Swansea University
Prifysgol Abertawe

R&D
RESEARCH & DEVELOPMENT
Abertawe Bro Morgannwg University Health Board

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Abertawe Bro Morgannwg
University Health Board

Human Samples in Research

Transportation of Human Tissue

Document Identifier		HTA-05-SOP-Transportation	
AUTHOR	**Name and role**	Dr Lisa Wakeman HTA Governance Officer	
	Signature and date	Signed copy held in ABM UHB R&D Office	
APPROVER	**Name and role**	Professor Catherine Thornton Designated Individual	
	Signature and date	Signed copy held in ABM UHB R&D Office	
EFFECTIVE DATE:	01.05.18	**REVIEW DATE:**	01.05.20

Document History

Version	Review Date	Comment	Replaces	Reviewed by
2.0	24.10.15	Front page, hyperlink and footer amendments, removal of MTA template. Addition of courier requirements for exempt specimens	1.0	Lisa Wakeman
3.0	01.09.16	Post-licence grant review, amendment from acting designated individual reference; minor text amendments. Update reference to DRI to REIS	2.0	Lisa Wakeman
4.0	18.04.18	Amendments to reflect revised HTA Codes of Practice and Standards Minor change to consent for transportation. Updated link to current transport regulations. Addition of insurance requirements for use of private vehicles	3.0	Lisa Wakeman

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that staff and students involved in research covered by the Human Tissue Act (HT Act) understand the procedure and mechanisms for the transportation of human tissue.

Human tissue samples collected as part of a clinical trial of an investigative medicinal product (CTIMP) that have their own procedures and requirements should not be handled in accordance with this SOP.

2. Background

The HT Act came fully in to force on 1 September 2006 to provide a legal framework regulating the storage and use of human tissue from the living and the removal storage and use of tissue from the deceased. The Human Tissue Authority (HTA) requires that an establishment have in place appropriate documented procedures for the transport of human tissue, which protect both the tissue and any individuals involved in transportation.

3. Roles and Responsibilities

This SOP applies to all Swansea University and ABM University Health Board (ABM UHB) employees and students who are responsible for collecting, using or storing human tissue for research and employees of other organisations holding relevant material under the HTA Licence. The SOP must be used in conjunction with the HTA Codes of Practice and all other relevant University and, where appropriate, ABM UHB policies and SOPs.

The Designated Individual is responsible for implementation and supervision of this SOP and the practices herein.

The Human Tissue Act Governance Officer is responsible for ensuring that this SOP remains fit for purpose.

4. Procedure

4.1 HTA Licensing

Transport of relevant material between two establishments within England, Wales and Northern Ireland for the purpose of research is permissible where both establishments hold a HTA licence or where one of the following exemptions applies:

a) Transportation of the material is covered by project specific NHS Research Ethics Committee (REC) approval.

b) The tissue is being held for no longer than 7 days incidental to transportation to an establishment which holds a HTA licence or where one of the exemptions applies.

c) The receiving establishment renders the tissue acellular within 7 days of receipt and the distributing establishment holds a HTA licence or one of the exemptions applies.

d) The tissue is distributed from a Research Tissue Bank (RTB) located on HTA licenced premises and which holds generic HRA REC approval.

e) The tissue is not relevant material.

f) The tissue is more than 100 years old.

Evidence of a HTA licence or exemption must be in place before tissue is transported from Swansea University or ABM UHB premises.

Guidance on the export of human tissue outside England, Wales and Northern Ireland is set out in *HTA-06-SOP-Import and Export*.

4.2 Consent

Donor consent should be in place for the transfer of tissue to other researchers within England, Wales and Northern Ireland or export outside of England, Wales and Northern Ireland. If such consent is not in place, consideration should be given to the feasibility of approaching donors for consent to transportation. If this is not feasible and the study has HRA REC approval for tissue transportation, the tissues may be transferred as long as they were obtained from the living and are anonymised.

4.3 Risk Management

Any individual involved in the transport of tissue samples must adhere to the Swansea University Health and Safety policies and procedures and, where activities take place in the Health Board, the ABM UHB Health and Safety Policy.

All individuals who transport human samples in private vehicles must hold fully comprehensive, business use insurance.

