Royal Papworth Hospital
NHS Foundation Trust

Document Title: Freezers: Management of Research and Development Freezers

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Staff involved in development: *Job titles only*	Senior R&D Manager, Clinical Project Managers Tissue Bank Team leader, Research Biomedical Scientist, HLRI CRF Operations Manager
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
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Summary of Amendments

Section(s):	Modification:
V5	Changes to 24 hour emergency protocol. Changes to location of freezers. Increased detail on freezer cleaning protocols
V4	Minor administrative changes.

Key related documents:	Trust Research Policy SOP011 Archiving of Research Studies GD005 R&D Freezer List GD038 HLRI CRF Temperature monitoring of HLRI freezer GD043 Management of Freezer Alerts and emergency sample transfer TPL029 Sample Log Template TPL049 Manual Monitoring Template

	HLRI CRF Business Continuity Plan R&D Business Continuity Plan

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who use the R & D freezers in either Royal Papworth Hospital, or the HLRI CRF Clinical Research Facility as part of their research.
- This document covers general freezer management and the emergency procedures that should be followed in the event of freezer failure, including who to contact and when samples are to be transferred to back up equipment. It should be read in conjunction with GD043 Management of freezer alerts and emergency sample transfer.
- HLRI-CRF, Tissue Bank and Mesobank have their own SOPs/Guidelines for managing the freezers/samples they are responsible for.

1. Purpose and Content

a. The document clarifies the requirements for the correct use and maintenance of freezers to ensure the secure and appropriate storage of samples generated as part of Research Studies and Clinical Trials.

b. This document defines the Trust's research SOP for provision of clear guidelines for all research staff using the R&D Freezers for Research Studies and Clinical Trials, specifically for the R&D freezer located on level 1.

2. Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties including those within CUHP AHSC and those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

b. Staff using or looking after the R&D Freezers must comply with the requirements set out in section 4.

c. The Principal Investigator must ensure that the samples generated by a research study are stored appropriately, securely and under conditions to maintain their integrity.

3. Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4. Procedure

4.1 General Guidelines

Identity and location of RPH owned freezers on site detailed in GD005 Freezer List.

a. All laboratory freezers should be used and maintained in accordance with the manufacturer's operating manual. Equipment should be serviced annually to ensure it is operating within the manufacturer's tolerances. This is arranged by the Research Pathology/Tissue Bank Assistant; service records are held centrally, and a copy is saved to the S/Shared/R&D/Pathology/Equipment/Freezers folder.

b. Protective gloves should be worn when loading and unloading freezers.

c. Samples must be clearly labelled and stored within freezer bags or storage boxes which are labelled with the study name and number. An annotated plan should be displayed on the freezer door to indicate what samples are stored in each freezer compartment – study name and number, contact name and phone number. This must be updated after a sample movement.

d. IMPORTANT: Spare freezer capacity is extremely limited and access to the HLRI CRF is restricted to authorised personal and may not be possible over the weekend. Therefore, samples should not be stored long-term in the freezer located in the hospital, but regularly processed or transported off site according to trial protocol/lab manual.

e. Details of samples must be recorded on the study sample template log (TPL029) and saved in S/Shared/R&D/Pathology/R&D Samples. If a study team wishes to store sample logs in the study site file, then a short cut must be made to the R&D Sample folder. Logs must be updated when samples are deposited or removed from the freezer. Keeping sample logs up to date is important for auditing and HTA reporting purposes, but also to facilitate the identification of suitable freezer space for defrosting of freezers and in the event of an emergency freezer breakdown. Information to assist in the event of an emergency transfer should be included on the sample log e.g. is the sample required for a primary outcome, secondary outcome, exploratory or back-up and whether the samples are suitable for short-term storage at -20^{o}C.

f. All freezers in the hospital are continuously monitored via the Connected Automated Monitoring (CAM) (previously known as Tutela Temperature Monitoring System).

g. Once a month the temperature logs should be accessed, downloaded and saved in the specified folder by the delegated member of staff. According to the code of practice for NHS records management, freezer charts should be retained for 11 years (DoH Managing NHS records 2006). These will be archived, as per SOP011 Archiving of Research Studies by the department administrator. Data is kept by CAM for 30 years. Reports can be produced from the CAM system to provide details of any relevant incident reports – instructions on how to do this are saved in the Temperature Monitoring folder.

