The Newcastle upon Tyne Hospitals NHS
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STANDARD OPERATING PROCEDURE NUMBER:			Newcastle University research sector HTA licence (Ref. 12534) Uteroplacental Tissue Bank UCS05.version 7
HUMAN TISSUE ACT – RESEARCH SECTOR			
TITLE	Procedure for the export and receipt of specimens to and from external laboratories		
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APPROVAL	M J Taggart Person Designate		
EFFECTIVE DATE:	26.10.18	**REVIEW DATE:**	25.10.20

Distribution

This SOP should be followed by all those obtaining, using and storing human tissue samples within the Uteroplacental Tissue Bank.

This document has been approved by Prof M J Taggart, PD. It is retained electronically in ntissue (\\campus\rdw\ICMr2\icmresearch) (V:). Printed copies are available within each laboratory for immediate referral but it should be noted that this document is controlled and may be updated electronically. Researchers should always refer to the electronic version.

Any changes to this SOP will be notified to researchers at the bi-monthly HTA meeting of the Uteroplacental Tissue Bank group. Minutes of this meeting will be circulated and researchers are required to confirm receipt and reading of the information contained in the minutes.

Change control

To request any changes to this document please contact Julie Taggart or Prof M J Taggart, PD

Revision Category

Category 1	This is a new/revised document. All personnel required to follow content must read this version and complete training	
Category 2	This is a revised document in which only the area of applicability has changed. All newly impacted personnel required to follow content must read this version and complete training	
Category 3	This is a new/revised document. All personnel required to follow content must read this version	
Category 4	No significant change to document content – no requirement to read or train	✓

Note: As applicable, documentation of reading and/or training must be completed prior to performing the procedure.

1. BACKGROUND

The Uteroplacental Tissue Bank is part of the Newcastle Biomedicine Biobank (NBB) and houses a range of biological materials, including both relevant and non-relevant material under the Human Tissue Act 2004 (HTA). Tissue samples collected within the Uteroplacental Tissue Bank and products of these tissues, eg protein, cells, DNA, cell free supernatants, may be transported to external laboratories for the purpose of collaborative research studies.

This SOP details the requirements for transporting biological samples and should be referred to when either packaging and sending out biological samples to external laboratories or receiving and unpacking biological samples from to external laboratories.

It is essential that these procedures are followed when sending samples that are regulated under the Human Tissue Act to external laboratories. These materials should be regarded as low hazard clinical and biological samples (Category B) and packaged accordingly.

When transporting human and animal tissue, the UN dangerous goods classification and The International Air Transport Association Packing Instruction 650 must be consulted and adhered to. Human and animal tissue falls into the UN dangerous goods Class 6: Toxic and infectious substances; and subclass 6.2: Infectious Substances (Category A and Category B)
Category A: 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 to humans or animals. This includes all agents classified as HG4 in the ACDP Approved List of biological agents, many HG3 agents and two HG2 agents (*Clostridium botulinum* and poliovirus). Those that can cause disease in humans or animals are assigned to UN 2814. Those that affect animals only are assigned to UN 2900 (additional requirements are in place for animal pathogens in the UK – see the DEFRA website for further details). Exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals. The packing and unpacking of samples that fall into Category A requires special staff training. Transport of Category A biological substances can only be done by licenced staff, and through liaising with Newcastle University Safety Office.

Category B: An infectious substance that does not meet the criteria for inclusion in Category A. These are assigned to UN 3373

The transport of human and animal tissue falls under Category B: An infectious substance that does not meet the criteria for inclusion in Category A. – UN 3373, unless it is known that a donor has an infectious disease such listed in Category A.

It is recommended that staff attend a specific safety course dedicated to the transport of biological samples and also read all documentation relating to the transport of biological samples on the University Safety Office website before transporting any biological samples.

2. SCOPE

This SOP applies to all individuals working with tissue stored or obtained under the Uteroplacental Tissue Bank Ethics approval (Newcastle and North Tyneside Research Ethics Committee 1 (Ref:16/NE/0167).

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Samples covered by this SOP include: Tissue
Cells
Protein
DNA
Cell free supernatants
Urine

All researchers who wish to send biological samples to external laboratories must be aware of the procedure and packaging required.

The purpose of this SOP is to ensure that samples are correctly packaged for transport to external sources in accordance with government legislation, The International Air Transport Association Packing Instruction 650. This SOP also aims to ensure that any members of staff receiving biological samples are aware of the correct packaging so that they can protect themselves when unpacking and storing samples.