All activities involving the handling and transportation of human tissues must be risk assessed and include risks to the individuals handling the tissue and to the tissue samples. Consideration must be given to the various additional risks involved in the transportation of human tissue including:

- Handling of heavy containers
- Appropriate biohazard labeling of containers
- Harmful preservative/fixative reagents

Further information on risk assessing the handling and transportation of human tissue to achieve compliance with HTA licensing standards is available in the Swansea University/ABM UHB standard operating procedures *HTA-01-SOP-SOPs* and *HTA-09-SOP-Risk Management*. All individuals involved in the transfer of a particular consignment of tissue should have the opportunity to contribute to the risk assessment.

4.4 Documentation

4.4.1 Traceability records

Human tissue used or stored for research must be traceable from collection to disposal including records of transport. Such records should include:

- Where the tissue was transported to
- When the tissue was transported (date of dispatch and date of receipt)
- How much tissue was transported
- Contact details for the person responsible for dispatch and receipt

4.4.2 Material Transfer Agreement

A Material Transfer Agreement (MTA) should set out pre-planned arrangements for the safe transfer of tissue and must be in place for tissue transferred out of or into the University or Health Board for research purposes. The MTA and should define the responsibility for tissue disposal and include relevant details of the any specific risks including those:

- posed by tissue to handlers (infection, contamination etc.)
- posed by fixatives/reagents to handlers
- to tissue during transfer
- related to the suitability and safety of modes of transport and routes

MTAs must not be signed by researchers. Health Board MTAs are signed by the R&D Director or nominated deputy. University MTAs are signed by an authorized representative of the Research Enterprise & Innovation Services. Copies of all fully signed MTAs covering relevant material are held with the HTA Governance Officer.

4.5. Classification of Infectious Substances

Because of the differences in the hazards posed by Category A infectious substances (UN 2814 and UN 2900) and Category B infectious substances (UN 3373) there are variations in the packaging, labelling and documentation requirements for the two categories.

The WHO Flowchart for the Classification of Infectious Substances and Patient Samples is reproduced in Appendix A for reference.

4.5.1 Category A Infectious Substance

Defined as an infectious substance transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria can be found in the referenced WHO guidance document (Annex 2). Infectious substances, including new or emerging pathogens, which do not appear in the guidance but which meet the same criteria shall be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it shall be included in Category A.

Infectious substances meeting the criteria which cause disease in humans or both in humans and animals shall be assigned to United Nations number UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900. The proper shipping name for UN 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS. The proper shipping name for UN 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only.

Assignment to UN 2814 or UN 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

4.5.2 Category B Infectious Substance

Defined as an infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373. The proper shipping name of UN 3373 is “BIOLOGICAL SUBSTANCE, CATEGORY B”.

4.5.3 Exemptions

Substances that do not contain infectious substances or that are unlikely to cause disease in humans or animals are not subject to dangerous goods regulations, unless they meet the criteria for inclusion in another class. Substances containing micro-organisms that are non-pathogenic to humans or animals or which are in a form in which any present pathogens have been neutralized or inactivated such that they no

longer pose a health risk are not subject to dangerous goods regulations unless they meet the criteria for inclusion in another class. Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests are not subject to dangerous goods regulations.

Human specimens (patient specimens) for which there is minimal likelihood that pathogens are present are not subject to dangerous goods regulations if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen”, as appropriate. Please note that some couriers insist on human samples that are considered to be exempt human specimens being packaged in line with 4.5.2 and marked with the UN 3373 symbol. Some couriers are unwilling to transport human material labelled under this exemption. Please check directly with couriers regarding their requirements and packaging specifications prior to transfer.

An element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions.

4.6 Packaging and Transportation Requirements for Human Tissue

Guidance on the transportation of human tissue is based on the WHO guidance document *Guidance on regulations for the Transport of Infectious Substances 2017–2018*

Sections of the WHO guidance are reproduced in this SOP for information.

Differences in hazards posed by Category A and Category B infectious substances dictate variations in packaging, labelling and documentation requirements for the two categories.

4.6.1 General Preparation for Shipment

The following general provisions should be observed for all tissue transfers:

- Hand carriage of Category A and Category B infectious substances and transport of these materials in diplomatic pouches are strictly prohibited by international air carriers.

- Inner packages containing infectious substances shall not be consolidated with inner packages containing unrelated types of goods.

- Shippers of infectious substances shall ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport.

- A basic triple packaging system shall be used for all infectious substances:

    - Primary receptacle - A primary watertight, leak-proof receptacle containing the specimen. The receptacle is packaged with enough absorbent material to absorb all fluid in case of breakage or leakage.

    - Secondary packaging - A second durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s). Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material shall be used to absorb all fluid in case of breakage or leakage.

