Document Title: Research Tissue Banks Transport of Human Tissue

Document Number: TB SOP134

Staff involved in development: *Job titles only*	Senior R&D Manager, Tissue Bank Team Leader, Tissue Bank Team, Clinical Project Managers.
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Directorate:	Research and Development
Department:	Research and Development
For use by:	Research Tissue Bank Staff
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Summary of Amendments

Version Number	Modification:
V1	New SOP (Reviewed and updated PRO/TE/TBR/005)

Key related documents:	DN001 Document Control Procedures DN361 Biological Materials for Research Use Policy DN101 Moving and Handling Policy DN271 Moving and Handling Procedure DN180 Needlestick Sharp and Splash Incidents involving blood or body fluids, Procedure Activity Location Guide **Risk Assessments** RAC/RD/TBR/005 Labelling Samples

	RAC/RD/TBR/007 Transport of Relevant Material RAC/RD/TBR/011 Use of Dry Ice FRM110 Mesobank Sample Release Form and Manifest Tissue Bank FRM/TIS/R&D/005 Sample Release Form Tissue Bank FRM/TIS/R&D/023 Outgoing Courier Sample Log

Key Points of this Document

1 Purpose and Contents

a. The integrity of human tissue samples must be protected at all times, necessitating proper packaging and transport around the Cambridge Biomedical Campus and to NHS, university or commercial organisations.

b. The Tissue Bank Application Form stipulates that the recipient of samples shall be responsible for organising and arranging the collection of tissues from the Trust. They must provide appropriately labelled containers, packaging and storage medium and arrange their safe transport to the recipient's premises or other location for the purpose of the Project.

c. Mesobank generally requires recipients to take responsibility for arranging the collection of tissue samples from the Trust. This includes organising safe transport, supplying suitable packaging, and providing sufficient dry ice when necessary. In cases where this is not feasible, and on an ad hoc basis, Mesobank may coordinate the transfer of samples using specialist courier services that are ISO-accredited and trained in the transport of human tissue, ensuring continued compliance with HTA regulations.

d. In compliance with HTA requirements, a fully executed Material Transfer Agreement (MTA) must be in place prior to the release or transfer of any human tissue samples. The MTA outlines the terms under which the material may be used, ensuring legal and ethical responsibilities are clearly defined and upheld by both the provider and the recipient institution. No samples will be released until the relevant MTA has been reviewed, approved, and signed by all authorised parties.

2 Roles & Responsibilities

Staff preparing samples must know how to transport samples appropriately. Training in this procedure will be carried out by a member of the Tissue Bank or Mesobank team.

3 Policy

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

Human tissue is collected by Royal Papworth NHS Trust porters in accordance with their own SOPs from designated collection points across the Trust and delivered to the Histology Department at Addenbrooke's Hospital.

Researchers are responsible for arranging transport of their allocated samples via an approved courier service, ensuring all HTA requirements for traceability and safe handling are met.

The Research Tissue Bank team is responsible for ensuring that appropriate packaging is used for internal transport across the Biomedical Campus. Fresh tissue samples must be transported in sealed specimen transport bags, while frozen tissue samples must be placed in clearly labelled polystyrene transport boxes with suitable temperature control measures.

4.1 Transport of Fresh Human Tissue

Fresh human tissue samples must be placed in a secure, leak-proof primary container, which is then sealed within a specimen transport bag. This should subsequently be placed into the courier's secondary packaging, compliant with UN3373 Biological Substance Category B transport requirements where applicable.

4.2 Transport of Frozen Human Tissue

Frozen human tissue samples must be secured in appropriate primary containers (e.g., cryovials or cassettes) and placed into a specimen transport bag. The bag should then be placed in insulated courier packaging with sufficient dry ice or cold packs to maintain the required temperature throughout transit.

4.3 Transport of Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue

FFPE tissue blocks must be individually wrapped in tissue paper or other non-adhesive protective material to prevent sticking or damage. These wrapped blocks should be placed into a specimen transport bag, followed by secondary packaging suitable for courier transport.

4.4 Transport of Glass Slides

Glass slides containing tissue sections must be placed in a rigid slide mailer (primary container) to protect against breakage. The mailer should then be sealed in a specimen transport bag and placed into courier-approved secondary packaging.

4.5 Documentation and Labelling

4.5.1 - Tissue Bank

All samples must be clearly labelled with a unique identifier and the project reference number the sample is associated with. A completed Sample Release Form (Tissue Bank Form FRM/TIS/R&D/005) must be included with each shipment. This form must be signed by the recipient upon receipt of the tissue and returned to the Tissue Bank team as confirmation of delivery.

Full traceability must be maintained at all stages of transport. This includes documentation of:

- Sample identifiers and type
- Project reference number
- Date and time of dispatch recorded on Tissue Bank Form FRM/TIS/R&D/023– Outgoing Courier Sample Log
- Confirmation of receipt (via signed Tissue Bank Form FRM/TIS/R&D/005)

Records must be retained in accordance with HTA requirements and internal SOPs for tissue release and tracking.

4.5.2 Mesobank

All samples must be clearly labelled with a unique identifier. The Mesobank database automatically generates and stores shipping manifests, which are included with every sample shipment. For samples not recorded in the database, include FRM110: Mesobank Sample Release Form and Manifest with the shipment. Upon delivery, recipients are required to confirm receipt of the samples; this confirmation is then recorded in the researcher's electronic file.

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.

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.

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*	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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