# Standard Operating Procedure

# Research Governance

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| **Title:** | **Transportation of Human Tissue** | | |
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Revision Log

| Previous Version number | Date of Review/Modification | Reason for Review/Modification | New Version Number |
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| QUB-HTA-011/01 | 14/02/2013 | Rewrite because of integration to Research Governance | v1.0 |
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| Final 3.0 | 17/05/2019 | Periodic review. Logo and name of Chair updated on cover page. Web links updated. | Final v4.0 |
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## 1. Purpose

This Standard Operating Procedure (SOP) describes the processes required for the transportation of human tissue as defined by the Human Tissue Act 2004 (HT Act).

## 2. Introduction

The HT Act came into force on the 1 September 2006 and provides a framework for regulation of research involving the removal, storage, use and disposal of human tissue. Relevant material must be packaged and transported in accordance with any applicable regulations for hazardous material. This SOP should be read in conjunction with the Human Tissue Authority (HTA) Code of Practice and Standards E Research. .

## 3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are involved in the transportation of relevant material in the areas under the HTA research licences at Queen's University Belfast.

Note: Human tissue samples collected as part of a clinical trial of an investigative medicinal product (CTIMP) or samples acquired and stored in the Northern Ireland Biobank (NIB) will have their own procedures and requirements and should not follow this SOP.

## 4. Responsibilities

### 4.1 Designated Individual

The Designated Individual (DI) is responsible for ensuring that appropriate transportation procedures are in place and that the storage premises are suitable as required by the terms of the HTA licence**.**

### 4.2 Person Designated

The Person Designated (PD) is responsible for referring researchers to the IATA trained member of staff for his/her area as appropriate.

### 4.3 Chief Investigator or Custodian

The Chief Investigator (CI) or custodian of the material is responsible for contacting the IATA trained member of staff for his/her area to ensure all relevant material is transported appropriately in accordance with this SOP and any applicable legislation. The CI or custodian must ensure that any individuals delegated responsibilities related to the transportation of human tissue are suitably trained to undertake the tasks.

### 4.4 Researcher and Support Staff

The researcher and/or other support staff delegated the tasks related to the transportation of human tissue samples must ensure that these tasks are carried out in accordance with this SOP and any applicable legislation.

## 5. Procedure

### 5.1 General

In circumstances where material collected before or after the implementation of the HT Act, is being transferred from the University to another organisation, and there are no existing research agreements in place to govern the transfer (e.g. Service Level Agreement (SLA), collaboration agreement or clinical trial agreement) then a Material Transfer Agreement (MTA) is required.

Where a MTA is required, authorised signatories from the sending and receiving organisations must both sign the agreement before any samples are sent.

The sender (CI or custodian) must ensure that appropriate consent and ethical approval is in place to use the material for the purpose for which it is being transferred.

For tissue transported within Northern Ireland, England or Wales, the receiving organisation must hold a licence from the Human Tissue Authority (unless the material will be rendered acellular or analysed immediately, disposed of appropriately and not stored) or ethical approval from a recognised Research Ethics Committee (REC) must be in place. For exported samples the receiving organisation must be compliant with the regulations in force in the destination country.

Relevant material must be packaged and transported in accordance with any applicable regulations for dangerous goods (e.g. the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 and subsequent amendments, the International Air Transport Association (IATA) Dangerous Goods Regulations, European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID), International Maritime Dangerous Goods (IMDG) Code).

All applicable health and safety policies and procedures must be adhered to. Risk assessments must be completed for all research activities involving human tissue including transportation. It is essential that all risks identified during the course of a scheduled purpose are appropriately recorded and acted upon.

A list of University staff trained in the transport and shipment of dangerous goods is available from the University's Safety Service. The trained staff members within each Centre/School should be contacted for advice and assistance on the transport of dangerous goods including human tissue.

### 5.2 Classification

For transport and shipping purposes infectious substances, including human tissue samples are categorised as Category A or Category B.

(i) Category A Infectious Substances are infectious substances in a form that when exposure occurs are capable of causing permanent disability, life-threatening or fatal disease to humans or animals. An indicative list of Category A infectious substances can be found in Appendix 1. They are assigned the following UN numbers and shipping names:
UN 2814 – Infectious substance, affecting humans
UN 2900 – Infectious substance affecting animals only

Category A Infectious Substances must be packaged in accordance with Packing Instruction 620 (PI 620). Details of transport requirements for Category A infectious substances are not provided in this SOP. Advice must be sought from Safety Services prior to the transport of any Category A infectious substances.