3. DEFINITIONS

UN3373	Samples of materials such as blood, tissue, excreta, secreta etc. collected from humans or animals are considered, as a minimum, Category B infectious substances. For example, samples from otherwise healthy individuals or where there is no reason to suspect that they are suffering from a severe infectious disease. However, if there is evidence to suggest otherwise, eg on the basis of know medical history, local endemic conditions or professional judgement concerning the circumstances of the source material, then such material should be assigned to Category A, and Category A specific packaging and transport requirements apply.
Sample	Tissue, cells, protein, DNA, cell free supernatants, urine - all must be in a labelled container

4. PROCEDURE

4.1 Containment

When transporting all Category B biological samples, a triple layer packaging system must be adopted, whether samples are solid, liquid, frozen or at ambient temperature.

4.1.1 Primary Containment

Primary receptacle: A primary watertight receptacle containing the biological specimen.
The receptacle needs to be packaged with enough absorbent material to absorb **all** fluid in case of breakage.

For solid samples:

The primary receptacle(s) must be siftproof and must not exceed the outer packaging weight limit – such as a cryovial with lid tightly sealed.

Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

For Liquid Samples:

- The primary receptacle(s) must be leakproof and must not contain more than 1 Litre for air travel.

4.1.2 Secondary Containment

- **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.

For Solid Samples:

- The secondary packaging must be siftproof – such as a cryobox that is sealed with tape or placed in a sealed bag.

For Liquid Samples:

- The secondary packaging must be leakproof – such as a sealed bag.
- Absorbent material must be in sufficient quantity to absorb the entire contents of the primary receptacle(s). For example, Vermiculite absorbent filling. Many companies now produce super absorbant pads which indicate maximum absorbancy (eg 120ml); where possible these should be used.
- For packages being transported by aircraft the primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa in the range of -40°C to 55°C (-40°F to 130°F).

4.1.3 Tertiary Containment

- Secondary packaging is placed in outer shipping package with suitable cushioning material.
- The outer packaging protects the contents from outside influences, such as physical damage, while in transit. The smallest overall external dimension shall be 10x10 cm.

4.1.4 Dry Ice – If needed

- Frozen samples are required to be inside secondary leakproof container (eg sealed cryobox or bag) in the event of a package being delayed or mislaid it is possible that dry ice may become depleted. In such an incident the category B contents may become liquid again so secondary containment and absorbant material must still be present.
- Ice /dry ice must be placed outside the secondary packaging. i.e. in a polystyrene box.
- If ice is used, the outside (tertiary) packaging must be leakproof. Pack dry ice around the secondary packaging. There must be sufficient dry ice to maintain the samples at -79°C for 48 hours.
    - If dry ice is used, the receptacle used to contain it, and the outer (tertiary) container must permit the release of CO2 to prevent a build-up of pressure.
    - For this receptacle, please use polystyrene.

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4.5 Outer Packaging

4.6 Labels

4.6.1 Category B specific labelling

- ALL 6.2 Category B items must bear this sign.
- Each **side** of the sign should be at least **50 mm** (2 in) in length and the **width** of the **line** forming the square should be at least **2mm**.
- Adjacent to the sign, in letters at least **6 mm** high, the packaging must bear the words

"BIOLOGICAL SUBSTANCE, CATEGORY B"

- Most company bought packaging will comply with these requirements, but this should be checked when ordering packaging.
- Adjacent to the sign, the packaging must display the following:

i. For air: the shipper's (sender's, consignor's) name, address and telephone number
ii. For air: the telephone number of a responsible person, knowledgeable about the shipment, the receiver's (consignee's) name, address and telephone number
iii. The required shipping name is ("BIOLOGICAL SUBSTANCE, CATEGORY B") adjacent to the diamond-shaped mark shown above
iv. Temperature storage requirements (optional).

4.6.2 Temperature specific labelling

- Frozen sample signage should be added to the packaging, if samples are being transported on dry ice or in cryogenic liquids. These are shown below.

Dry Ice Cryogenic Liquids

- If PDP or another suitable courier is used, then the provided packaging will come with the appropriate labels.

4.7 Maximum quantities

Surface transport: no maximum quantity per package

Air transport: **Primary receptacle = 1 Litre**
Outer packaging = 4 Litre

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

4.8 Shipping Documentation

4.8.1 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 and value
- An import and/or export permit and/or declaration if required.

4.8.2 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 journeys.

4.9 Tracking of specimens

If any specimen is sent to an external laboratory this must be tracked on the Achiever sample tracking system. The following details should be recorded:

- Specimen Number and description
- External Referral Laboratory Address with contact details
- Mode of transport used
- Name of person dispatching specimen and date of dispatch
- Confirmation of specimen receipt by external laboratory

5. DOCUMENT REVISION HISTORY

Section affected	Description of changes	Reason for change
All	Prof M Taggart was documented as PD	Prof M Taggart undertook the role of PD when the previous PD retired
Background	A new address for the shared drive was documented	A new shared drive was required due to Institutional change

6. APPENDICES

Contact the University safety office for further information.

Refer to the Joint Research Office Website http://www.newcastlejro.org.uk/ for information about material transfer agreements relating to external transport and receipt of biological samples out of and into the Uteroplacental Tissue Bank.