Document Title: Freezing Fresh Tissue Samples

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

Version Number	Modification:
V1	**Reviewed and updated SOP PRO/TE/TBR/004**

Key Points of this Document

1 Purpose and Contents

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

b. Tissue samples (surplus to the needs of Pathology) are collected from patients that have been through the informed consent process (SOP103) and have agreed to participate in the research projects. Fresh tissue collections are a valuable resource for research purposes. Tissues are frozen in a timely and appropriate manner after the pathologist has assessed the specimens and collected the required samples.

c. Fresh tissue should be frozen as soon as possible.

2 Roles & Responsibilities

a. Staff involved in freezing tissue must comply with the requirements set out in Section 4. This Policy applies to all personnel who freeze fresh tissue and they 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

4.1 Snap frozen samples

a. Samples collected for freezing must be labelled with a Tissue Bank Number and encased in pre-printed cassettes or other suitable container, under the hood in the Laboratory. Once

samples are in an appropriate container and labelled, pack the samples in a box with ice packs to transport and freeze under the designated CAT 1 hood.

b. Collect liquid nitrogen from Liquid Nitrogen store. A buddy system is in place for collecting Liquid Nitrogen.

c. Submerge the specimen into liquid nitrogen. The specimen should freeze within 30-60 seconds (the liquid nitrogen will stop bubbling when the tissue is frozen). Once snap frozen, transfer the sample directly to the designated -80ºC freezer. Samples should be carried to the freezer in the appropriately labelled transport container as soon as possible, preferably with dry ice, but if not with available ice packs.

d. For samples being stored in tissue bank, record the storage location in the Tissue Banking track and trace sheet. The samples' freezer locations can be added onto the Tissue Bank database (follow SOP101 - How to use the Tissue Bank database).

4.2 Samples for freezing in -80ºC freezer

a. Fluid samples (blood and cytology) are handled and stored according to their project protocol. Blood or cytology samples, which do not require any processing, are put straight into the freezer in the tubes/pots they arrive in. If the fluid samples need to be processed, centrifuge and aliquot before storing. Store in the designated -80°C freezer.

b. Record the storage location on the excel daily log spreadsheet and on the Tissue Bank database.

4.3 Samples for frozen section and storage in -80ºC freezer

a. Embed the tissue sample in OCT compound on a frozen section chuck and freeze by suspension in liquid nitrogen. Do not remove the tissue from the liquid nitrogen until freezing is complete (the liquid nitrogen will stop bubbling when the tissue is frozen). Cut the frozen section (follow HLRI Cryostat procedures). A H&E stained frozen section will be reviewed by a pathologist to validate the sample. After sectioning, the OCT frozen sample will be removed from the chuck and will be transferred to the designated -80ºC freezer. For samples being stored in Tissue Bank record the storage location on the database.

4.4 Samples for refrigeration for 24hrs (RNAlater) and subsequent storage in -80ºC freezer

a. Place the sample into a cryovial of RNAlater and store it in the fridge in the designated Tissue Bank laboratory for 24hours. Refer to individual project forms for researcher

preferences on how to freeze samples after 24 hours in RNAlater. For samples stored in tissue bank, record the storage location on the excel daily log spreadsheet and on the Tissue Bank database.

b. All frozen sample locations can be identified by looking on the Tissue Bank database.

5 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 (2023) Human Tissue Act 2004
Key related documents:	Trust Research Policy Trust Policy DN1 Document Control Procedures Activity Location Guide **SOPS** SOP103 – Tissue Bank Consent, Request Forms and Withdrawal of Consent SOP104 – Zebra Printer SOP101 – How to use the Tissue Bank Database **Risk Assessments** RAC/RD/TBR/005 - Labelling samples (DATIX 2400) RAC/RD/TBR/036- Freezing samples RAC/RD/TBR/004 - Fresh samples RAC/RD/RBR/034- Tissue Bank consent and request forms and withdrawal of consent. RAC/RD/TBR-037 – Handling, Processing and Freezing Fresh Tissue and Blood in the HLRI.

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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