York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
SOP
Pharm/S108

Pharmacy Clinical Trials Ultra-Low Freezer

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&I Department's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&I Department SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&I Department website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Date:	21st August 2025
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	2nd September 2025

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	15th March 2022		New document
2.0	30th September 2025	Dominic Burns	Addition of ultra-low freezer validation.

Contents

1 Introduction, Background and Purpose

The Clinical Trials Ultra-Low Freezer runs at extremely low temperatures (between -60°C and -80°C), and as such, special precautions and instructions must be put in place when using the Ultra-Low Freezer. It is possible that, due to the COVID-19 pandemic, this piece of equipment may be used by both Pharmacy Clinical Trials staff, and staff from the wider Pharmacy department, including Pharmacy stores, and hence this SOP is to ensure the continuity of use of the Ultra-Low Freezer.

2 Who Should Use This SOP

This SOP is intended to be used by the Pharmacy Clinical Trials team and should be used by any other members of the Pharmacy department if using the Ultra-Low Freezer.

3 When this SOP Should be Used

When new stock is being placed into the Ultra-Low Freezer, stock is removed from the freezer, and for the daily running and monitoring of the Ultra-Low Freezer.

4 Procedure(s)

The Clinical Trials Ultra-Low Freezer is located underneath the dispensing bench in the Clinical Trials Dispensary. The Ultra-Low Freezer will be locked when not in use, and the key is kept with the other clinical trials keys in the Clinical Trials office. For out of hours access, both the clinical trials office and dispensary are locked, however can be accessed by the key holders in department.

When using the Ultra-Low Freezer, **insulated gloves**, **safety goggles**, and an **insulated apron** must be worn. Any **exposed skin** must also be **covered**, and closed shoes must be worn.
Insulated gloves can be found with the Ultra-Low Freezer in the Clinical Trials dispensary, and **must** be returned to this location after use. Safety goggles, insulated apron and spare insulated gloves are located in Pharmacy stores.

4.1 Using the Ultra-Low Freezer

Adding stock to the Ultra-Low Freezer

When stock requiring storage in the Ultra-Low Freezer is received and has been checked as per relevant SOPs, take the entire container to the Pharmacy Clinical Trials dispensary and follow the below steps:

- Locate the key from the Clinical Trials office
- Unlock the freezer using the lock on the freezer door handle and ensure that all necessary PPE is worn for this process (as above).

- Ensure that the temperature displayed on the freezer is within specified temperature range. If the temperature displayed is outside of the specified range, please see Section 4.3.

- Remove the cartons from the outer container and place them onto the dispensing bench and replace the lid on the outer container to contain the dry ice.

- Check the stock's expiry date and batch number, and check for any damages.

- If the stock is deemed suitable, open the door of the Ultra-Low Freezer, and place the stock inside on the shelf as quickly as possible.

Note: Ensure that stock is not stacked up to the roof of the freezer, as this may disrupt the air-flow and overall temperature, of the Ultra-Low Freezer. Stock should be appropriately spaced if possible and should not rest against the side-walls of the freezer.

Note: Once the door has been opened and closed again, the door will be unable to be re-opened for 1-2 minutes to allow for the temperature to regulate.

- Close and lock the door, ensuring that the latch is closed fully.

- Return the key to the appropriate storage location in the Clinical Trials office.

Note: When adding stock to the Ultra-Low freezer, ensure it is done so in a timely manner so the door of the Ultra-Low freezer is not open for an extended period of time as this may trigger a temperature excursion (see Section 4.3).

Note: If any discrepancies or damages are highlighted, place the stock into the Ultra-Low freezer, but ensure it is in a bag clearly labelled as 'quarantine stock'. Plastic bags can be found above the dispensing bench in the Clinical Trials dispensary. This should then be reported to procurement team (for hospital stock) and the sponsor (for clinical trials stock) immediately.

- Place the empty container in the Pharmacy Flammable store located outside Pharmacy Stores and place the dry ice warning poster (copies of which are located on the Ultra-Low freezer) on the box and leave for at least 24 hours.

