an NHS Research Ethics Committee).

How does the Code apply to Scotland?

Most of the HT Act 2004 applies to England, Wales and Northern Ireland, except one section (relating to DNA analysis) which applies to the whole of the UK⁸. The Code defines import and export as into/from England, Wales or Northern Ireland from/to a place outside these countries (see Definitions). Therefore, receipt of tissue in England, Wales or Northern Ireland from Scotland is considered import and vice versa is considered export (except for the purposes of importing and exporting tissue for human application under the EU Tissues and Cells Directive, EUTCD)⁹.

The HTA expects requirements applying to tissue imported from Scotland will be maintained at the level of the rest of the UK. A forthcoming Scottish Health Department Letter is expected to align arrangements for use of tissue taken from living people for purposes such as research as closely as possible with those established by the HTA for the rest of the UK.

References

1. Human Tissue Act 2004 www.opsi.gov.uk/acts/acts2004/20040030.htm
2. Human Tissue Authority (HTA) website www.hta.gov.uk
3. HTA Code of Practice: Import and export of human bodies, body parts and tissue http://www.hta.gov.uk/guidance/codes_of_practice.cfm
4. Human Tissue Authority guidance on relevant material http://www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm
5. MRC Research and Human Tissue Legislation Series: 'Consent' www.rsc.mrc.ac.uk
6. HTA Code of Practice: The removal, storage and disposal of human organs and tissue http://www.hta.gov.uk/guidance/codes_of_practice.cfm
7. MRC Research and Human Tissue Legislation Series: 'Disposal' www.rsc.mrc.ac.uk
8. MRC Research and Human Tissue Legislation Series: 'Summary of legal requirements for research with human tissue in Scotland' www.rsc.mrc.ac.uk
9. EU Tissues and Cells Directive http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l1_102/l1_10220040407en00480058.pdf