Document Title: Sample Transport

Document Number: R&D SOP097

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers and Research Pathology
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
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Summary of Amendments

Version Number	Modification:
V1.0	

Key Points of this Document

1 Purpose and Contents

a. It is important to transport tissue safely whether it is around the campus or when sending samples to an external user. Several factors must be considered, for example, whether or not the samples are fixed or fresh, as fresh samples have biological risk. The temperature the samples are transported in may need extra consideration, for example transporting samples with dry ice. If samples stored in media or in a fixative, then adequate absorbent material must be in place. Sample locations must be documented, manifested and sample storage must be updated to comply with Human Tissue Act 2004 which is regulated by Human Tissue Authority (HTA).

2 Roles & Responsibilities

a. Staff who are transporting samples must know how to transport samples appropriately. The samples must be packaged appropriately for the method of transport being used and the samples must be packed according to the various authorities' regulations'. International Air Transport Association (IATA), Regulations Concerning the International Transport of Dangerous Goods by Rail (RID), European Agreement concerning the International Carriage of Dangerous Goods by Road (ADRO or International Maritime Organization (IMO).

b. Before transporting any samples the relevant documentation must be in place to comply with HTA.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

4.1 Documentation

a. Prior sample can be sent off site all appropriate documentation should be in place.

4.1.2 Material transfer agreement (MTA)

a. An MTA is a legal agreement between Royal Papworth Hospital (RPH) and the organisation that will receive the samples. Ensure there is an MTA (or alternative project -specific agreement) between RPH and the recipient institutions in place before sending samples away.

b. There is a generic MTA between Cambridge University Hospital and RPH, and a schedule is completed for each separate project.

4.1.3 Consent

a. Check that there is a valid informed consent form for the samples being sent and that the patient has not withdrawn from the study.

4.1.4 Audit samples – if they have been stored for more than a month or there is a large volume of samples.

a. Use Audit Report FRM025 form to complete an audit, comparing the sample log to the freezer samples. Especially if there are a large number of samples that have been stored for a long time, it is important to make sure that the records are accurate before creating a sample manifest.

4.1.5 Manifest

a. A manifest must be created to send with the samples so that the recipient can check that all samples have been received.

b. Studies may provide specific manifests.

c. If a sample transfer/ release form is not provided by a study sponsor, then use the R and D Samples Release Confirmation Form -FRM082.

4.1.6 Tracking

a. All samples must be tracked.

b. When sending samples using Royal mail, these samples must be signed for.

c. If a courier~~s~~ provides a tracking reference number this needs to be sent to the recipient.

d. Request confirmation of the safe receipt of samples.

4.1.7 Customs form

a. A Customs form maybe required if sending samples outside the UK.

b. Use a recommended international courier, and confirm what additional documentation is required.

4.2 Fixed or unfixed tissue

a. There are different regulations depending on whether or not the sample fixed or unfixed. Fresh tissue holds a biological risk and needs to be labelled UN3373 on the outside of the box.

4.2.2 Transporting fixed tissue

a. Samples fixed in formalin include paraffin blocks (FFPE) and microscope slides. These are classed as 'Exempt Human specimen' and need this label on the outside of the envelope.

b. Tissue stored in formalin are 'exempt human specimens'. Extra precautions need to be taken during transport to avoid spills. Unless samples are going to histology, do not transport samples with formalin, make sure samples are fixed properly, and remove as much formalin as possible from pot.

4.2.3 Transporting fixed samples around the Cambridge Biomedical Campus

a. All samples transported around the Cambridge Biomedical Campus must be in a secure container and any patient identifiable information is covered.

b. Slides and wax blocks can be transported in a specimen bag and put into a confidential bag.

4.2.4 Sending fixed tissue by post

a. Slides and blocks can be sent through the post. Ensure there is adequate packaging.

b. Put slide in a slide mailer. Wrap the wax blocks in tissue or put them in a rigid plastic container.