- Return all PPE to its respective storage locations.

Removing stock from the Ultra-Low Freezer

Before removing any stock from the Ultra-Low freezer, ensure that the appropriate PPE is worn (as above), and collect a blue fridge porter (Helapet) from the cold store, and a trolley from Pharmacy stores.

- Retrieve the key for the Ultra-Low Freezer from the Clinical Trials office

- Unlock the freezer and ensure that the temperature displayed on the freezer is within specified temperature range. If the temperature displayed is outside of the specified range, please see Section 4.3.

- Open the door of the Ultra-Low Freezer, and remove the required stock, ensuring the stock is placed immediately into the blue fridge porter situated on a trolley, directly adjacent to the freezer. If individual vials of stock are being removed from the freezer, ensure that tongs are used to pick up the vials. Tongs are located in Pharmacy Stores.

Note: Ensure when removing stock from the Ultra-Low freezer it is done so in a timely manner so the door of the Ultra-Low freezer is not open for an extended period of time during this process as it may trigger a temperature excursion.

- Close the door, ensuring the latch is closed fully and lock the door.
- Return the key to the clinical trials office.
- Close and seal the blue fridge porter and transport the stock to its desired location.

Note: If the stock is intended to be defrosted, transport the stock to the cold room or designated clinical trials fridge. Complete all necessary paperwork and labels to document the time and date the stock was removed from the freezer, and the new expiry date and time.

- Remove all PPE and return to the appropriate storage location.
- Return the blue fridge porter to the cold room and the trolley to Pharmacy stores once the stock has been delivered successfully.

4.2 Temperature Monitoring

The temperature of the Ultra-Low Freezer is monitored using EMS on a daily basis as per the 'Temperature monitoring (Clinical Trials)' **Pharm/S48** SOP.

The primary source of temperature monitoring the ultra-low freezer is EMS which can be viewed online 24/7 recording every 5 minutes. A secondary temperature monitoring system cannot be kept within the freezer as this can cause the port to become weak and result in temperature excursions and damage the freezer.

Members of the Clinical Trials team will record the daily minimum, maximum and average temperatures of the freezer on the 'Daily Clinical Trials Temperature Checks' (Pharm/F108) form in the Temperature Monitoring file in the Clinical Trials office.

The Ultra-Low Freezer also has an external temperature display, which shows the 'Set' temperature and the 'actual' temperature. This temperature display should be checked to ensure it is within the specified temperature range before any stock is added to, or removed, from the freezer. (refer to the ultra-low freezer user guide)

4.3 Temperature Excursions

Due to the extremely low temperature of the Ultra-Low Freezer, a temperature excursion can be triggered by leaving the door of the freezer open for an extended period when putting new stock in, or removing stock from, the freezer. Therefore, it is important to ensure the door is open for as little time as possible.

In the case of a temperature excursion occurring, this will be picked up on EMS by an EMS temperature alarm or by the daily temperature checks conducted in clinical trials.

- During working hours, notify the Pharmacy Quality Assurance Team of any temperature excursions and affected stock immediately (if being used by the wider Pharmacy department), and quarantine the stock within the Ultra-Low freezer by placing a sign on the stock to show that the stock is quarantined. Note: the correct PPE must be worn before opening the freezer.
- For clinical trials stock in the Ultra-Low freezer, quarantine the stock immediately by placing a Quarantine Notice (Pharm/F42) on the outside of the freezer, and notify any sponsors/suppliers as necessary

OR

- IMP may also be quarantined in another ultra-low freezer within the Trust, this maybe the Research lab freezer, this will be discussed with an individual trial sponsor prior to the trial opening. Refer to the study specific SOP in the individual Pharmacy Site File if this quarantine option has been set up and how to transfer the IMP from one ultra-low freezer to another within the agreements of the trial.

