



BLDEA's
SSM College of Pharmacy and Research Centre,
VIAJAYAPUR-586101,

Department of Pharmacognosy

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Refrigerator and Freezer Use and Monitoring SOP

1.0 POLICY

This standard operating procedure (SOP) outlines the use and maintenance/monitoring of the research laboratory refrigerator and freezer units located within the BLDE SSM College of Pharmacy and Research Center Vijayapura. The research laboratory refrigerator is located in the Micro-Biology Lab and the research freezer units (two -86°C freezers and one -20°C freezer) are located in the Research Freezer Room. The research laboratory refrigerator and freezer units are maintained by BLDE SSM COP, Vijayapura.

2.0 PURPOSE

To ensure the validity of clinical research data collected from human participants by users of the BLDE SSM COP for all investigator-initiated and industry-sponsored research, including drug, natural health product, medical device, and other clinical trials. The storage of pharmaceuticals, biological

samples (specimens) and other substances require specific and strict environmental temperature controls in order to not affect the generation, measurement, or assessment of research data.

RESPONSIBILITY

Users are responsible for:

Equipment Use:

- Food and beverages for human consumption MUST only be stored in refrigerators/freezers located in designated kitchen/nourishment areas within BLDE SSM COP. No food or beverages are allowed in the research laboratory refrigerator and freezer units located in the Research Centrifuge Room and Research Freezer Room within BLDE SSM COP.
- All biological samples or any substances requiring refrigeration will be placed in an appropriate container to prevent the possibility of spills, leakage, odors, or spoilage prior to storage in the research laboratory refrigerator and/or freezer units within BLDE SSM COP.

- Bottles, tubes, and containers with a cap or top must be stored in an upright position and in such a way to ensure their stability.
- All biological samples or any substances stored in the research laboratory refrigerator and/or freezer units will be appropriately labeled. At a minimum the label should include participant ID number, protocol number, and date. Additionally, containers of substances that have been removed from their original manufacturer/distributor packaging must be labelled so as to identify their contents and any health or safety precautions that should be considered.
- Personal protective equipment (PPE) MUST be worn when using the research laboratory refrigerator and freezer units within BLDE SSM COP. See “Personal Protective Equipment” SOP. Insulated thermal gloves (located in the Research Freezer Room) should also be worn over your nitrile gloves when storing specimens in the research freezer units. Temperatures of -70 °C to -80 °C can quickly cause frostbite and samples stored at these temperatures can damage the skin if handled with bare hands. When transporting specimens between the Research Centrifuge Room to the Research Freezer room, users must don a new pair of nitrile gloves after hand hygiene techniques applied.
- Be familiar with the location of your specimens (which freezer

unit, which compartment, which drawer) before you open the freezer unit door to retrieve them from storage. Open the appropriate inner door and remove the storage box from location and retrieve or deposit your specimens. Work quickly as the temperature in the interior rises very quickly. Return the box to the same location in the freezer unit when finished.

- Check the freezer unit door gasket and be sure that it is free of ice buildup. Brush frost off doors, especially in the summer when the humidity is increased, using the scraper provided in the Research Freezer Room.
- Quickly close all freezer unit doors making sure outer latch is closed properly. **Be careful fingers are not placed such that the outer latch of the door can crush them.**
- Note that the freezer unit may vacuum down the door and it may take several minutes for the door to re-open.
- Place absorbent pads or paper towels on floor to soak up water from melting frost/ice, and hang the “WET FLOOR” sign on the glass door in room to prevent injury to other users. The sign is located in the Research Freezer Room.
- DO NOT put specimens into bags to store in the freezer unit. Specimens MUST be in boxes. Boxes must be in

assigned freezer racks.

- Keep accurate records of where samples are stored and when they are used using the Research Freezer log book.
- If the freezer unit is in alarm mode, immediately report the incident to the designated staff member on site during normal business hours only. After hours and on weekends, please contact Principal BLDE SSM COP. DO NOT remove/move other users' specimens to other freezer units.

BLDE SSM COP is responsible for:

Equipment Maintenance and Monitoring:

- Ensuring that the research laboratory refrigerator and freezer units are regularly inspected, appropriately cleaned and maintained in good working order, and are available to all users of BLDE SSM COP as required. A designated staff member will inspect the condition of each refrigerator and freezer unit, including the electrical cord/plug to ensure safe operation, clean the outside of the units periodically by wiping down with a mild disinfectant/soap solution, and ensure that any additional maintenance/service be performed by authorized personnel. Equipment determined to be unsafe will be removed from service immediately. At least monthly the designated staff member shall inspect, date, and initial the log to ensure the laboratory refrigerator and freezer units (and its contents) are being properly maintained. These logs

will be stored for retention with the designated staff member and available upon request.

- Responsible for the monitoring of the research laboratory refrigerator and freezer units located in the Research Centrifuge Room and Research Freezer Room within BLDE SSM COP. The laboratory refrigerator and freezer units are remotely monitored using Scigiene's monitoring solutions software for temperature, humidity and hygiene that is HACCP, 21 CFR Part 11, GMP and ISO9000 compliant. These records are retained by the designated staff member and available upon request.

REFERENCES

- Refer to each manufacturer's manual for additional information related to the laboratory refrigerator and freezer units.