    - Outer packaging - Secondary packagings are placed in outer shipping packagings with suitable cushioning material. Outer packagings protect their contents from outside influences, such as physical damage, while in transit. The smallest overall external dimension shall be 10 x 10 cm.

    - Each completed package should be correctly marked, labelled and contain the appropriate shipping documents as described in sections 4.6.2 and 4.6.3

4.6.2 Transport of Category A Infectious Substances (UN2814 and UN 2900)

4.6.2.1 Packaging

Infectious substances in Category A and designated as UN 2814 or UN 2900 may only be transported in packaging that meets the United Nations class 6.2 specifications and complies with Packing Instruction P620. The outer packaging shall bear the United Nations packaging specification marking. Details of P620 instruction and package marking are available in the WHO Guidance on Regulations for the Transport of Infectious Substances 2017-2018.

The primary receptacle or the secondary packaging shall be capable of withstanding a pressure differential of not less than 95kPa. The United Nations packaging specification marking alone does not indicate that a test for this has been undertaken.

For surface transport there is no maximum quantity per package. For air transport the limits per package are as follows:

- 50 ml or 50g for passenger aircraft
- 4 litres or 4 kg for cargo aircraft

Any primary receptacle with a capacity of more than 50ml shall be oriented in the outer packaging so that the closures are upwards. Orientation labels ("UP" arrows) shall be affixed to two opposite sides of the outer packaging.

4.6.2.2 Marking

Each package shall clearly display the following information on the outer packaging:

- The shipper's (sender's, consignor's) name and address
- The telephone number of a responsible person, knowledgeable about the shipment
- The receiver's (consignee's) name and address
- The United Nations number followed by the proper shipping name (UN 2814 "INFECTIOUS SUBSTANCE, AFFECTING HUMANS" or UN 2900 "INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only", as appropriate). Technical names need not be shown on the package
- Temperature storage requirements
- When dry ice or liquid nitrogen is used; the technical name of the refrigerant, the appropriate United Nations number, and the net quantity.

4.6.2.3 Labelling

Hazard labels are required depending on the contents of the shipment including any refrigerants (dry ice, liquid nitrogen, cryogenic liquid) used to maintain the tissue during transport. The relevant hazard labels for infectious substances and refrigerants are detailed in the WHO Guidance on Regulations for the Transport of Infectious Substances 2017-2018.

4.6.2.4 Documentation

To be prepared and signed by the shipper:

- For air: the shipper's Declaration for Dangerous Goods
- A packing list / proforma invoice that includes the receiver's address, the number of packages, detail of contents, weight, value (Note: for international transport, a minimal value shall be indicated, for customs purposes, if the items are supplied free of charge)
- An import and/or export permit and/or declaration if required.

To be prepared by the shipper or the shipper's agent:

- An air waybill for air transport or equivalent documents for road, rail and sea shipments.

- For UN 2814 and UN 2900, an itemized list of contents shall be enclosed between the secondary packaging and the outer packaging.

- For the purposes of documentation, the proper shipping name shall be supplemented with the technical name. Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A and assignment to UN 2814 or UN 2900, the words "suspected Category A infectious substance" shall be shown, in parentheses, following the proper shipping name on the transport document, but not on the outer packagings.

4.6.3 Transport of Category B Infectious Substances

4.6.3.1 Packaging

Triple packaging requirements detailed in section 4.6.1 apply, including for local surface transport. Testing documents are not required. Packaging should comply with the requirements of P650 as set out in the WHO Guidance on Regulations for the Transport of Infectious Substances 2017-2018. Compliance with P650 when packaging category B infectious substances is sufficient to make a shipment.

For surface transport there is no maximum quantity per package. For air transport:

- No primary receptacle shall exceed 1 litre and the outer packaging must not contain more than 4 litres (for liquids).

- Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg (for solids).

4.6.3.2 Marking

Each package shall display the following information:

- Air: the shipper's (sender's, consignor's) name, address and telephone number
- Air: the telephone number of a responsible person, knowledgeable about the shipment
- The receiver's (consignee's) name, address and telephone number
- Temperature storage requirements
- The proper shipping name ("BIOLOGICAL SUBSTANCE, CATEGORY B") adjacent to the diamond-shaped UN 3373 mark shown below:

The UN mark shall conform to the following:

- Minimum dimension: the width of the line forming the square shall be at least 2 mm, and the letters and numbers shall be at least 6 mm high. For air transport, each side of the square shall have a length of at least 50 mm.
- The mark is displayed on the external surface of the outer packaging on a background of contrasting colour and that it is clearly visible and legible.
- The words “BIOLOGICAL SUBSTANCE, CATEGORY B” in letters at least 6 mm high shall be displayed adjacent to the mark.