Out of hours, if the Ultra-Low Freezer is being used by the wider Pharmacy, the on-call Pharmacist will be contacted to alert them of this excursion. The necessary action should then be taken by the on-call Pharmacist in regard to the non-trial stock stored in the Ultra-Low Freezer.

Out of hours, if clinical trial stock is being stored in the Ultra-Low Freezer, the on-call pharmacist will be notified of the temperature excursion, and the on-call pharmacist should then contact the Pharmacy Clinical Trials Lead (or delegate) on the PANDO app. Following the study specific SOP in the individual Pharmacy Site file, IMP may be moved to the Research lab ultra-low freezer location, as advised by Pharmacy Clinical Trials.

If there is no IMP currently being held in the ultra-low freezer then the on-call Pharmacist will not be notified of the temperature excursion. This temperature excursion will be identified and handled by the Clinical Trials team during working hours.

Ensure that the Pharmacy Quality Assurance team are informed whether the on-call Pharmacist should be notifiable depending on whether IMP is included in the ultra-low freezer. Pharmacy Quality Assurance will then alter the EMS settings as applicable.

4.4 Freezer Validation

Ultra-low freezer validation will be accepted in form of the annual EMS probe calibration. Ellab will send a delegate annually to validate the ultra-low freezer along with other units in the pharmacy department.

The EMS probe is kept inside the ultra-low freezer in a central location and connected to the 24/7 monitoring system. Due to the internal volume of the ultra-low freezer and infrequent use of the freezer itself, there is no requirement for further temperature validation.

During the probe calibration process, stock will remain in place and the probe will be removed from the freezer by being passed through the back of the freezer. During this time the built-in temperature reading will be relied upon.

The Ellab delegate will produce a calibration certificate based on the EMS temperature probe passing calibration successfully.

In the event of a calibration failure, the sensor can be returned to Ellab to be fixed, or a new sensor can be purchased. Obtain the contact details for the Ellab account manager from the Pharmacy Quality Assurance team if necessary.

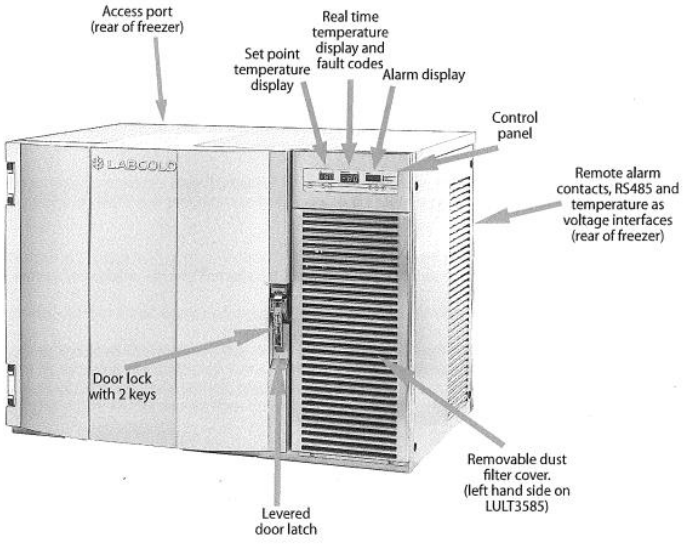
4.5 Freezer Cleaning and Maintenance

Labcold recommend that the Fin Coil Heat Exchanger is cleaned at least every six months. This is to prevent dust build up and prevent the unit over heating and shutting down.

To do this:

- Disconnect the unit from the mains power.
- Remove the two fastening screws located under the removable dust filter cover (see image below) at the front of the unit.

Product Overview



- Slide grille down and remove.
- Clean black fin coil heat exchanger with compressed air or brush/vacuum cleaner.

- Replace grille and refit two fastening screws.

Please ensure there is sufficient room (approx. 30cm) around the unit to when returning under the counter to allow for proper ventilation.

5 Related SOPs and Documents

Temperature Monitoring (Clinical Trials) – Pharm/S48

Daily Clinical Trials Temperature Checks - Pharm/F108

Quarantine Notice - Pharm/F42