Standard Operating Procedure CCTU/SOP016

Packaging Requirements for the Transport of Biological Samples

1. Scope

This Standard Operating Procedure applies to trial teams working on Cambridge Sponsored CTIMPs or clinical studies coordinated by the CCTU.

2. Purpose

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.

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC OR Sponsored by: Cambridge University Hospitals NHS Foundation Trust (CUH) or CUH jointly with the University of Cambridge or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
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, e.g. on the basis of known 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	Samples of materials such as blood, tissue, excreta, secreta etc in appropriate labelled container
Wadding	Absorbent material

Traceability paperwork	e.g. laboratory storage/processing log

3.2. Abbreviations

Abbreviation	Meaning
SLA	Service Level Agreement
QMS	Quality Management System

4. Undertaken by

Clinical trials staff where specific instructions for the transport of biological samples have not been provided in the protocol.

5. Items Required

Labels

Wadding, tape

Approved primary container/receptacle for samples (sourced commercially)

Outer package e.g. box, jiffy bag

Dry ice or cool packs if required

Transport documentation

Labeled Sample

6. Summary of Significant Changes

Dry ice label updated

7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

Biological samples from clinical trials are classified as UN3373

7.1. Packing Instructions

- Samples must be labeled according to protocol, or if not specified in protocol with patient trial number, participating site identifier (if applicable), date of collection as a minimum
- Patients anonymity must be maintained (i.e. no hospital stickers, no name of patient, no patient address or patient hospital number)
- The primary container(s)/receptacle must be leak proof and robust
- Absorbent material is placed between the sample primary container(s)/receptacles(s)
- Multiple samples should be individually wrapped before being packed
- There must be sufficient absorbent material to absorb the entire contents of the samples within the primary container(s)/receptacle(s) to ensure that

any release of liquid substance will not compromise the integrity of the outer packaging

- The outer packaging should be of a type tested and approved by the Department of Transport and marked accordingly An itemised list of contents must be enclosed in the package
- Traceability paperwork must be completed for a complete audit trail
- Transport documentation must be filled in

7.2. Frozen Samples

- Dry ice is placed in the outer packaging normally a polystyrene box
- The primary receptacle is covered in the dry ice
- Dry ice will sublimate and release carbon dioxide gas
- Do not tape down the lid (prevents build-up of gas) of polystyrene box
- Place the polystyrene box inside a cardboard box
- Secure the box in such a way that there can be release of carbon dioxide gas this prevents a build-up of pressure that could rupture the packaging
- Instructions for filling and closing such packages are normally provided by the packaging manufacturer

7.3. Samples Transported at Ambient Temperature

- A fridge pack or gel pack may be packed between the sample and the absorbent material, or if specified according to protocol.
- Sample absorbent material and gel pack are placed inside a leak proof primary receptacle
- Pack in a suitable outer container, sturdy cardboard, jiffy bag, polystyrene box

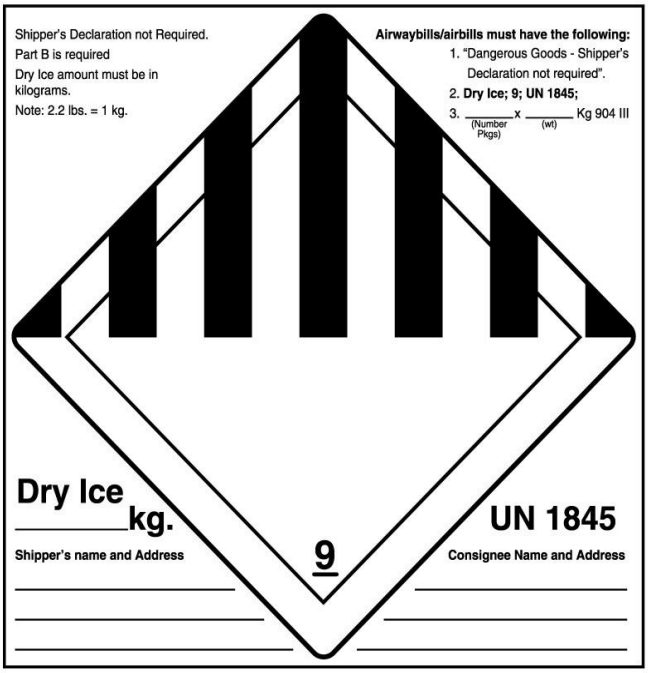
7.4. Labelling all Packages

- All packages must be marked with a square each side being 50mm or 2inches set at 45°. Within the square is UN3373. Written next to the symbol in letters at least 6mm high is "Biological Substance Category B"
- Address should be clear
- The name of the sender should be accessible

BIOLOGICAL SUBSTANCES
CATEGORY B

7.5. Labelling Packages containing Dry Ice

- Packages containing dry ice must use a UN1845 label also have the following additional label filled in by the sender



7.6. Packages that are Time and Temperature Sensitive

- Only to be used when there is a specific agreement in place with the stakeholders (shipper, forwarder, carrier, etc)
- Only to be completed as indicated in that agreement (i.e. in the SLA, QMS, SOP, etc)
- The temperature indicated on the label is the only one that will be followed during transport (other package markings will be disregarded)
- Informs on the external handling temperatures
- The label will be a 3 colour label with gradients for the effect of the different blues

7.7. Tracking

Samples should be accounted for during transport refer to CCTU/SOP044 Research Sample Management

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.

MHRA, Good Clinical Practice "Grey Guide"

International Air Transport Association. Packing Instruction 650

10. Associated Documents

CCTU/SOP044 Research Sample Management

CCTU/TPL031 Sample Tracking and Processing Template

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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