Document Title: Fresh Tissue

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Summary of Amendments

Version Number	Modification:
V1	**Reviewed and updated SOP PRO/TE/TBR/002**
V2	**Additional information included for cytology processing.**

Key related documents:	Trust Policy DN001 Document Control Procedure Trust Policy DN361 Biological Materials for Research Use Policy Activity Location Guide CSCI-RA-046 – Ducted Fume Cabinet (JCBC) ADD.HIS.10995 Control of Airborne Contaminates & ADD.HIS.5606 Housekeeping main lab and cut-up. SOP096 Centrifuges SOP098 Pipetting SOP101 How to use the Tissue Bank Database SOP104 Zebra Printer

	SOP108 Freezing Fresh Tissue SOP114 Extraction Hoods – Biological Safety Cabinets and Fume Hoods SOP134 Research Tissue Bank Sample Transport GD044 Research and Development Laboratory User Manual School of Clinical Medicine (SCM) Core Safety Manual **Risk Assessments** RAC/RD/TBR/007 - Transport of relevant material RAC/RD/TBR/004 - Fresh samples RAC/RD/TBR/036- Freezing samples RAC/RD/TBR/034- Tissue Bank consent and request forms and withdrawal of consent. RAC/RD/TBR/029- Tissue bank Database RAC/RD/TBR/037- Handling, Processing and Freezing Fresh Tissue and Blood in the HLRI

Key Points of this Document

1 Purpose and Contents

a. This document defines the Trust's procedure for handling fresh tissue.

b. The document details the requirements and procedures for correct handling of fresh human tissue.

2 Roles & Responsibilities

a. Staff involved in handling fresh tissue must comply with the requirements set out in Section 4.

b. Training in this procedure will be by a competent member of the RPH research team.

c. Following a period of supervision (depending on the individual needs of the trainee) there will be an informal assessment.

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

Introduction

4.1 Fresh tissue is a biohazard. Always wear a laboratory coat and gloves when handling any sample in the cut-up room.

Wear eye protection when handling any unfixed fresh samples. Always open sample containers in the Class II Biological Safety Cabinet in the laboratory.

4.2 Fresh samples from theatres will be delivered to the Addenbrookes Pathology department via the porter following their SOPS. These include explanted organs, resection specimens or other surgical samples.

4.3 Fresh samples are sometimes collected by one of the RPH Research Tissue Bank team if there is a short time frame for banking the tissue. These samples are set-up for "bespoke" collection.

4.4 Fresh samples can also be collected by the research team directly from theatres without the support of Tissue Bank. This is due to samples being available for the research team during out-of-hours and the project has a surgical collaborator. These samples are set-up as "virtual" samples.

4.5 Any handling and processing of fresh tissue samples is always done under a Class II Biological Safety Cabinet. This includes weighing, further dissection of large tissue and foil wrapping for freezer storage.

5 Protocol

a. Tissue Bank staff check the day's theatre list. Samples will be stored in Addenbrooke's histology fridge until they have been banked. To know if a patient is suitable for an active project, Tissue Bank staff check the patient's details, in their electronic medical records, against the day's theatre list. The patient's referral letter can be printed out and taken to the pathologist later at cut up so they can see the patient's clinical history.

b. Once a suitable case is identified, print the 'Tissue Collection checklist' specific to that condition; all projects and their requirements are listed on it.

c. Liaise with the duty pathologist on surgical/transplant duty for banking on that specific day to arrange a time to bank.

d. Tissue Bank staff collect, and check, the consent forms and will only bank from a specimen if the patient has provided valid consent. Sometimes, if collecting samples direct from theatres, then the consent form will be collected with the sample in theatres. If there is no physical consent form present., check the scanned folder or patient medical record. If consent is not in place, leave the histology pot in theatres or specimen fridge for the porter to collect and inform the Addenbrookes histology staff that the tissue will not be banked and can be fixed.

