Document Title: Sample Transport

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Summary of Amendments

Version Number	Modification:
V2.0	Section 4.1.6 wording states all samples must be tracked and signed for. Change of wording to include statement "or as per sponsor instruction" to cover all studies.
V3.0	Changes to wording of 4.1.a. Appendix 1 Risk Assessment removed. Reference to Risk Assessments RAC/RD/TBR/007 and RAC/RD/TBR/011 added to key documents. Reviewed for changes in regards to the new clinical trial E6 R3 regs.

Key related documents:	DN361 – Biological Materials for Research Use 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 Risk Assessments RAC/RD/TBR/007 Transport of Relevant Material RAC/RD/TBR/011 Use of Dry Ice SOP124 Biological Sample Handling FRM082 Samples Release Confirmation Form

Key Points of this Document

1 Purpose and Contents

a. Tissue must be transported safely whether it is around the campus or sending and receiving samples from an external recipient.

b. Several factors must be considered, for example, whether or not the samples are fixed or fresh, the temperature the samples are transported, and if samples are stored in media or in a fixative.

c. Prior to samples being transferred all appropriate documentation should be in place, these include a Material Transfer Agreement (MTA), appropriate participant consent forms, and a manifest of the samples expected.

2 Roles & Responsibilities

a. Staff 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 authorities' regulations. These include:

- 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).
- Regulations concerning sea transport is by International Maritime Organization (IMO) and the International Convention for the Safety of Life at Sea (SOLAS).

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 to samples being transferred all appropriate documentation should be in place, these include a Material Transfer Agreement (MTA), appropriate participant consent forms, and a manifest of the samples expected.

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

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. You must ensure there is an MTA (or alternative project - specific Agreement) between RPH and the external institution in place before sending or receiving samples.

b. Contact papworth.randdenquiries@nhs.net for information on how to set these up.

4.1.3 Consent

a. Check that there is a valid informed consent form for the samples being sent and that the participant has not withdrawn their consent for samples to be used.

4.1.4 Sample Audit

a. Regular auditing should be completed especially if there are a large number of samples that have been stored for a significant amount of time (more than a month). It is important to make sure that the records are accurate before creating a sample manifest. **This should be recorded on the sample log.**

b. Before releasing any samples check that samples have been audited and that the manifest matches all the samples to be transferred.

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, depending on the level of detail required. If one is not provided by the sponsor, make a manifest form using the sample log.

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

4.1.6 Tracking

a. All samples must be tracked as per the study protocol.

b. If a courier provides a tracking reference number, this should be sent to the recipient.

c. Request confirmation of the safe receipt of samples.

4.1.7 Customs form for exporting goods outside of the UK: normally supplied by courier also refer to the UK government website on export of goods https://www.gov.uk/export-goods

a. All items containing goods sent outside the UK, including to the Channel Islands, must include a completed customs declaration form (CN22/23 for mail or CP72 if using Parcelforce).

b. The following mandatory information should be included. If you do not complete and sign the documentation as required, it increases the likelihood of delayed delivery or return:

1. Sender's details - your full name, address, postcode and telephone number
2. Recipient's details - the details of the person or business you're posting items to and must include their full name, address, postcode, telephone number (local, not UK)
3. Item description – you must include a clear and detailed description and value of each item. For instance, write 'house deeds' rather than 'documents'; 'women's leather jacket' rather than 'jacket'*. Businesses must provide the HS tariff number, which can be found on GOV.UK

4. Item category and value – you must include the item category and value. If the item is a document tick the 'Documents' box. Value type (e.g. £, $) must match that on the invoice and all other documents
5. Your signature

c. Business customers must include their GB EORI number or VAT registered number.

4.1.8 Further documentation for sending samples outside of UK

a. Sending ethically approved human tissue samples outside the UK requires ensuring informed consent covers international transfer, documenting compliance with both UK and destination country laws and that it is used in accordance with the consent that has been obtained. While no HTA export licence is needed, samples should be handled, stored, transported and disposed of in a manner consistent with safety considerations, dignity and in accordance with the original consent. A Material Transfer Agreement (MTA) is also required.

b. Traceability Records: You must maintain detailed records of the transfer, including what was sent, where, and when.

c. Commercial/Customs Invoice: Must clearly state the contents, often noting "Human samples for research - no commercial value".

d. Transport Documentation: An Air Waybill (AWB) is required, along with a Packing List.

e. Dangerous Goods Declaration: If the samples are classified as infectious substances (Category A or B), a specific "Shipper's Declaration for Dangerous Goods" is required.

f. Import Permit: The recipient must often provide an import permit from their own country's regulatory authority.

g. Material Safety Data Sheet (MSDS): A document outlining the nature of the material.

h. For USA

1. Commercial Invoice: Must include a detailed description, value (even if nominal), and the statement "Biological specimens - no commercial value".
2. Importer Certification Statement: Required for samples not known to contain infectious agents.
3. CDC Import Permit: Required if the shipment contains a known or suspected infectious biological agent.
4. Air Waybill: Must clearly state if the material is an "Exempt Human Specimen" or "Biological Substance, Category B".

5. Letter of Authorization/No Jurisdiction: Sometimes required if the item does not fall under specific agency regulations.

4.2 Fixed or unfixed tissue

4.2.1 Transporting fixed tissue

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

b. Tissue stored in formalin are also classed as 'exempt human specimens'. Extra precautions need to be taken during transport to avoid spills. The maximum amount of formalin that should be transported in one delivery is 50ml of formalin. If larger volumes of formalin are needing to be transported then please review the additional requirements for labelling with the sponsor. Make sure samples are fixed properly and remove as much formalin as possible from pot.