4.2 Cleaning of a -80ºC freezer

a. If it is likely that the freezer temperature will rise during a deeper clean or large sample movements. Therefore, the sensor alarm should be isolated to prevent alerts and for a clear audit trail. Ensure the sensor alarm is reactivated after the freezer task is completed. It is best practice to isolate the alarm for a fixed period of time via the temperature monitoring website. Once logged on, select the correct freezer probe from the list and proceed to 'Manage Isolations' to select the timeframe for the alarm to be isolated. Once this is completed the 'bell icon' on the list of freezer probes will change from green to amber. Alarm isolations can also be completed directly with CAM (contact details 01252 406361 or tutelasupport@checkit.net).

b. Be aware that if the -80ºC freezer does not close properly due to a build-up of frost/ice a major defrost and clean could be required at short notice; this will be prevented by a weekly inspection and clean if required. This is especially important for the R&D freezer on level 1 in Royal Papworth Hospital as the room is warm and multiple users open the door daily.

c. Weekly cleaning consists of scraping the inner/ outer door of any build-up. Particular attention must be paid to the locking system of the inner door. If the handles of the inner door are not fully closed due to frost this will increase the amount of ice build up to the extent where the outer door will not close properly. Ice also accumulates at the corners of inner doors which might prevent the door from closing. A dustpan and brush should be used to brush the 'snow' from the shelving units. If there is a lot of 'snow', this falls at the back of the shelving unit pushing the shelving unit forward, and eventually, the door will not close properly.

d. To minimize the need to defrost the freezer, which involves removing everything from the freezer and switching it off, a deeper clean should be done every 4-6 months. This takes at least 2 people as the freezer shelving units are quite heavy, especially if they contain boxes of samples and could involve removing the shelving units and cleaning the built-up 'snow'. Transfer the samples to another shelving unit whilst this is done.

Remove one shelving unit at a time, clean and return to the freezer before taking out the next one. Returning the shelving unit and all the shelves/drawers back into the freezer all at once will increase the temperature of the freezer rapidly. Therefore, leave plenty of time between cleaning individual units to allow for the freezer to return to temperature. Log to record freezer cleaning is stored in S/Shared/R&D/Pathology/R&D/Freezers.

4.3 Using Connected Automated Monitoring of freezers

a. Requests for new users or for users to be removed from the system should be sent to one of the system administrators. New users are set up with a common password that needs to be personalised, along with a Passcode PIN that is used for saving information/making changes: https://camplus.checkit.net/main/login

b. The CAM system is used for reporting, monitoring of sensors, management of incidents, supervisor closing of incidents, isolation of sensors in preparation for undertaking freezer related tasks, administrative rights to manage users and for responding to out of hours calls.

c. There are three levels of users: administrators, key users/supervisors and general users - all with different permissions. Spreadsheet of current users is saved in: S/Shared/R&D/Pathology/R&D/Freezers/Temperature monitoring.

d. User guides are in S/Shared/R&D/Pathology/R&D/Freezers/Temperature monitoring/Connected Auto-Checkit instructions and various training videos on the website: https://camplus.checkit.net/main/Training

4.3.1 Manual monitoring of freezers

Should the remote monitoring system not be in use for any reason (for example new freezer probe is required) the freezer temperature must be manually checked at regular intervals throughout the day and recorded on the Manual Monitoring Template (TPL049) by delegated members of staff. Once the monitoring system is back in use this document should be saved in the temperature monitoring folder.

4.4 Responding to freezer alerts

a. An alert will be activated if the freezer temperature rises above a certain level or the signal from the freezer probe is interrupted. This alarm will be audible within the freezer location area and will alert the relevant remote monitoring system. The freezer alarm can be silenced by pressing the button on the control panel. If the reason for causing the alert continues, the audible alarm will sound again after 30 minutes.