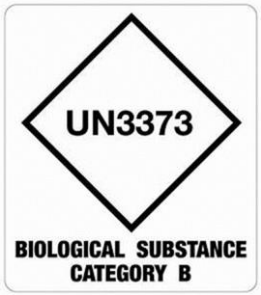
c. In summer months, adding a cool pack can be added to prevent wax blocks from being damaged by heat.

d. As samples are exempt put a label ‘exempt human specimen’ on the envelope.

4.3 Transporting Biohazard samples Biological Substances, Category B

a. Infectious substances are substances that are known or are reasonably expected to contain pathogens.

b. Unfixed human tissue is in this category, e.g. blood samples. Any samples that come into this category must have a UN3373 label on the outside of the box.



4.3.2 Transporting biohazard samples around the site

a. Samples must be packed so they are protected during transport.

b. Samples that are liquid or contain liquid must contain absorbent material.

c. Samples must be packed with an inner packing e.g. within a clear sample bag, this should be put into the outer packing which should contain absorbent material.

d. The outer container must be rigid and adequate for both the primary and secondary container. For example, a plastic or polystyrene box. The lid must be secure in case of trip or accident and wherever possible use a medical transport bag.

4.3.3 Sending biohazard samples by post

a. Samples can be sent through the post using a safebox. Alternatively, the samples can be sent using the following packaging:

- primary packaging – sealed plastic bag;
- secondary packaging – sealed plastic bag; with suitable absorbent material for leakages
- outer packaging – cardboard box. Suitably outer packaging must have a minimum dimension of 100mm x 100mm and have the UN3373 label.

4.3.4 Sending samples by air

a. The primary or secondary container must be certified at both -40°C and +55°C. There must be absorbent material within the secondary container and a rigid outer box.

b. Samples sent by air will come under international travel regulations. Please refer to IATA regulations on the IATA website: https://www.iata.org/.

4.3.5 Sending samples by road (courier)

a. The primary or secondary container must be certified at 95kPa. There must be absorbent material within the secondary container. A rigid box is only required if the secondary container is not rigid.

b. Samples sent by road come under the European agreement concerning the International Carriage of Dangerous Goods by Road.

4.4 Transporting temperature sensitive samples

4.4.1 Transporting temperature sensitive samples around the Cambridge Biomedical Campus.

a. Frozen samples may be transported around the Cambridge Biomedical Campus using ice packs that are stored in a -80 freezer. Use a sample transport carrier or a Styrofoam box.

b. Ensure there is at least two large ice packs below and above the sample container. If necessary, put ice packs on the side. Store ice packs at in fridge/ or freezer, so they are at the same temperature as the samples.

c. Samples must be unpacked and put in freezer as soon as they are delivered to new location.

4.4.2 Transporting frozen samples outside the Cambridge Biomedical Campus using a specialised courier.

a. Dry ice is considered dangerous goods by the Department of Transportation and IATA.

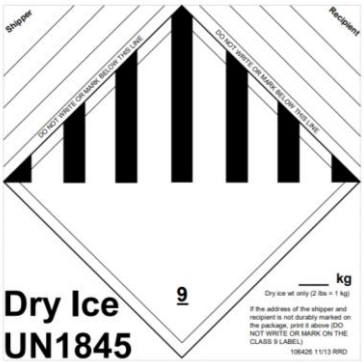
b. The shipping box must be labelled to indicate that it contains dry ice alerting the shipper to its special handling instructions.

c. Wear cryo-protective gloves when handling dry ice as it can cause 3rd degree burns when it contacts exposed skin. See dry ice COSHH form for the area you are working.

4.4.3 Packing samples in dry ice

1. Cover the bottom of the Styrofoam liner with a layer of dry ice.
2. Place the specimen box in the centre of the Styrofoam liner.
3. If required add an activated temperature sensor in a plastic bag.
4. Pack additional dry ice around the side and top of the specimen box (~ 9-18 kg depending on size of box.).
5. You do not need to completely fill the container, however the more you use the better. Leave room for the Styrofoam lid to fit flat.
6. If shipping multiple specimen boxes in the shipper, place them side by side in the Styrofoam liner and pack additional dry ice around the side and top of the box.
7. Use a sufficient amount of dry ice to maintain temperature during transit.
8. Tape the top of the Styrofoam container. DO NOT tape the sides of the lid as this may cause a build-up of pressure which can result in an explosion of the package.
9. Securely tape the top of the large fibreboard outer box shut.