4.2.2 Transporting fixed samples around the Cambridge Biomedical Campus

a. All samples transported around the Cambridge Biomedical Campus must be in a secure container and no participant identifiable information should be visible.

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

4.2.3 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.

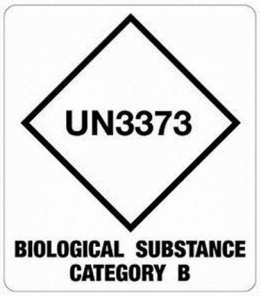
c. In summer months, a cool pack should be added to prevent wax blocks from being damaged by heat.

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

4.3 Transporting Fresh Tissue

Only fresh tissue that is Biohazard Samples Biological Substances Category B can be transported (see Appendix A for a list of pathogens in Category A & B).

a. Unfixed human tissue e.g. blood samples category must have a UN3373 label on the outside of the box. These should be provided by the sponsor.



4.2.4 Transporting biohazard samples around the Cambridge Biomedical Campus

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

b. Samples that are liquid or contain liquid must be packed in a container surrounded by absorbent material.

c. 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.

4.2.5 Sending biohazard samples by Royal Mail

a. Samples can be sent through the post using a Royal Mail 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

4.2.6 Sending biohazard samples by air

a. The primary or secondary container must be certified at both -40°C and +55°C and certified at 95kPa (Able to drop sample at 9 meters without it breaking). 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/.

4.2.7 Sending biohazard 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.

4.3 Transporting temperature sensitive samples

4.3.1 Transporting temperature sensitive samples around the Cambridge Biomedical Campus.

a. Frozen samples may be transported around the Cambridge Biomedical Campus in a sample transport carrier or a Styrofoam box.

b. Ensure there is at least one ice pack in the sample container. If necessary, put ice packs on the side. Store ice packs in the fridge/ or freezer (as applicable), so they are at the same temperature as the samples you are transporting.

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

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

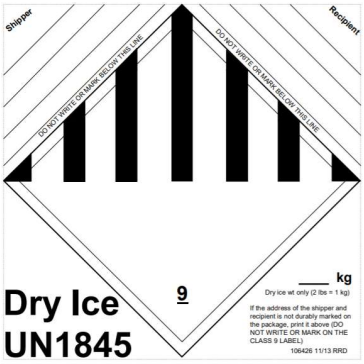
a. Frozen samples being transported outside the Cambridge Biomedical Campus should be sent in dry ice.

b. Dry ice is considered dangerous goods by the Department of Transportation and IATA and so 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 the dry ice COSHH form for the area you are working.

4.3.3 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 in a cross shape. DO NOT seal around 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 must read all COSHH forms relating to handling biohazardous material and chemicals used in the event of a spillage; e.g. if samples have leaked in transport. Any samples that have leaked in transport should be unpacked in the biological hood. Try to contain the liquid as much as possible. Use an appropriate cleaning chemical according to the size of the leak, see Handling of Biological Samples R&D SOP124. A COSHH form must be completed for transport media/fixative used. If required samples and packaging will need hazard symbols depending on chemical components.

b. 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.

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) (Amendment) Regulations 2025 (and any subsequent amendments) UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter Human Tissue Act (2004)

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							

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Appendix A: Biohazard Samples - Biological Substances Categories

Category A: Infectious Substances (High Risk)

These are substances that, upon exposure, are capable of causing permanent disability, life-threatening, or fatal disease in otherwise healthy humans or animals.

Examples: Cultures of microorganisms (e.g., Bacillus anthracis, Ebola virus), patient samples known to contain these pathogens.

UN Numbers: UN 2814 (Infectious Substance, Affecting Humans), UN 2900 (Infectious Substance, Affecting Animals).

Shipping Label: Must show the UN number and Proper Shipping Name (e.g., UN 2814, "Infectious Substance, Affecting Humans").

Note: The following list is not exhaustive. Infectious substances, including those containing new or emerging pathogens, which do not appear in the following list but which meet the same criteria, must be transported as a Category A infectious substance. In addition, if there is doubt as to whether a pathogen falls within this category it must be transported as a Category A infectious substance.

UN 2814 (Infectious Substance, Affecting Humans)

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 (cultures only)

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)

Variola virus

Venezuelan equine encephalitis virus (cultures only)

West Nile virus (cultures only)

Yellow fever virus (cultures only)

Yersinia pestis (cultures only)

UN 2900 Infectious substances affecting animals

African swine fever virus (cultures only)

Avian paramyxovirus Type 1–Velogenic Newcastle disease virus (cultures only)

Classical swine fever virus (cultures only)

Foot and mouth disease virus (cultures only)

Goatpox virus (cultures only)

Lumpy skin disease virus (cultures only)

Mycoplasma mycoides–Contagious bovine pleuropneumonia (cultures only)

Peste des petits ruminants virus (cultures only)

Rinderpest virus (cultures only)

Sheep-pox virus (cultures only)

Swine vesicular disease virus (cultures only)

Vesicular stomatitis virus (cultures only)

Category B: Biological Substance (Lower Risk)

These are infectious substances that do not meet the criteria for Category A. They are typically diagnostic specimens, such as blood, tissue, or body fluids, being sent for research or testing.

Examples: Blood samples for HIV testing, suspected Streptococcus A, routine lab samples.

UN Number: UN 3373.

Proper Shipping Name: "Biological Substance, Category B".

Key Requirements: Rigid outer packaging, appropriate absorbent material, and a 50x50mm diamond-shaped label.