Human Samples in Research

Import and Export of Human Tissue

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that staff and students understand the requirements under the Human Tissue Act (HT Act) for the import and export of human tissue for research purposes. The Human Tissue Authority (HTA) requires that licensed establishments have in place a Quality Management System (QMS) to govern the processes of importing and exporting human tissue, including documentation on the ultimate fate of imported and exported material.

This SOP details the procedures for the import and export of human tissue for research purposes. Import and export in this context are defined respectively as the movement of human tissue into or out of England, Wales or Northern Ireland. This SOP applies to the import and export, for research, of human bodies, body parts and tissues which fall under the HTA classification of 'relevant material' including:

- Human bodies or body parts removed after death.
- All relevant material removed at biopsy and during surgery, including paraffin blocks and slides.

This SOP does not apply to the import or export of human material that falls outside the remit of the HT Act (gametes, acellular material) for research.

2. Background

The import and export of human tissue for research is a common activity. Prior to the HT Act 2004, no regulation existed for the import or export of human bodies, tissues or cells. The HT Act 2004 sets out guidance for the procurement, handling, recording and disposal of imports of human bodies, body parts and tissue for research.

Imported and exported tissue should be procured, used, handled, stored, transported and disposed of 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.

The remit of the HTA within the HT Act provided the statutory basis for the HTA to regulate the import or export, for a Scheduled Purpose, of:

- The body of a deceased person
- Relevant material which has come from a human body

The HTA standards for the research sector require that there be in place, policies and procedures covering all activities related to the storage of relevant material for the purposes of research in connection with disorders, or the functioning of the body.

3. Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place in licensed establishments and establish systems to comply with the HTA Codes of Practice. *E;* The DI must act as a gatekeeper for any imported tissue and should be satisfied that a Service Level Agreement (SLA) or Material Transfer Agreement (MTA) is in place detailing compliance with consent, ethical, governance, disposal and documentation requirements.

It is the responsibility of Persons Designate (PD) to assist the DI in implementing and adhering to governance processes.

All researchers involved in the import or export of human tissue have the responsibility of assigning a unique, traceable code to each sample of tissue and for tracking individual samples and there derivatives throughout all stages of receipt, use, storage and disposal.

The HTA Governance Officer is responsible for ensuring this SOP remains fit for purpose.

4. Procedure

4.1 Licence Requirements

The import and export of relevant material is not a licensable activity under the HT Act however the storage of the material, once imported may licensable if stored for a Scheduled Purpose. Research in connection with disorders, or the functioning, of the body is a Scheduled Purpose under the HT Act. The HTA recommends that the import and export of human tissue for research takes place under the governance of a HTA licensing regime incorporating a DI and suitable QMS.

Storage of imported material may be held on unlicensed premises if it has been collected from the living and imported for a specific HRA Research Ethics Committee (REC) approved project or one of the following purposes:

- Clinical audit
- Performance assessment (e.g. analyser validation)
- Public health monitoring
- Quality assurance

4.2 Justification of Need

Any researcher planning to import material into the University or Health Board for research must demonstrate that comparable material sourced from within England, Wales or Northern Ireland cannot satisfy their requirements. Importation of human material for research should only proceed following documented consideration of the following:

- Integrity of material
- Assurance that appropriate consent is in place
- Need for import in terms of:
    - Accessibility
    - Quality
    - Timeliness of supply
    - Infection risk
    - Quality of service
    - Cost effectiveness
    - Scientific/research need

The documented assessment must be available for internal audit and external inspection by the HTA.

4.3 Consent

Consent is not required for the import of human tissue; however, the HTA recommends that researchers satisfy themselves that appropriate consent has been obtained in line with the proposed use of the material. Further guidance on seeking appropriate consent is set out in *HTA-02-SOP-Consent*.