It is the responsibility of all R&D staff to respond to an alarm on the freezer and to make a preliminary assessment of the situation. If the reason for causing the activation of the alarm can be immediately rectified (for example the door had not been closed properly) and staff member is a CAM user, they should follow the process in section 4.4.3 Closing Alerts for resolving the incident on the system. If they are not a CAM user, they should escalate to their team leader.

b. In the event of an emergency transfer the HLRI-CRF and RPH have a reciprocal agreement to provide emergency freezer space to temporarily store samples whilst the freezer issue is dealt with.

i). Level 1 Hospital: If there is a temperature deviation of the -80ºC freezer by 10°C in the hospital the alarm will initiate a CAM response. The CAM system will automatically contact the relevant emergency contact.
ii). HLRI CRF: If there is a temperature deviation of the -80ºC freezer it will initiate SenseAnywhere response and its emergency protocol. If appropriate the relevant HLRI CRF team will be notified, who will respond in accordance with their protocols and GD038 HLRI CRF Temperature monitoring of fridges and freezers which details actions required for dealing with temperature deviations etc.

4.4.1 For alerts during normal working hours (defined by 8 to 5pm Monday to Friday)

a. The responsibility for being the principal contact for dealing with in hours alerts will be assigned to a specific staff member who will carry a mobile phone allocated for this purpose (Mob 07384424714). The CAM system also have this number for in hours alerts.

b. Freezer located in the hospital: the initial responder to the alarm assesses the freezer problem and if necessary, seek advice on whether samples need to be transferred. If transfer is required appropriate action should be taken to transfer samples to the spare freezer capacity in the HLRI/CRF (in accordance with the Guidelines for Managing alerts and emergency transfer of samples GD043).

4.4.2. For Out of Hours alerts (defined as before 8am and after 5pm Monday to Friday and any time during the weekend)

a. All staff on the emergency out of hours contact list for the RPH freezer on level 1 must familiarise themselves with the freezer location in the hospital and the freezer in the HLRI-CRF. The emergency contact list for CAM has mobile telephone numbers and email addresses for the department staff identified as available to respond to out of hours alert. The list is saved in S:\shared\R&D\Pathology\Equipment\Freezers\Temperature monitoring and should be checked for accuracy on a quarterly basis.

b. The Emergency Contact logs onto the monitoring system and identifies the cause of the alert, including whether the freezer appears to have failed.

c. If further investigation is required to confirm the cause of the out of hours alert the Blood Transfusion team can be called to request an onsite staff member to act as first responder to check what has happened to the freezer. They will call back the Emergency Contact with their observations – that is the end of their responsibility for dealing with the alert.

4.4.3 Closing alerts

Once the issue that caused the alert is resolved the incident should be closed on the monitoring system. For CAM this is done by accessing the incident from the sensor list and completing the audit report to include a description of the cause, the corrective action taken and when the incident was resolved. Once this is completed the appropriate supervisor can fully close the incident by signing it off.

4.5 Access to dry ice

a. Planned use of dry ice for tasks such as freezer defrosting**:** if no other dry ice is available, the members of staff undertaking the freezer defrost must order dry ice to be delivered to the modular build at RPH on the day.

b. Emergency transfer of samples: if dry ice is required for an emergency transfer dry ice can be obtained from:
   - Dry ice storage box on Level 1 in HLRI.
   - Polystyrene boxes used to carry dry ice are limited due to lack of storage on site, but there will be at least one in the following locations: Mini-lab in outpatients, R&D Basement room, HLRI -CRF and the HLRI Goods In (Tissue Bank store two boxes on the top shelf) and HLRI staff can provide access 8-4pm if a member of staff does not have the required card access.
   - If any boxes are used for cleaning a freezer or for transferring samples, they MUST be returned to their original location to be available in the event of an emergency transfer.

4.6 Reporting Alarms

In the event of the freezer alarm being activated and the temperature rising above -50˚C for the -80 ˚C and above -15 ˚C for the – 20 ˚C a Datix Incident form will be completed by the initial responder.

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 active version approved 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. R UK Policy Framework for Health and Social Care Research (2023)

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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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