Where dry ice or cryogenic liquids are used for air transport, the relevant label shall be affixed.

4.6.3.3 Documentation

Dangerous goods documentation is not required for transport of Category B infectious substances.

The following documentation should be prepared by the consignor:

- For international shipments: a packing list/proforma invoice that includes the shipper's and the receiver’s address, the number of packages, detail of contents, weight, value (Note: the statement “no commercial value” shall appear if the items are supplied free of charge).
- An import and/or export permit and/or declaration if required.

The following documentation should be prepared by the shipper:

- An air waybill for air transport or equivalent documents for road, rail and sea journeys.

4.6.4 Combining Packages for Transportation

"Overpack" is the term used when several packages are combined to form one unit and sent to the same destination by a single shipper. When refrigerants are used to protect contents, the overpacks may comprise insulated vessels or flasks. Whenever an overpack is used, the required marks and labels shown on the outer packaging must be repeated on the outermost layer of the overpack. This requirement applies to infectious substances in Categories A and B. Overpacks must be marked with the word “overpack”.

Do not reproduce the UN specification marking on the overpack.

4.6.5 Reusing Packaging

Before reusing a package, the shipper must make sure all markings and labels reflect the substances actually being shipped. The packaging material must be disinfected before re-use.

4.7 Refrigerants

- Where infectious substances assigned to packing instructions P620 or P650 require cooling during transport, the package must meet the relevant instruction.

- Ice, ice pads or dry ice shall be placed outside the secondary receptacle or in an outer packaging or in an overpack.

- Wet ice shall be placed in a leak-proof container; the outer packaging or overpack shall also be leak-proof.

- Dry ice must not be placed inside the primary or secondary receptacle because of the risk of explosions. A specially designed insulated packaging may be used to contain dry ice. The packaging must permit the release of carbon dioxide gas if dry ice is used. Packing instruction P003 (ICAO/IATA PI954) shall be observed. International Civil Aviation Organisation Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO) can be viewed at http://www.icao.int/publications/Documents/guidance_doc_infectious_substances.pdf

- The secondary receptacle shall be secured within the outer package to maintain the original orientation of the inner packages after the refrigerant has melted or dissipated.

- If dry ice is used to ship infectious substances in Category A, the details shall appear on the shipper's Declaration for Dangerous Goods. If dry ice is used to ship infectious substances in Category B or Exempt samples, the shipper's Declaration of Dangerous Goods is not required. In any case, the outermost packaging shall carry the hazard label for dry ice, the appropriate markings, including the UN number and the proper shipping name followed by the words "AS COOLANT", and an indication of the net quantity of dry ice in kilograms.

- If liquid nitrogen is used as a refrigerant, special arrangements shall be made in advance with the carrier. Primary receptacles shall be capable of withstanding extremely low temperatures, and packaging and documentation requirements for liquid nitrogen shall be observed. The outermost packaging must carry the hazard label for liquid nitrogen. For air transport, the handling label for cryogenic liquids shall also be affixed.

- When shipping with liquid nitrogen, "dry shippers" can be used. Correctly prepared "dry shippers" do not contain free liquid nitrogen. While liquid nitrogen is a regulated dangerous good, a properly prepared "dry shipper" is not. When shipping with "dry shippers", the dangerous goods label for class 2 (non-flammable, non-toxic gases) is NOT required. Shippers must properly mark and label the outside of dry shipper packages containing infectious substances. Appropriate documentation should discuss the presence of infectious substances. For Category A this information will be included in the Dangerous Goods Declaration. For Category B and Exempt packages this information should be provided on the Air Waybill.

4.8 Modes of Transport

In all cases, transport of human tissue must be pre-planned and comply with the HTA *Code of Practice 8: Import and Export of Human Bodies, Body Parts and Tissue*. All plans for tissue transport should be risk assessed before the transfer occurs. Ideally specialist couriers with appropriate documented procedures should be employed for the transfer of human tissue.

4.8.1 Transport by Sea or Air

- Where possible, use a professional courier service and seek advice on any specific procedures they require.

- The transport of category A or B substances as hand luggage is forbidden by International air carriers.

- Consideration must be given to human tissue regulation in the destination country

- The packaging of category A and B substances must comply with the requirements set out in sections 4.6.2 and 4.6.3.

4.8.2 Summary Guidance for Transport by Post

- Infectious substances in Category A will not be accepted through postal services including by air mail.