Good practice requires that robust processes be in place to describe the acquisition of evidence of the receipt of informed consent from the tissue donor. If a third party is responsible for importing the material, a SLA should be in place demonstrating that there is a record of consent. SLAs should be in place to ensure that human tissue exported by the University or Health Board is used in accordance with the consent obtained.

The HT Act and HTA Codes of Practice explicitly stipulate that human tissue must not be exported and then imported to avoid the consent requirements of the Act.

4.4 Ethical Approval

Any researcher who intends to import human tissue must satisfy themselves that the material has been sourced consistently with the legal and ethical requirements that exist in England, Wales and Northern Ireland. When importing material, researchers

should obtain evidence of ethical review in the source country prior to importation. The ethical standards of the reviewing body should be scrutinized before proceeding with importation. Advice, guidance and assurances of the robustness of ethical processes should be sought from collaborators in the source country.

Consent forms for the imported tissue should accompany the material. If this is not feasible, a blank copy of the patient information sheet and consent form should be retained by the researcher. In the event that assurance of sufficient ethical review in the supplying country is not available, HRA REC approval covering the importation must be obtained. In such cases the advice and approval of the DI must also be sought.

4.5 Documentation

Standard documentation for the collection, use, storage and disposal of human tissue (refer to *HTA-07-SOP-Management of Records*) must be maintained for imported human tissue.

Note: Receipt of tissue in England, Wales or Northern Ireland from Scotland for research is considered importation and vice versa is considered exportation. The HTA expects requirements applying to tissue imported from Scotland will be maintained at the level of the rest of the UK.

4.5.1 Tissue Identification and Traceability

A donor ID system must be implemented by any researcher who imports or exports human tissue to ensure tissue traceability. Each sample and all associated products should be assigned a unique code. All documentation relating to the system used to identify and trace imported and exported tissue should be available for inspection by internal audit and the HTA.

4.5.2 Import and Export Records

Before any human tissue is imported, authorization must be obtained from the DI by completion and submission of *HTA-09-FORM-Authorisation to Import Human Tissue*. The form should be submitted to the DI with a copy to the HTA Governance Officer. A signed copy must be kept by the CI and be available for internal audit and inspection by the HTA. No material should be transferred until the authorization is complete.

In addition, the following records must be kept and be available for inspection by the HTA:

- Details of transport and delivery
- MTAs with tissue suppliers
- SLAs with courier companies

- Risk assessment covering the risk to handlers and tissue during transport
- A register of details of the tissue imported
- Suppliers record and consignment documentation

4.5.4 HM Revenue and Customs

Researchers must normally declare imports and exports of human tissue must to HM Revenue and Customs (HMRC). Further advice can be obtained from the HM Revenue Customs National Advice Service (0845 0109000).

4.5.5 Retention of Records

The person undertaking the export should retain supplier records and other documentation of each consignment of imported human bodies, body parts and tissue for at least five years after disposal of the last part included in the consignment.

The register maintained by the person undertaking the import should similarly be retained for at least five years after disposal of the last body part recorded in it.

HMRC import and export entries, declarations and related documentation must be retained for a minimum of three years and up to six years.

4.6 Transportation

Imported and exported tissue should be packaged and transported in line with *HTA-05-SOP-Transportation* and The World Health Organization (WHO) Guidance on regulations for the Transport of Infectious Substances 2017–2018. Both documents must be read in conjunction with this SOP.

The Air Navigation (Dangerous Goods) Regulations 2002 (and related amendments) make detailed requirements for the carriage of “dangerous goods” which means any article or substance identified as such in the Technical Instructions approved and published by the International Civil Aviation Authority, such as an infectious substances or dry ice packaging.

Where possible, researchers should use professional courier services when transporting internationally.

A material transfer agreement (MTA) should be in place and signed by the importing and supplying establishments. All Health Board MTAs shall be signed by the ABM University Health Board (ABM UHB) R&D Department. All University MTAs shall be signed by the Research Engagement and Innovation Services (REIS).