(ii) Category B Infectious Substances are infectious substances that do not meet the criteria for Category A. They are assigned the following UN number and shipping name:
UN 3373 – Biological Substance, Category B

Exemptions:
Dried blood spots collected by applying a drop of blood onto absorbent material or faecal occult blood screening tests are exempt from the classification requirements. Substances in a form whereby any pathogens have been neutralised or inactivated such that they no longer pose a health risk are not subject to the classifications above and associated regulations, unless they fall into another classification of dangerous goods.

## 5.3 Packaging

Category B Infectious Substances must be packaged in accordance with Packing Instruction 650 (PI 650). The packaging requirements of PI 650 are summarised in Appendix 2.

Human tissue samples which are exempt from the regulations must be packaged in appropriate leak proof or break resistant containers to prevent contamination and minimise any possible risks associated with a breakage, spillage or leak. The packaging must be suitable and sufficiently robust for the planned mode of transport.

When shipping is undertaken by a third party (e.g. courier), the packaging requirements stipulated by the third party should also be adhered to when shipping samples.

## 5.4 Labelling

Category B Infectious Substances must be labelled in accordance with PI 650. The labelling requirements of PI 650 are summarised in Appendix 2.

For exempt samples the package must be labelled ‘EXEMPT HUMAN SPECIMEN’.

All labelling and marking must be clearly visible and sufficiently secure to withstand the mode of transport and remain legible.

Samples must be labelled with an appropriate identification code.

The name, address and contact details of the sender and the recipient must be clearly visible.

If previously used packaging is being re-used, any unnecessary or incorrect labels must be removed.

All necessary hazard information and handling labels must be applied.

When transport is undertaken by a third party (e.g. courier), any additional labelling guidelines supplied by the third party should be adhered to when shipping samples.

### 5.5 Temperature Maintenance

Human tissue samples may require temperature maintenance during transportation and refrigerants such as cool packs, dry ice and liquid nitrogen may be used. Any refrigerants used must be packaged appropriately to maintain sample integrity and in accordance with any applicable legislation.

Consideration must be given to the amount of refrigerant to be packed to ensure the sample integrity is maintained during transport.

When human tissue samples are shipped by air and the package contains dry ice all applicable requirements of Packing Instruction 954 (PI 954) must be adhered to. Appendix 3 contains summary guidance for PI 954.

### 5.6 Chemical Preservation

Chemicals may be used to preserve or stabilise human tissue samples during transportation. Advice from University staff trained in the transport of dangerous goods should be sought to determine if the chemical substance(s) is considered dangerous goods for the purpose of transportation.

When the transportation process involves other chemical or biological hazards then a COSHH assessment must be completed as appropriate.

A list of University staff trained in the transport and shipment of dangerous goods is available from the University's Safety Service.

### 5.7 Use of Third Parties

When a third party (e.g. professional courier) is used they should have established and reliable procedures for the transport of relevant material.

When a third party (e.g. courier) is used a secure tracking system should be in place to maintain traceability of relevant material during transport.

Consideration should be given to the dates and timing selected for transport. Sending samples destined to arrive on public holidays and/or weekends should be avoided unless the receiving organisation is prepared to accept samples on such days. It is the responsibility of the sender to ensure the receiving organisation is aware of the transport of the relevant material and prepared for receipt.

Senders should be aware of the courier's time commitment for delivery and when temperature maintenance is required, use sufficient quantities of refrigerant to ensure sample integrity is maintained for the duration of transport. Consideration should also be given to possible delays in transport (e.g. at customs or due to adverse weather conditions) and the use of couriers who are prepared to replenish refrigerants in the event that delays occur.

### 5.8 Use of Private Vehicles

If a private vehicle is to be used it is the responsibility of the registered owner to ensure that their insurance is valid for business use and the purpose of sample transport.

The packaging, labelling and marking requirements as described in Appendix 2 will apply for Category B infectious substances transported on public roads.

Transport by road should be by a direct route and human tissue samples should not be left unattended unnecessarily in private vehicles.