e. If valid consent is in place, and banking is about to commence, a colleague, who is supporting the person banking, should book the sample onto the tissue bank database (refer to SOP101). They will also print out the labels using the zebra printer (refer to SOP 104). Do not book or generate a tissue bank number for a possible sample collection until you have seen the tissue consent form.

f. If the sample is for a project with an agreed bespoke direct collection from theatres, check the Tissue consent form has been completely and correctly filled in by the patient and person taking consent before taking the specimen. Do not collect the specimen if the consent is invalid. When collecting straight from theatres, Form003-Theatre Sample Release Form should be filled out and left with theatre staff. All specimens that are collected from theatres before the operation is finished must have a patient addressograph attached.

g. If the sample is for a project set-up for virtual collection, the research team will have a collaborator to collect the samples directly from theatres without the support of the tissue bank team and pathologist. Their sample will be placed straight to their sample transport media. The research team will be responsible for informing the Tissue Bank that they have acquired a tissue and checking the Tissue consent and send the form or a scanned copy to Tissue Bank who will double check it is correctly filled out. If consent is valid, a generated TB number will be sent to the researcher via email after booking it in the database. If the consent is not valid and a sample was collected, you must inform the researcher who will have to discard the tissue. This type of collection usually happens during out-of-hours. During working hours and depending on the workload, the tissue bank team can still be involved in the collection.

h. All tissue dissection and processing will be done in the Addenbrookes pathology laboratory or HLRI Pathology Laboratory under the Class II Biological Safety Cabinets. Follow local

guidelines and the instruction note on how to turn the Biological Safety Cabinet on and off and how to clean after activity.

i. All unfixed cytology samples must be handled under a Class II Biological Safety Cabinet in a CL2 laboratory, following local guidelines in HLRI - see School of Clinical Medicine (SCM) Core Safety Manual. Samples must never be exposed to the room or user. When centrifugation is required, samples are placed into centrifuge buckets under the Biological Safety Cabinet and once centrifugation is complete, the samples must be removed from the centrifuge **in sealed buckets and placed under the Biological Safety Cabinet prior to removing lids for further processing.** Samples and vial remnants/supernatants must be inactivated by fixation or autoclaving prior to disposal, as per SCM Core Safety Manual.

j. All project pots with transport media needed as per the 'Tissue collection checklist' (labelled with their respective T0 number and researchers' names) are in the fridge located in Addenbrookes pathology laboratory or Tissue Bank Fridge in RPH. Do not open a new bottle of media if there is still one opened and in-date.

k. To collect samples for fresh freezing, print the cassettes using the cassette printer in the laboratory. Wrap tissue for freezing in foil and stick zebra labels appropriately before encasing in cassettes ready for submersing in liquid nitrogen.

l. After banking the specimen, inform the histology staff that the specimen has been banked and is ready for inflation/fixing. If the specimen was collected direct from theatres, inform the Histology staff that a Theatre sample release form will accompany the pending samples for that case, so they must wait for all specimens to arrive.

m. Once all specimens are collected, pack the fresh samples together with the samples in cassettes for freezing or processing. Following the SOP134 Research Tissue Bank Sample Transport, freezing samples will be carried out in the designated tissue bank laboratory space following the SOP108 (Freezing Fresh Tissue Samples). Then transport the remaining fresh samples in transport media to the Royal Papworth Hospital Tissue Bank laboratory to store in the 4oC fridge overnight for next day courier collection.

n. Once all samples have been banked, individual researchers for projects collected for need to be notified, via email or phone call, that they have a sample ready for them. The researchers are then responsible for arranging couriers and collections. To package a sample for release to researcher/courier, refer to SOP134 Research Tissue Bank Sample Transport.

o. For spillages refer to local guidelines in Addenbrookes Pathology Laboratory or School of Medicine Core Safety Manual in HLRI Laboratories.

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) (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

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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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