University Hospitals Clinical Research Center

UH CLINICAL RESEARCH CENTER
11100 Euclid Avenue, Lakeside 1400
Cleveland, Ohio 44106
ClinicalResearch@UHhospitals.org

UH Researcher Cold Storage Reference

Cold storage units across the system can vary by location, type of emergency back-up power, and allowable contents. It is important to be aware of the operation and appropriate usage of units related to your research.

Below are applicable policies, key points, definitions and best practices regarding cold storage at UH; curated to enhance researcher awareness and safety, mitigate potential research compliance risks, and offer points to consider when anticipating a shipment to IDS or submitting an IDS Exception Request.

Definitions (UH System Policy MM-44):

- **Freezer** - A temperature-controlled environment between -25ºC and -10ºC (-13ºF and 14ºF).
- **Refrigerator** - A temperature-controlled environment between 2ºC and 8ºC (36ºF and 46ºF).
- **Controlled Room Temperature** - Usual and customary working environment of 20ºC to 25ºC (68ºF to 77ºF).
- **Package Insert** – A manufacturer's medication reference that may define storage requirements.
- **Isensix Guardian** - A proprietary tool assisting in monitoring and notification of staff that temperatures or other measures in a given refrigerator/freezer, room, incubator or area are within or outside of its intended range or set parameter. (UH System Policy CP-100)

<table>
<tr><th colspan="5">Cold Storage Classification Tiers – Refrigerators/Freezers (UH System Policy CP-144)</th></tr>
<tr><th>Storage Unit Tier</th><th>Grade</th><th>Emergency Back-up</th><th>Contents</th><th>Exception</th></tr>
<tr><td>Level 1 – High Risk
• All Liquid Nitrogen Cooled Units
• Non-Public Areas
• Controlled Access Using a UH ID Card Access System
• Remote Min/Max Monitoring</td><td>Medical</td><td>Generator</td><td>• Stem Cells
• IVF Tissue (embryos, eggs, and sperm)
Not Research-Based:
• Implants
• Bone Implants
• Human Tissue</td><td>Level 1 and 2 Contents May Comingle – Cold Storage Unit Will Follow Level 1 Requirements</td></tr>
<tr><td>Level 2 – Moderate Risk
• Medical Center
• Level I or II Ambulatory Health Center
• Remote Min/Max Monitoring</td><td rowspan="2">Medical</td><td>Generator</td><td rowspan="2">• Blood Products
• Specimens Used For Research
• Infusion Supplies
• Vaccines
• Medications
• Patient Breast Milk</td><td rowspan="2">Level 1 and 2 Contents May Comingle – Cold Storage Unit Will Follow Level 1 Requirements</td></tr>
<tr><td>Level 2 – Moderate Risk
• Level III or IV Ambulatory Health Center
• Remote Min/Max Monitoring</td><td>Battery</td></tr>
<tr><td>Level 3 – Low Risk</td><td>Residential</td><td>Not Required</td><td>• Food Refrigerators
• Food Freezers</td><td>Contents May Never Comingle with the contents of Level 1 or 2 Units</td></tr>
<tr><td colspan="5">Investigational Drug Services: Isensix Guardian Monitoring (UH System Policy CP-100), Main Hospital Generator, Continuous Temperature Readings (every five minutes)</td></tr>
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Best Practices

- Check your study protocol/manual for temperature and temperature monitoring requirements.
- Verify that you have access to the cold storage unit you need for your study.
- When adding or relocating a cold storage unit, confirm with building services that the circuit the unit would be plugged into can handle the new electrical load (existing wiring may not have the capacity, exceeding electrical capacity may trip a fuse and cut off power to everything plugged into that circuit, etc.) a new dedicated line may need to be installed.
- If your cold storage unit requires being plugged into a certain outlet or circuit, ensure that it is and verify that other things that should not be are not.
- Create a cold storage emergency plan (UH System Policy CP-144).
- In the event of a temperature deviation, separate and quarantine (bag or box) items and check your protocol for sponsor notification requirements. Label bagged or boxed quarantined items as such to help avoid inadvertent use until it has been approved for use by the sponsor.
- Ensure there is enough space in the unit for all immediate and future storage needs.
- Plan ahead for temperature logging coverage if the primary or secondary contact takes a vacation or otherwise becomes unavailable.
- If there are issues such as missed temperature logging, confirm the storage and monitoring documentation requirements and provide re-education, as necessary. Save process improvement and retraining documentation and file in the research record.
- DO NOT place blood tubes or any other specimen collection, vaccines, human tissue, etc. in a Level 3 Cold Storage Unit.
- DO NOT place food items in a Level 1 or 2 Cold Storage Unit.
- If there is frequent activity and opening/closing of the cold storage door creating an opportunity for a temperature excursion, consider a different cold storage unit for primary use.
- If anything out of the ordinary occurs such as a research blood tube found in a Level 3 cold storage unit, remember to report it and document it! Remember the who, what, when, where, why, and how's of good documentation practices (ALCOA+C).
- DO NOT store research samples labeled with patient identifiers. If samples need to be picked up and transferred off UH grounds to CWRU or picked up by a non-UH employee that is also **non**-research credentialed, you are at risk of a patient privacy breach. Label tubes with study IDs. If a non-UH employee will be on UH grounds around patients/patient information, they must first complete the UH Research Credentialing process and have a current certification on file.
- Know where the maintenance and calibration records are stored and how you can access them or file copies of those records in a central binder.

A Note about Study Medications

Per UH Policy, all investigational product must be stored in Investigational Drug Services (IDS). Refer to the Investigator Manual for IRB Submission, System Policy MM-4 – Investigational Products, IDS webpage and policies, and UH Clinical Research SOPs. In the event an IDS exception has been granted and Investigational Product is being stored in a departmental unit, consider the following:

- If you are aware IDS will be receiving a shipment soon, inform the IDS team of the anticipated study order delivery date to allow for advance cold storage logistical planning.
- Consider splitting study medications between different units. If one unit becomes disabled, it may not disrupt enrollment because you will still have an immediately usable supply in the functioning unit.
- Before you take a study medication out of the unit and administer or dispense it to a patient, double check that the item hasn't had an unreported temperature excursion requiring quarantine procedures
- When medication storage requirements are not found in a study protocol refer to the package insert.
- What is the storage and accountability plan for returned containers and unused drug? Does the sponsor require that you to keep used or partially used vials or containers and what are the labeling and storage requirements for that?