### 5.9 Transportation between University premises

Samples transferred on foot between the University premises (and the Belfast Health and Social Care Trust) must be transported in appropriate containers to prevent contamination and minimise any possible risks associated with a spillage, breakage or leak.

### 5.10 Documentation

The CI (or designated researcher) must ensure all relevant documentation relating to the transport of relevant material is maintained, including MTAs/SLAs, customs declarations, records of transport and confirmation from the receiving organisation of safe receipt of the material.

The QOL Tissue Register must be updated to reflect the transfer of relevant material.

## 6. References

Human Tissue Authority Code of Practice and Standards E Research
https://www.hta.gov.uk/hta-codes-practice-and-standards (last accessed May 2019)

Human Tissue Authority definition of relevant material https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004 (last accessed May 2019)

Human Tissue Authority Code of Practice and Standards A Guiding Principles and the Fundamental Principle of Consent
https://www.hta.gov.uk/hta-codes-practice-and-standards (last accessed May 2019)

QUB Safety Service
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/ (last accessed May 2019)

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 and subsequent amendments (http://www.legislation.gov.uk/nisr/2011/365/made) (last accessed May 2019)

International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air http://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx (last accessed May 2019)

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) http://www.unece.org/trans/danger/publi/adr/adr_e.html (last accessed May 2019)

Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)
http://otif.org/fileadmin/new/3-Reference-Text/3B-RID/RID_2017_E.pdf (last accessed May 2019)

International Maritime Dangerous Goods (IMDG) Code
http://www.imo.org/Publications/IMDGCode/Pages/Default.aspx (last accessed May 2019)

International Air Transport Association (IATA) Dangerous Goods Regulations (http://www.iata.org) (last accessed May 2019)

## 7. Appendices

Appendix 1 Indicative List of Category A Infectious Substance;
Appendix 2 Category B Infectious Substances - Summary Transportation Requirements;
Appendix 3 Dry Ice - Summary Transportation Requirements.

## Category A Infectious Substances, Affecting Humans – UN2814

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| Bacillus anthracis (cultures only) |
| Brucella abortus (cultures only) |
| Brucella melitensis (cultures only) |
| Brucella suis (cultures only) |
| Burkholderia mallei–Pseudomonas mallei–Glanders (cultures only) |
| Burkholderia pseudomallei–Pseudomonas pseudomallei (cultures only) |
| Chlamydia psittaci–avian strains (cultures only) |
| Clostridium botulinum (cultures only) |
| Coccidioides immitis (cultures only) |
| Coxiella burnetii (cultures only) |
| Crimean-Congo haemorrhagic fever virus |
| Dengue virus (cultures only) |
| Eastern equine encephalitis virus (cultures only) |
| Escherichia coli, verotoxigenic (cultures only) |
| Ebola virus |
| Flexal virus |
| Francisella tularensis (cultures only) |
| Guanarito virus |
| Hantaan virus |
| Hantavirus causing hemorrhagic fever with renal syndrome |
| Hendra virus |
| Hepatitis B virus (cultures only) |
| Herpes B virus (cultures only) |
| Human immunodeficiency virus (cultures only) |
| Highly pathogenic avian influenza virus (cultures only) |
| Japanese Encephalitis virus (cultures only) |
| Junin virus |
| Kyasanur Forest disease virus |
| Lassa virus |
| Machupo virus |
| Marburg virus |
| Monkeypox virus |
| Mycobacterium tuberculosis (cultures only) |
| Nipah virus |
| Omsk haemorrhagic fever virus |
| Poliovirus (cultures only) |
| Rabies virus (cultures only) |
| Rickettsia prowazekii (cultures only) |
| Rickettsia rickettsii (cultures only) |
| Rift Valley fever virus (cultures only) |
| Russian spring-summer encephalitis virus (cultures only) |
| Sabia virus |
| Shigella dysenteriae type 1 (cultures only) |
| Tick-borne encephalitis virus (cultures only) 3 |
| Variola virus |
| Venezuelan equine encephalitis virus (cultures only) 3.6 |
| West Nile virus (cultures only) |
| Yellow fever virus (cultures only) |
| Yersinia pestis (cultures only) |

## Infectious Substance Category B - Transportation Requirements Summary*

*Packing Instruction 650 should be referred to for detailed instructions.