- Postal transport of Category B infectious substances are prohibited in the international post, but may be carried within the UK provided strict conditions are met. Samples must be packaged in accordance with Packing Instruction P650.

- There are several commercially available packing systems that are fully compliant with Packing Instructions P650 and the requirements of Category B infectious substances, including the Royal Mail 'Safebox'.

- Postal transport of dry ice is prohibited.

- Infectious substances in Category B may be shipped by registered air mail, and the Universal Postal Union recommends the following procedure:

    - The basic triple packaging system is used with the same requirements as for other means of transport. The address label shall display the word "Letter" and the green Customs Declaration Label for Postal Mail is required for international mailing. "BIOLOGICAL SUBSTANCE, CATEGORY B" shall be identified with the white diamond label with black letters "UN 3373" (see section 4.6.3.2).

- Local/international restrictions may be in force therefore prior contact should be made with the national public operator to ascertain whether the packaged material will be accepted by the postal service in question.

4.8.3 Summary Guidance for Transport by Road or Person

- The transport of dangerous goods by road must comply with the European Agreement concerning the International Carriage of Goods by Road (2010) which can be accessed at:

- Packaging must comply with the instructions detailed in section 4.6.

- The material must never be left unattended during transport.
- Clear instructions for action in an emergency must be available during the transfer.
- The driver must be aware of the contents of the consignment but not of any personal information therein.
- Organisational policies relating to the use of personal and hire vehicles must be observed.
- Cryogenic gases, such as dry ice, must be kept separate from the driver / passengers. Vehicles should have a separate cab or trailer. Cryogenic gases should never be transported in cars.
- Organisational health and safety procedures should be observed when transporting human tissue and refrigerants.
- Public transport must not be used to transport human tissue.

4.9 Use of Couriers

- Tissue transfer should be tracked and auditable.
- Specialist couriers should be used to transport fresh unfixed human tissue. Fixed/embedded tissue may be transported by secure couriers.
- A Service Level Agreement should be in place with courier companies.

4.10 Training

Individuals responsible for the shipping of Category A infectious substances must undergo and satisfy the requirements of suitable training at approved courses.

Individuals responsible for the shipping of Category B infectious substances must be provided with clear instruction on the use of the packaging which will be considered to be sufficient training. However, if such specimens are to be consigned with other dangerous goods (e.g. flammable liquids, radioactive materials, liquefied gases, etc.) then personnel must be trained in the proper procedures for their transport.

5 References

HTA Code of Practice A: Guiding Principles and the Fundamental Principle of Consent
https://www.hta.gov.uk/sites/default/files/files/HTA%20Code%20A.pdf

HTA Code of Practice E: Research; Code of Practice and Standards
https://www.hta.gov.uk/sites/default/files/Code%20E.pdf

International Civil Aviation Organisation Technical Instructions for the Safe Transport of Dangerous Goods by Air 2005-2006

http://www.icao.int/publications/Documents/guidance_doc_infectious_substances.pdf

United Nations Economic Commission for Europe: European Agreement concerning the International Carriage of Dangerous Goods by Road

http://www.unece.org/trans/danger/danger.html

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

Category A Infectious Substance – An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

Category B Infectious Substance – An infectious substance that does not meet the criteria for inclusion in Category A.

Consignor- Shipper or sender of packaged material

Consignee – Recipient of packaged material

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

Diplomatic pouch – Also known as a Diplomatic bag is a container with certain legal protections used for carrying official correspondence or other items between a diplomatic mission and its home government or other diplomatic, consular, or

otherwise official entities. The physical concept of a "diplomatic bag" is flexible and therefore can take many forms e.g., a cardboard box, briefcase, duffel bag, large suitcase, crate or shipping container.

Exempt Human Specimen – Human specimens for which there is minimal likelihood that pathogens are present.

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

Human Tissue Authority (HTA) – The governing body set up to regulate activities that come under the HT Act. The HTA is a watchdog that supports public confidence by licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions.

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 material between two organisations where the recipient intends to use the material for their own research.

Pathogens - Micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions which can cause disease in humans or animals.

Patient Specimens – Specimens collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

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..

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

Service Level Agreement – A document defining the level of service required between a provider and their customer including performance, operation, priorities responsibilities and guarantees.

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.

Waybill - A document attached to goods in transit specifying their nature, point of origin, and destination as well as the route to be taken and the rate to be charged.

Appendix A - WHO Flowchart for the Classification of Infectious Substances and Patient Samples