Royal Papworth Hospital
NHS Foundation Trust

Document Title: Freezers: Management of Research and Development Freezers

Document Number: R&D SOP029

Staff involved in development: *Job titles only*	RM&G Manager, R&D Administration Manager, Research Officers
Document author/owner:	R&D Administration Manager
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Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
	Minor administrative changes

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 the Royal Papworth Pathology department as part of their research study.

- This document covers 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.

1. Purpose and Content

a. This document defines the Trust's procedures to be followed when using the R&D freezers within the Pathology Department for storing samples generated as part of Research Studies and Clinical Trials.

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

c. 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.

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 in Pathology 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 so as 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

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 Pathology Manager, and maintenance records are held in the Pathology department.

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

c. Samples should be clearly labelled and stored within freezer bags or storage boxes which are labelled with the study name and number. An annotated plan will be placed on the freezer door to indicate what samples are stored in each freezer compartment – study name and number, contact name and phone number.

d. All samples should be logged on the study sample log and regularly updated. The study sample logs are located N:\shared\LISTS OF R&D RESEARCH SAMPLES

e. All freezers (apart from the -20°C freezer belonging to the CF Unit) are continuously monitored via the Tutela Temperature Monitoring System. Once a month the temperature logs must be accessed, printed off and filed in the Freezer Log folder located in the R&D Admin office. 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 SOP 011 Archiving of Research Studies by the department administrator. Data is kept by Tutela for 30 years.

f. Freezers must be defrosted on a six monthly basis by a delegate from the R&D department to prevent build-up of ice on the compartment doors. Samples should be moved into the back-up freezer whilst this happens and then transferred back into the defrosted freezer once it is back to temperature.

g. Prior to defrosting contact Tutela to notify them which freezer will be defrosted and the time frame. This is for Tutela's audit purposes (Tutela contact number 01252 406361).

h. Prior to defrosting the delegated member of staff responsible for the defrosting should notify switchboard that they will be defrosting a freezer and which one. Similarly switchboard should be notified when defrosting is complete and the freezer is back down to temperature so that they can respond to any subsequent alarms as an emergency.

i. CF Unit freezer is manually checked and readings recorded Monday to Friday. Samples are not stored in this freezer overnight, they are transferred to -80°C freezer.

4.2 24 Hours Emergency Protocol

a. In the case of -80ºC freezer failure in the Freezer Room, Ground Floor Pathology Department, appropriate action should be taken to transfer samples to back-up storage without damaging samples or losing record of the sample's identity and tracking. Follow all standard guidelines and universal precautions for working with biohazardous materials. Use gloves, eye protection, coats or gowns and other appropriate apparel for protection from exposure to blood borne pathogens or other potentially infectious materials in accordance with DN441: Personal Protective Equipment (PPE) Procedure.

b. The Freezer Room has four -80°C freezers located on the ground floor of the Pathology building. These freezers are set to operate at -80ºC, a 10º C deviation on either side of the set temperature will result in the alarm sounding; this alarm will be audible within the freezer room area and will alert Tutela and Switchboard. See Guidance Document GD:005

c. The alarm will initiate a Tutela response and they will contact someone on the emergency contact list; by systematically going from one phone number to the next until they have successfully contacted an individual who can investigate the cause of the alarm. On occasions when Tutela is unable to contact anyone on the list by phone, they will follow up with an email to all. This email will detail the failed attempts to make contact by phone and also the time that the alarm was initiated.

d. The Emergency Contact will make a note of the time of attendance and the temperature of the freezers. The Emergency contact will notify switchboard that they are in attendance and dealing with the alarm.

e. All staff listed on the emergency out of hours contact list must familiarise themselves with the freezer room location in Pathology. The emergency contact list will have home and mobile telephone numbers for the department staff identified as available to respond to out of hours calls.

f. The list will be checked for accuracy on a quarterly basis by the Senior R&D Manager. Out of hours is defined as before 9am and after 5pm Monday to Friday and any time during the weekend.

g. The Freezer alarm can be silenced by pressing the buzzer button on the control panel. If the alarm condition continues, the audible alarm will sound again after 30 minutes.

h. The Emergency Contact will identify which freezer is faulty and the samples within this freezer will be moved to the adjacent freezer (see 4.3). If freezer #3 (PlaqueTec) is faulty (Sanyo HCFC-Free Ultra-Low Temperature Freezer model MDF-U3386S - serial number 09100105) contact someone from PlaqueTec. The list of out of hours contact numbers for the PlaqueTec staff is on the front of their freezer; systematically go from one phone number to the next until you have successfully contacted one of them.

i. If there is a serious problem causing the temperature of more than one freezer to rise, the Emergency Contact will need to contact an on-call member of staff from the Pathology Labs (via Switchboard) to see if there is –80°C Freezer space within their department.

4.3 Sample Transfer

a. The initial responder to the freezer failure assesses the freezer failure and whether samples need to be transferred (dependent on current freezer temperature, time of day, weekend/weekday). Samples should be transferred if the freezer temperature is -50°C or above, and the temperature of both the freezer where the samples were transferred from and also the freezer where the samples were transferred to should be monitored.

b. Using the proper equipment, samples are quickly transferred from the failing freezer to the back-up freezer. During the transfer of samples every effort must be made to ensure that the freezer doors are kept shut as much as possible to minimise the adverse effects on the samples (see section 4.2a).

c. Boxes are labelled with original shelf rack, box location to ensure correct return of samples to assigned locations.

d. The Chief/Principal Investigator and Research Nurse/Clinical Trial Coordinator for the studies affected should be informed that a sample transfer had to be performed

4.4 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. Research Governance Framework for Health and Social Care (2005)
Key related documents:	Trust Research Policy [Insert list of linked or relevant documents to this SOP]

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.

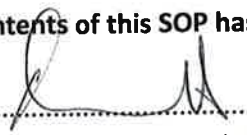
Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	No	No	No	No	No	No	No
Positive/Negative							

Review date:	November 2020

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0				
2.0				
3.0				
4.0				

I certify the contents of this SOP has been reviewed and ratified



Signed by Dr Ian Smith, Clinical Director of R&D

3rd Febru 2018

Date

SOP release date: 12th February 2018