10. Label the top of the large fibreboard outer box with the labels (Exempt Human Specimens) or (Biological Substances, Class B).
11. Enter the weight of the dry ice in Kg on the Dry Ice Label.



5 Health and safety

5.1 COSHH

a. Staff members need read all COSHH forms relating to handling biohazardous material, especially if samples have leaked in transport

1. Tristel duo and Tristel fuse
2. Chemicals in biohazard cleaning kit- Haz -Tab- chlorine releasing disinfectant granules and tablet
3. Clinell wipes and /or 70% alcohol

b. A COSHH for must be completed for and transport media/fixative used while transporting samples. If required samples and packaging will need hazard symbols depending on chemical components.

c. If handling dry ice see area's COSHH risk assessment form for handling/ disposing of dry ice.

6 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part

of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018) Human Tissue Act (2004)
Key related documents:	Trust Research Policy DN101- Moving and Handling Policy Trust Policy DN271-Moving and Handling Procedure DN180 -Needlestick Sharp and Splash Incidents involving blood or body fluids, Procedure

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	DATE

I certify the contents of this SOP has been reviewed and ratified

DocuSigned by:
Patrick Calvert
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05-Sep-2023

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Signed by Dr Patrick Calvert, Clinical Director of R&D — Date

SOP Release Date: ……

Appendix 1: Sample transport risk assessment

Description of Activity • Sample packed to be transported either around the biomedical campus or shipped to an external user. • Samples may be fresh or fixed. • Sample may be transported at different temperature	**Significant Hazards** • Sample delivered to the wrong destination. • Samples not labeled or packaged properly. • Samples may be fresh/ unfixed and therefore biohazardous. • Samples may be stored in fixatives or media which may have a hazard. • Samples stored at very cold temperatures the removal from freezers requires correct PPE • Use of dry ice when sending sample
Frequency: Depending on project	**Duration: Dependent on number of samples**
Adverse Effects • Potential of losing relevant material if handed to the wrong transport system. • Loss of tissue viability for specific experiments/studies. • Frozen samples thawing during removal from freezers. • Fresh tissue transport media leaking.	**People at Risk** • Research team • Clinical Trial Co-ordinator • Tissuebank staff
	Number of People Affected: Variable

What Precautions exist to control the risk:

- Sample outer packaging is labelled with sender and recipient contact information, in case issue arise when sample is in transit.
- Seal and pack samples appropriately. Affix UN3373 labels on all packages containing human tissue, UN1845 if containing dry ice, Formaldehyde hazard warning if with formalin and fragile if they are glass slides.
- Use ice packs stored in freezers to transport samples around site to avoid risk associated with dry ice.
- Where appropriate personal protection while packing samples. Insulated gloves/ lab coat may be required when removing samples from freezer to prevent skin contact on metal racking. Insulated gloves also required when handling dry ice. If samples are sent at ambient or refrigerated temperature standard gloves must be used while handing samples
- Work with dry ice in well-ventilated areas. Keep the dry ice container close when dry ice is not in use. Each area has a COSHH risk assessment on how to handle/ dispose of dry ice.
- Inform contact person that samples are sent via the pre-arranged transport system by telephone call or email so they can look out for them or pick them up at their post office/reception area.

- Use of “Sample Release Confirmation Form” or a manifest for all outgoing samples. Keep records of samples receipt confirmation.
- See sample transport guidance notes for specific details on sending samples in different areas.

Risk Rate:

Likelihood 3	**Severity 2**	**RRN 6**	**H S M L N**
Are these arrangements satisfactory: Yes			
If No, What further measures are necessary **Re-evaluated Risk Rate:**			