MRC Medical Research Council

Regulatory Support Centre

Research and the Human Tissue Act 2004 **Import & Export**

Produced in consultation with the Human Tissue Authority

Terms are defined on page 3

The Human Tissue Act 2004[1] (HT Act) sets out a legal framework for regulating the storage and use of human tissue from the living, and the 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 Authority[2] (HTA) has produced Codes of Practice and Standards[3]. **The following summarises both good practice and legal requirements when importing and exporting tissue for research.**

What is included under the HT Act?

The import and export of: '***Relevant material***' *which has come from a human body for use for a scheduled purpose (such as research)* into / out of England, Wales or Northern Ireland. When 'relevant material' is coming into England, Wales or Northern Ireland from Scotland it is considered an import and vice versa an export.

Import and export are not considered licensable activities under the HT Act. However, the storage of relevant material for research once imported is (i.e. imported relevant material stored for research needs to be held under licence, unless an exemption applies). Please see the HTA website[4] or our Licensing summary[5] for more on licensing.

What is excluded?

Relevant material is excluded if it is:

- from the living and only intended for diagnostic use (diagnosis is not considered a scheduled purpose),
- under the jurisdiction of the Coroner/Procurator Fiscal,
- being brought into or removed from England, Wales and Northern Ireland for lawful disposal, or
- historical human remains, or human remains incorporated into artefacts older than 100 years, imported by museums.

Consent requirements under the HT Act

Although consent is a fundamental principle of the HT Act, the consent provisions **do not apply to imported material**. That said it is good practice to gain assurance that consent has been obtained in the source country. The HT Act makes clear that relevant material are not to be exported and re-imported to avoid the consent requirements. For further guidance on consent, please see our Consent summary[5].

Research involving human application

There are specific requirements relating to the import and export of tissues and cells covered by the Q&S Regulations 2007 (as amended)[6]. These requirements apply UK wide (**including** Scotland) and will not be covered here. For further details please see the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment v2 April 2018[7].

Guiding principle for imports

Dignity should be paramount in the treatment of human tissue. Where relevant material is imported, importers should try to ensure that it is sourced from a country with an appropriate ethical and legal framework.

If possible, ethical approval should be obtained from a Research Ethics Committee (REC) or equivalent in the source country. This will help judge ethical acceptance of the research in line with local customs and traditions. You should comply with the legal and ethical framework applicable in the source/recipient country, bearing in mind this may differ from the UK. MRC guidance on global health trials gives advice on the considerations for low and middle income countries[8].

If you cannot ensure that ethical standards are in place, the risks of accepting the material should be assessed.

HTA Research Code of Practice guidance

- Where material will be imported, the need to do so should be justified and documented (e.g. in terms of accessibility, quality of service, timeliness, etc.)
- Imported and exported tissue should be procured, used, handled, stored, transported and disposed of in accordance with the consent given. There should be due regard to safety considerations, expectations of the source / recipient country and the dignity and respect accorded to the human body and its parts.
- It is the responsibility of those importing or exporting samples into / out of England, Wales or Northern Ireland to follow the HTA's good practice guidance[3].
- Where material will be exported, it is good practice to inform participants during the consent process that their samples and any associated data may be transported abroad and used in accordance with their consent. When exporting data abroad you must also meet any other relevant legal requirements.
- For both imports and exports of human tissue, documented agreements should be in place to ensure all issues relating to consent are considered and agreed with the source/recipient country.

The role of the Designated Individual (DI)

The HTA recommends that, whenever possible, the import and export of tissue is conducted via the HTA licensing scheme under the supervision of a Designated Individual (DI). The DI takes responsibility for ensuring that suitable practices and systems are in place to meet the requirements of the HT Act and HTA Codes of Practice[3]. Some examples follow:

Consent

There should be processes to evidence the consent in place for imported material. These processes can be policies and/or Standard Operating Procedures (SOPs), and include how the confidentiality of all consent information will be safeguarded.

Governance, Quality & Safety

Systems should be in place to cover the use of imported tissue e.g. quality management, SOPs, coding and records to ensure audit trails, risk assessment and traceability.

The integrity of the sample should be protected during transport to ensure that it is still fit for purpose on arrival.

Where there is a risk of infection from imported material, you should minimise risks to the health and safety of those who may come into contact with it, and demonstrate expertise in its handling and packaging. Material transfer agreements should document governance arrangements relating to consent, confidentiality, sharing with third parties and disposal / return of any remaining tissue.

Transportation

You should consider how to ensure sample integrity during transit. This should include how traceability can be maintained during transport or whether legislative requirements apply, such as the carriage of 'dangerous goods' under the Air Navigation (Dangerous Goods) Regulations 2002 (as amended)[9]. The World Health Organization (WHO) guidance on regulations for the Transport of Infectious Substances should also be taken into account. Imports and exports of human tissue should normally be declared to HM Revenues and Customs.

Disposal

Unless otherwise stipulated disposal of imported material should meet the requirements detailed in our Disposal summary[5]. Where there are specific requests regarding the disposal of any remaining material, these should be carried out. This may include the return of material to the country of origin. A register containing relevant details of any imported or exported tissue should be kept for at least five years after disposal of the last item.

Research in Scotland

There are some legal differences to consider in Scotland (to learn more please see our Scotland Summary[5]). However, similar standards are expected for the import and export of human tissue into/out of Scotland.

Definitions

EXPORT: 'Relevant material' exported from England, Wales or Northern Ireland to a place outside these countries.

IMPORT: 'Relevant material' imported into England, Wales or Northern Ireland from a place outside these countries.

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 website[10] has more information on relevant material.

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

References

1. Human Tissue Act 2004 http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1
2. Human Tissue Authority (HTA) website https://www.hta.gov.uk
3. HTA Codes of Practice and Standards https://www.hta.gov.uk/hta-codes-practice-and-standards-0
4. HTA Licensing requirements https://www.hta.gov.uk/policies/licensing-under-human-tissue-act
5. MRC Human Tissue Legislation summaries: available from mrc.ukri.org/regulatorysupportcentre
6. HTA Licensing under the Quality and Safety Regulations https://www.hta.gov.uk/policies/licensing-under-quality-and-safety-regulations
7. HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment v2 April 2018 https://www.hta.gov.uk/file/hta-guide-quality-and-safety-assurance-human-tissue-and-cells-patient-treatment-v2-april
8. MRC Guidelines for the management of global health trials https://mrc.ukri.org/documents/pdf/guidelines-for-management-of-global-health-trials/
9. The Air Navigation (Dangerous Goods) (Amendment) Regulations 2017 http://www.legislation.gov.uk/uksi/2017/28/made
10. HTA definition of relevant material https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004