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| **Classification** | Class 6.2 |
| **UN Number** | UN 3373 |
| **Shipping Name** | Infectious Substance Category B |
| **Packing Instruction** | PI 650 |
| **Packaging Requirements** | The packaging must be of adequate strength to withstand the mode of transport chosen (including manual or mechanical handling) and the material must be packaged in such a manner as to prevent any deterioration or contamination that might be caused by conditions of transport<br><br>Primary receptacles must be placed in secondary packing in such a way that under normal transport conditions they cannot break or leak their contents into the secondary packaging<br><br>**<u>For liquid substances</u>**<br><br>The packaging must consist of three components:<br>(a) leakproof primary receptacle<br>(b) leakproof secondary packaging<br>(c) outer packaging (for transport by air the outer packaging must be rigid)<br><br>Absorbent material (eg cotton wool) must be placed between the primary receptacle and secondary packaging in a sufficient quantity to absorb the entire contents of the primary receptacle and maintain the integrity of the outer packaging<br><br>**<u>For solid substances</u>**<br><br>The packaging must consist of three components:<br>(a) siftproof primary receptacle<br>(b) siftproof secondary packaging<br>(c) outer packaging (for transport by air the outer packaging must be rigid)<br><br>For solid samples transported and the primary receptacle must not exceed the outer packaging weight limit |
| **Packaging size** | One surface of the outer packaging must have minimum dimensions of 100 x 100mm |
| **Packaging Testing** | The packaging must be capable of passing a 1.2m drop test<br><br>For transport by air, the primary receptacle or secondary packaging must be capable of withstanding without leakage an internal pressure of 95 kPa |
| **Quantity Limits (Air only)** | For liquid substances the primary receptacle cannot contain more than 1 litre and the outer packaging must not contain more than 4 litres (excluding ice, dry ice or liquid nitrogen) |

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| | For solid substances the outer packaging must not contain more than 4 kilograms (excluding ice, dry ice or liquid nitrogen and not applicable to body parts or organs) |
| **Labelling** | The label illustrated below must be clearly displayed on the outer packaging:<br>  <br><br>The package surface must be a contrasting colour to the background of the mark<br><br>Each side of the mark must have a length of at least 50mm, the width of the line must be at least 2mm and the letters and numbers at least 6mm high<br><br>The term 'BIOLOGICAL SUBSTANCE, CATEGORY B', must be marked adjacent to the label and the letters must be at least 6mm high<br><br>The name, address and contact details of the sender and the recipient must be clearly visible (including emergency contact details if applicable) |
| **Documentation** | For transport by air an itemised list of contents must be included between the secondary and outer packaging<br><br>Other documentation such as Air Waybill, Shipper's Declaration or customs declaration to be completed as required |

## Dry Ice - Transportation Requirements Summary*

*Packing Instruction PI 954 should be referred to for detailed instructions.

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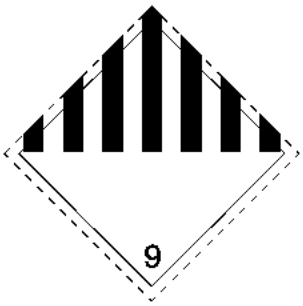
|---|---|
| **Classification** | Class 9 |
| **UN Number** | UN 1845 |
| **Shipping Name** | Dry Ice |
| **Packing Instruction** | PI 954 |
| **Packaging Requirements** | When used, dry ice must be placed outside the secondary packaging or alternatively in an overpack<br><br>Interior supports must be used to secure the secondary packaging in the original position after the dry ice has dissipated<br><br>The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were lost<br><br>The packaging must permit the release of carbon dioxide gas |
| **Packaging size** | No minimum packaging size |
| **Packaging Testing** | Not required |
| **Quantity Limits (Air only)** | Not more than 200kg per package |
| **Labelling** | The hazard warning label shown below must be displayed for transport by air:<br><br>  <br><br><br>The label must be at least 10cm x 10cm in size and have black text on a white background and a line 5mm inside the edge running parallel to it<br><br>The UN number UN1845, the words dry ice and the net weight of the dry ice (kgs) must be marked on the outer package<br><br>The name, address and contact details of the sender and the recipient must be clearly visible (including emergency contact details if applicable)<br><br>When samples are transported by road, the package must be marked with the words ‘Dry Ice’ - the UN number and hazard label are not required |
| **Documentation** | Other documentation such as Air Waybill, Shipper’s Declaration or customs declaration to be completed as required |