Document Title: Research Tissue Bank Freezer Storage, Maintenance and Breakdown

Document Number: TB SOP131

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For use by:	Tissue Bank Staff / Research Staff
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Summary of Amendments

Version Number	Modification:
V1	Reviewed, updated and combined PRO/TE/TBR/022 and PRO/TE/TBR/019

Key related documents:	DN361 Biological Materials for Research Use Policy Trust Policy DN001 Document Control Procedures Activity Location Guide TScan Manual **SOPS** SOP029 Freezers: Management of Research and Development Freezers **Risk Assessments** RAC/RD/TBR/016 - Freezer breakdown contingency RAC/RD/TBR/006 - Event of storage failure and loss of relevant material

Key Points of this Document

1 Purpose and Contents

- This SOP sets out the requirements for the maintenance and monitoring of refrigerators and freezers used to store relevant material held under HTA license 12212 for research purposes or stored for NHS REC-approved studies with planned storage under the license at the end of the study. It also outlines best practices for samples of non-relevant material or those stored under NHS REC approval without planned future storage under the license.
- The Human Tissue Authority (HTA) standards for research require processes to ensure the robust maintenance and monitoring of storage units housing human samples for research.
- The temperatures of some of the freezers are connected to the T-Scan continual monitoring system. – see TScan user manual for instructions.
- Tissue bank samples are stored in -80°C or -70°C freezers and are labelled with an anonymised number that can be traced back to the tissue bank database. The freezers are set to operate with a 10°C deviation on either side of the set temperature.
- Mesobank samples are stored in -80°C freezers and are labelled with a unique 9-digit barcode that can be traced back to a donor using the web based Mesobank sample tracker application. Mesobank freezers are set to operate between -65°C and -90°C.
- In the event of a freezer failure, additional capacity is to be used to provide temporary storage to prevent degradation of the samples.

2 Roles & Responsibilities

a. The Designated Individual is responsible for ensuring that processes are in place to provide assurance and evidence of compliance with the HTA standards.

b. Ensure the temperature of a freezer is at the required level before opening it. If the temperature has risen to above -75°C do not open the freezer until it has reached the required temperature of -80°C. The freezer temperatures are automatically recorded via the T-Scan monitoring system.

c. If the temperature is outside of the expected range the alarm will sound to indicate this, unless it has been muted. Perform the following checks before calling an engineer:

Check if a member of Tissue Bank or Mesobank has recently accessed the freezer. Prolonged opening of the freezer door will cause the temperature to rise and the alarm to sound. This is not a problem, and the freezer will reach the correct temperature once

the freezer door is kept closed.
Ensure the freezer unit is plugged in and the power to the unit is functioning. If there is no power, contact the University Security Team on 01223 331818.

See if the freezer is over filled. If this is the case reduce the load of the freezer.
Ensure the door is closed properly and locked.
Check if the air intake vent is blocked. If it is, remove the obstruction.
Check the filter of the freezer.
Check the set temperature is correct.

If the above checks do not highlight the cause of the temperature change, then an engineer should be called. Current servicing contract and contact details can be found on the Equipment Master List - S:\shared\R&D\Pathology\Equipment.

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 Temperature alarm limits

The – 80 freezers should be operated between -65 and -90°C. Failure to do so could result in malfunction of the freezers. If the temperature is outside of this range, contact estates or the company providing the maintenance contract.

4.2 Isolating the Alarm

When carrying out large sample retrievals, auditing or cleaning/defrosting, it is possible to isolate the alarm system via the T-Scan monitoring system website. This prevents expected alarm notifications being sent to users whilst known maintenance/retrievals are taking place. Refer to manual.

4.3 Cleaning and monitoring

The detergent used for cleaning the freezers should be made up following the manufacturer's instructions.

Weekly – Check the floor around the freezers is clear.

Monthly – Check and, if required, clean the filter. Check the inner doors for frost build up.

Annually – Check if a defrost is required.

4.4 Freezer temperature monitoring – see Tscan user manual

a. Login to T-Scan
The username and passwords will be issued to relevant members of staff who need access to monitor the freezers. Contact R&D Managers or Tissue Bank Team leader if required.

b. Users have 5 attempts to login, after 5 unsuccessful attempts, the user is blocked from attempting to login for 10 minutes, this is a security measure designed to avoid circumvention of password security utilising repeated login attempts.

c. The sensors installed on site can be accessed through the Real-Time sensors page which displays all the sensors being monitored on site. Each single sensor is displayed as a "Sensor bubble" on the default view. For full instructions refer to the user manual.

The T-Scan system is used to review freezer temperature trends monthly. This is used to observe if there is a trend indicating freezer failure i.e. Increase in temperature over time, or if there have been any significant ad hoc temperature changes which may affect sample quality.

If a trend is observed:

Increase in temperature

1. Review freezer maintenance and ensure filters are cleaned.
2. Move to weekly monitoring of the temperature trend.
3. Arrange a freezer service.

Decrease in temperature

1. Move to weekly monitoring of temperature trend.
2. Arrange a freezer service.

4.5 Defrosting a freezer

Before defrosting a freezer make sure there is adequate space in other units for samples to be temporarily relocated to. Any sample relocation should be undertaken by two members of staff with the appropriate personal protective equipment, sample transport boxes and sufficient dry ice to keep the samples in a frozen state. Any transfer of samples should be carried out as efficiently and speedily as possible.
Keep a dated record of the interim sample location(s).

To defrost the freezer, switch off the power, leave the door open, place adequate absorbent material on the floor to keep it dry.
DO NOT use any sharp tools for removing frost.
Switch freezer back on and allow to reach desired temperature before replacing the contents.

4.6 Servicing

a. The freezers are serviced annually, as per SOP 029 Freezers: Management of Research and Development Freezers.

4.7 Freezer Failure

a. If there is a freezer failure t-Scan will alarm, and they will contact someone on the emergency contact list by systematically going from one contact to another until they have contacted someone who can investigate the cause of the alarm. The person(s) who acknowledges the notification will be required to log onto t-Scan to make a contingency plan, this may require keeping an eye on the temperature remotely or a visit onsite to rearrange samples from the affected freezers.

b. In the event of a temperature alarm a designated person will attend the freezer and check the freezer concerned for obvious fault i.e. door open. If there is nothing obvious a plan for the transfer of samples should be considered, see next point. The freezers own alarm can be silenced by pressing the buzzer button on the control panel. If the alarm continues the audible alarm will sound again after 30 minutes.

c. If the freezer has failed, first ascertain where the free storage space is in the other freezers, before opening the failed freezer's door.

d. Ascertain how many samples are in the failed freezer, being mindful that the "door open" time should be kept to an absolute minimum to maintain the low temperature within the failed freezer as long as possible.

e. Calculate how much temporary storage is required and map that into the available storage space.

f. If the freezers temperature is -40 °C or above for the -70°C freezer or -50°C or above for the -80°C freezer samples should be transferred to other freezers.

g. Using the appropriate equipment move the samples from the failed freezer, one rack at a time, ensuring that "door open" time is kept to a minimum.

h. Record the location of the samples that have been moved by putting a notice on the front of the freezer the samples have been moved from informing where they have been moved to, and one on the freezer it has been moved to temporarily to show where in the freezer they are located.

i. At the earliest opportunity, contact the buildings manager or freezer maintenance contractor and arrange an engineer visit to repair the failed freezer.

j. Do not return the samples to the failed freezer until after the repair has been completed and the freezer is at the required temperature.

k. Once the samples have been returned to the repaired freezer, update the front of the freezers.

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
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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