



Clinical Research Center Freezer/Refrigerator/Cold Centrifuge Use and Monitoring	CR-504
Clinical Research Standard Practices	Effective Date: August 2024

SCOPE AND PURPOSE This document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

<input checked="" type="checkbox"/> Principal Investigator	<input type="checkbox"/> Regulatory Specialists
<input checked="" type="checkbox"/> Sub-Investigators	<input checked="" type="checkbox"/> Key Study Ancillary Personnel
<input checked="" type="checkbox"/> Study Coordinators/Associates	<input type="checkbox"/> Financial Analyst/Contract Management Accountants
<input type="checkbox"/> Data Specialist	<input type="checkbox"/> Central Research Office Personnel

This standard operating procedure (SOP) is to define the use, maintenance, and monitoring of freezer and refrigerated units for research specimens located in the Clinical Research Center (CRC) unit of the Penn State Health Milton S. Hershey Medical Center.

This SOP may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. Equipment Use
 - a. Freezers, refrigerators and cold centrifuges may only be used for research samples for CRC approved protocols.
 - b. The CRC unit provides short term storage only (up to six (6) months). The CRC unit does not provide long term storage of samples.
 - c. All freezers and refrigerators are regularly inspected and kept clean and free of obstructions. No boxes or supplies may be placed on top of the units.
 - d. All specimens requiring freezer storage **must** be placed in a box with a lid, appropriately labeled and stored in an upright position by the research team or supported CRC staff. Appropriate labelling for the box includes the Principal Investigator's last name, IRB# and contact phone number or extension. Samples may **NOT** be placed in any bags when in a freezer.
 - e. No food, beverages, or medications can be stored in research specimen refrigerator or freezers.
2. Equipment Monitoring
 - a. The CRC research nursing staff are responsible for monitoring the status of the freezers and refrigerators.
 - b. Freezers will be electronically monitored through the Facilities Department of Penn State Health Milton S. Hershey Medical Center.
 - c. Daily temperature readings are manually documented Monday through Friday on the CRC Refrigerator/Freezer temperature logs, except for holidays and unit closure.
 - d. Temperature logs are scanned yearly to their respective folders under the CTSI folder on the secure hershey.med.net network.

3. Maintenance

- a. Penn State Health Facilities and Clinical Engineering are responsible for inspection and condition of all freezers and cold centrifuges on a yearly basis to ensure safe operation. Inspection labels are updated yearly on each unit inspected.

RELATED POLICIES AND REFERENCES

Cleaning of Non-Critical Equipment in Patient Care Areas (IV-12)

Freezer Safety Standards for Penn State College of Medicine (PS05SPM)

Temperature Monitoring of Refrigerators, Freezers and Point of Care Testing (A-54 HAM)

APPROVALS

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