Importers of human tissue should make a customs declaration to HMRC or the UK Border Agency.

4.7 Tissue Disposal

Imported human material should be disposed of in the same manner as tissue sourced within England, Wales and Northern Ireland. Disposal of material should be performed with sensitivity and regard for the dignity of the donor. The responsibilities for disposal of imported and exported material should be set out in a MTA. Disposal of imported material should be in line with the donor wishes, where stipulated.

Detailed guidance is available in *HTA-04-SOP-Disposal* and the HTA Code of Practice E: Research.

4.8 Adverse Events

The processes for reporting and handling human tissue related adverse events are set out in *HTA-11-SOP-Adverse Events*. Investigations will take place into adverse events arising from the import or export of human tissue and corrective and preventative actions implemented as required. Evidence of correct handling of adverse events must be available for internal audit and inspection by the HTA.

5. References

HTA Code of Practice E: Research; Code of Practice and Standards

https://www.hta.gov.uk/sites/default/files/Code%20E.pdf

WHO Guidance on regulations for the Transport of Infectious Substances 2017–2018

http://www.who.int/ihr/publications/WHO-WHE-CPI-2017.8/en/

6. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

7. Definitions

Acquisition: The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Audit - The evaluation of a system, process or procedure in order to ascertain its effectiveness and the validity and reliability of the information.

Chief Investigator – The individual who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the Chief Investigator takes responsibility for the design,

management and reporting of the study, co-ordinating the investigators who take the lead at each site.

Consent - Process by which an individual confirms his/her willingness to participate in a particular procedure. The individual must have been informed of all aspects of the procedure/request that are relevant to the decision to participate. The individual must be competent to take the particular decision, be acting voluntarily and not be acting under duress.

Designated Individual - The person who is authorised and, supervises the activities under a licence issued by the Human Tissue Authority (HTA).

Disposal – Incineration, burial, cremation or use in processing of human tissue.

Existing Holdings – Identifiable or unidentifiable material that was stored for a scheduled purpose when the HT Act came into force on September 1st 2006.

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

Human Tissue – Any and all constituent parts of the human body formed by cells.

Human Tissue Act 2004 - Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The Human Tissue Act lists the purposes for which consent are required (Scheduled Purposes).

Human Tissue Authority - The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice - Provide guidance and lay down expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support professionals by giving advice and guidance based on real-life experience.

HTA Standards - Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

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

Infectious Substance – A substance known to contain, or are reasonably expected to contain, pathogens.

Material Transfer Agreement (MTA) – A contract governing the transfer of research materials between two organisations where the recipient intends to use the material for their own research.

Research Ethics Service – A core function of the Health Research Authority (HRA). It provides an efficient and robust ethics review service to protect the rights, safety, dignity and well-being of research participants.

Person Designate - Individual appointed by the DI to assist in supervising the licensable activities carried out within their organisation.

Principal Investigator – A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

Records - Information created, received, documented and maintained as evidence and information by an organization or person, in pursuance of legal obligations or business transactions.

Relevant Material – Any material, other than gametes, removed from the body which consists of or includes human cells. In the HT Act references to relevant material from a human body do not include:

- embryos outside the human body
- hair and nail from the body of a living person
- cell lines or any other human material created outside the human body
- serum, plasma, DNA and RNA

Research - A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

Retention - An agreed period of time during which record(s) are retained within the records management system, at the expiration of which the record(s) are confidentially destroyed or transferred to archives for permanent retention.

Risk Assessment - a careful examination of what could cause harm to people or resources. Workers and others have a right to be protected from harm caused by a failure to take reasonable control measures.

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.

Standard Operating Procedure - Detailed, written instructions to achieve uniformity of the performance of a specific function which an integral part of a quality management system. In the context of research using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g. acquisition, storage, transfer and disposal).

Storage – Maintaining the tissue under appropriate controlled conditions.

Appendix A – Flowchart for Importation of Human Tissue for Research Projects