Royal Papworth Hospital
NHS Foundation Trust

GD024

Management of R&D Freezers

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

The document contains clear guidelines for all research staff using the R&D Freezers for Research Studies and Clinical Trials.

1.General guidelines

- 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 Research Pathology/Tissue Bank Assistant; service records are held by Pathology Research/Tissue Bank and a copy is saved to the N:\shared\R&D SAMPLES folder

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

- 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.

- All samples should be logged on the study sample log and updated when samples are deposited or removed from the freezer

- All freezers in the hospital are continuously monitored via the Tutela Temperature Monitoring System. Once a month the temperature logs should be accessed, downloaded and saved in the relevant N drive 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 SOP 011 Archiving of Research Studies by the department administrator. Data is kept by Tutela for 30 years. The study sample logs are located N:\shared\R&D SAMPLES within the relevant freezer folder

- R&D freezers located in the CAB are monitored by the University T-scan system. The temperature logs must be accessed, downloaded and saved in the relevant folder within N:\shared\R&D SAMPLES by the delegated member of staff.
- Freezers must be defrosted on a regular 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 or kept on dry ice whilst this happens and then transferred back into the defrosted freezer once it is back to temperature.

- The freezer located in the hospital is to be defrosted on a quarterly basis. The delegated member of staff responsible for the defrosting should 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).

- Freezers located in the CAB are to be defrosted on a six monthly basis. The delegated member of staff should make arrangements with the CAB Papworth Research staff to gain access to the freezers and also for them to notify the University system prior to the defrosting.

IMPORTANT: The only spare -80°C freezer space available in the case of freezer failure is within CAB. Spare freezer capacity is limited and also access to the CAB is restricted to authorised personal and will not be possible over the weekend. Therefore, samples should not be stored long-term in the freezer located in the hospital, but regularly transferred over to the CAB or transported off site in line with a trial protocol.

2.Emergency Protocol

- The -80 °C freezers are set to operate at -80ºC, a 10º C deviation on either side of the set temperature will result in the freezer alarm sounding (this alarm will be audible within the freezer location area) and will alert the relevant remote monitoring system. The -20°C freezers are set to operate at -20°C, a 5°C deviation on either side of the set temperature will result in the freezer alarm sounding and initiation of a remote monitoring alert.

- Hospital: If there is a temperature deviation of the -80ºC freezer in the hospital the alarm will initiate a Tutela response. Tutela will systematically go through the contact list 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 and also the time that the alarm was initiated. See Guidance Document GD:005.

- CAB: If there is a temperature deviation of the freezers located in the CAB the alarm will initiate a T-scan response and its emergency protocol. If appropriate Papworth CAB team will be notified, who will respond in accordance with their protocols (PRO/TE/TBR/019 and SOP PRO/AD/TBR/010 saved and contact R&D if required.

For alerts during normal working hours (defined by 9 to 5pm Monday to Friday).

- The CAB team will identify spare freezer space to transfer the samples into if there is not suitable space in the R&D freezers. Sample transfer should be 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.
- Freezer located in the hospital: the initial responder to the alarm assesses the freezer problem and whether samples need to be transferred. If transfer is required appropriate action should

be taken to transfer samples to back-up storage within the CAB by calling 638073 or 638319 to request access. The CAB research team will identify the spare freezer space to be used if there is not suitable space in the R&D freezers. Sample transfer should be on dry ice 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.

For Out of Hours alerts (defined as before 9am and after 5pm Monday to Friday and any time during the weekend)

- All staff listed on the emergency out of hours contact list must familiarise themselves with the freezer location in the hospital. The emergency contact list will have home and mobile telephone numbers for the department staff identified as available to respond to out of hours call. The list will be checked for accuracy on a quarterly basis by the Senior R&D Manager.
- 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
- The Emergency Contact will identify the cause of the temperature deviation or whether the freezer has failed and the samples need to be moved to the back-up freezer in the CAB.
- CAB facility team are included on T-scan out of hours emergency rota and will be first responder; either CAB facility team contact or Dr Rassl will arrange for access to R&D freezer should transfer be required.

3.Sample transfer in the event of an emergency

- 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.
- 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.
- Boxes are labelled with original shelf rack, box location to ensure correct return of samples to assigned locations.
- 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 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 should be completed by the initial responder.

This document can be read in conjunction with the R&D Business Continuity Plan.