

Clinical Trials Fridge/Freezer Cleaning

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&D Unit'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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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&D Unit 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&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance/ and/or Q-Pulse

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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	Details of significant changes
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1 Introduction, Background and Purpose

The function of the clinical trials refrigerators and freezers is to ensure that the physical, and chemical stability of pharmaceutical products stored within them are maintained in agreement with manufacturer and sponsor storage requirements.

Regular cleaning and temperature monitoring of storage areas forms part of the Quality Management System (QMS) and allows the Quality Assurance (QA) team to provide documented evidence to show that manufacturers storage requirements have been satisfied and the quality of the pharmaceutical products stored within the refrigerators and freezers can be assured during storage.

Temperatures of all storage locations within pharmacy clinical trials are monitored in accordance with Pharm/S48 - Temperature Monitoring (Clinical Trials)

2 Who Should Use This SOP

This SOP should be used by any member of the Clinical Trials team undertaking the cleaning of any of the Fridge or Freezer locations used by Clinical Trials.

3 When this SOP Should be Used

This SOP should be used when conducting the cleaning of any of the Clinical Trial Fridges or Freezers.

Clinical Trial Refrigerators are to be cleaned once every quarter, totalling four instances in a calendar year. Freezers are to be cleaned twice per calendar year, 6 months apart.

4 Procedure(s)

Before this procedure is carried out ensure the daily workload is considered. Plan cleaning around prescriptions and orders that may be due in and schedule the most appropriate time. For example, when a fridge or freezer has low stock levels and is waiting for new supplies to arrive from the sponsors this would be the most suitable time to clean a fridge/freezer to minimise the amount of stock which could be affected by the cleaning process.

Empty the Refrigerator/Freezer:

1. Proceed to the refrigerator or freezer; complete the details necessary on **Form Pharm/F40** (Kept on the side of CTF3). Identify a suitable temporary storage area, another fridge or freezer as required, to transfer the stock into for the duration of cleaning; making sure it is within temperature range. Keep the doors of all **fridges** closed as much as possible for the duration of the process to try and prevent temperature excursions.
2. Transfer the items into the alternative fridge or freezer as appropriate, ensuring the Denward logger that is inside the fridge or freezer (which is to be cleaned) is transferred with the stock, this is to show a continuation of temperature recording during the cleaning process.

3. For refrigerator cleaning now proceed to step 8 (Cleaning internal surfaces)

Defrost Freezer:

Check if the freezer is “self-defrosting” if it is and there is no ice build-up it will not be required to be defrosted

Sponsor supplied ultra-low freezers will have their own procedures for defrosting and cleaning. Refer to manufactures specific manuals for specialist of equipment.

4. Turn off and unplug freezer at the wall
5. Open door and leave ajar, place wet floor sign outside of freezer in case of spillage
6. Leave until all ice has completely defrosted
7. Mop up all water inside the freezer with paper towels and any water on the floor with a mop from the cleaners cupboard within the pharmacy department.

Clean internal surfaces:

8. Remove any shelving and place on a safe flat surface.
9. Collect the Clinell wipes found in the clinical trials dispensary or obtain a new pack from pharmacy stores if required.
10. Using a wipe, working from top to bottom wipe all internal surfaces of the fridge or freezer.
11. Using a Clinell wipe, wipe the shelving. Replace them in their original position in the refrigerator or freezer (be careful not to damage the refrigerator or freezer).
12. Close the refrigerator or freezer door to allow the unit to return to temperature.

Cleaning refrigerator/freezer external surfaces and components:

13. Using Clinell wipes, wipe the exterior panels of the refrigerator or freezer. Do not wipe directly onto working electrical parts; extra care must be taken to avoid contact with the LED display, to ensure accidental temperature adjustment or power interruption is avoided.
14. Once cleaning has been completed, log the finish time on **FormPharm/F40**. Next, verify the temperature of the fridge/freezer is in range and place all stock back in the cleaned refrigerator or freezer.
 - Fridge temperature range: 2°C to 8°C
 - Freezer: -15°C to -25°C

Ensure that NotionPro is reading at the required temperature before the stock is transferred back to the original location. The Denward logger that was transferred with the stock to the temporary location should be checked for any excursions before returning to the original location.

If a temperature excursion is recorded on the accompanying Denward logger or in the temporary location then a file note must be produced to document the occurrence. The temperature excursion will then need to be handled in the usual manner. A file note will be required to accompany the monthly saved graph produced from Notionpro for the original (cleaned location) to show why the records show an excursion. Ensure that the Denward logger data is produced and saved for this month to show a continuation of temperature recording. The times provided on **Form Pharm/F40** will provide evidence of stock being located elsewhere at the time of excursion.

Upon completion of cleaning, ensure all details on **Form Pharm/F40** are completed and return it to the storage location on the side of CTF3. If the sheet is completed for the year file it in the allocated space in the Temperature Monitoring File in the clinical trials office.

5 Related SOPs and Documents

Pharm/F40 - Clinical Trials Fridge/Freezer Cleaning Schedule

Pharm/S48 - Temperature Monitoring (Clinical Trials)

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