

**UC Riverside, School of Medicine Policies and Procedures****Policy Title: Refrigerator / Freezer Temperature Controls****Policy Number: 950-03-007**

<b>Responsible Officer:</b>	Clinical Manager
<b>Responsible Office:</b>	Clinic Operations
<b>Origination Date:</b>	2/26/2016
<b>Date of Revision:</b>	5/9/2019; 06/12/2023; 09/18/2023
<b>Scope:</b>	UCR SOM Owned and Managed Faculty Practice Sites

**I. Policy Summary**

To set forth the requirements to monitor and record the temperature of refrigerators / freezers utilized for the storage of medications that require refrigeration, according to manufacturer's instructions, to ensure proper maintenance and efficacy of medications.

**II. Policy Text**

Medication or drug refrigerators / freezers should be kept solely for the purpose of storing medications that require refrigeration according to manufacturer's instructions and/or CDC guidelines.

Frozen Vaccine storage between -58 degree F to 5 degree F or -50 degree C to -15 degree C.<sup>1</sup>

Refrigerated vaccine storage between 36 degree F to 46 degree F or 2 degree C to 8 degree C.<sup>2</sup>

**IV. Responsibilities**

Designated Clinical Staff

**V. Procedures**

**A.** An accurately calibrated thermometer must be kept in each refrigerator and freezer at all times.

1. Thermometer is calibrated yearly, or as needed, by the current approved calibration vendor

**B.** The temperature of any refrigerator / freezer that contains drugs must be logged twice daily to ensure proper temperature control. Daily Refrigerator / freezer Temperature Log (Attachment A) will contain:

1. Date
2. Morning Temperature
3. Low-High Range as indicated on the thermometer
4. Staff Initials
5. End of day Temperature
6. Low-High Range as indicated on the thermometer
7. Staff Initials

<sup>1</sup> CDC: Vaccine storage and handling, Temperature monitoring best practices for frozen vaccine, 2018 February (cited 2023, August 1), available from: <https://www.cdc.gov/vaccines/hcp/admin/storage/index.html>

<sup>2</sup> CDC: Vaccine storage and handling, Temperature monitoring best practices for refrigerated vaccine, 2018 February (cited 2023, August 1), available from: <https://www.cdc.gov/vaccines/hcp/admin/storage/index.html>

- C. If the clinic has an electronic temperature log, it is the responsibility of the clinic manager is to verify the electronic log accuracy compared to the manual log. Once the accuracy of the electronic log is verified, it is the responsibility of the manager, upon reopening the office after the clinic closure, to review the electronic temperature log to ensure that temperatures were within range. When an electronic temperature log is present, an electronic alert system is required to notify the clinic manager when the temperatures falls out of range.
- D. If temperatures register above or below the appropriate range, all stored items shall be removed, the viability of the items stored shall be determined and non-viable items shall be handled as directed by supervisor or state/local health department. A Vaccine Storage Troubleshooting Record (Attachment B) will be completed for each incident. This Record will include:
1. Date and Time of event
  2. Temperature at time of discovery (Low-High)
  3. Room Temperature at time of event
  4. Name and Title of person completing report
- E. In addition, the Vaccine Storage Troubleshooting Record will include a general description of the event including:
1. Length of time between the last acceptable temperature and the event.
  2. Inventory of medications (including Lot Numbers) being stored in the affected unit.
  3. List of other items stored in the affected unit the time of the event.
- F. Documentation of the following actions taken:
1. Date when the affected medications were placed in proper storage conditions.
  2. List of all persons contacted regarding the event (supervisor, manufacture(s), state/local health department.
  3. Steps taken to prevent recurrence of event.
  4. Final disposition of affected medications.
- G. All events involving out of range refrigerator / freezer temperatures when medications are stored and affected will be reported to the Compliance Office. Clinic manager will file an incident report.
- H. Daily Refrigerator / freezer Temperature Logs and Vaccine Storage Troubleshooting Records will be maintained in accordance with Record Retention Policy and Procedures.

## VI. Forms/Attachments

- Attachment A – Refrigerator / freezer Temperature Log Sheet  
Attachment B – Vaccine Storage Troubleshooting Record

**APPROVALS:**

COMPLIANCE COMMITTEE (08/22/2023)

DocuSigned by:

*Paul Hackman*

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PAUL HACKMAN, J.D., L.L.M.  
CHIEF COMPLIANCE AND PRIVACY OFFICER,  
SCHOOL OF MEDICINE

DATE

DocuSigned by:

*Deborah Deas*

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DEBORAH DEAS, M.D., M.P.H  
VICE CHANCELLOR, HEALTH SCIENCES  
DEAN, SCHOOL OF MEDICINE

DATE

**Attachment A**  
**Daily Refrigerator / Freezer Temperature Log**

**Instructions:** This log will be maintained for each refrigerator / freezer in the facility. Each morning, at the beginning of shift, please document the current temperature as well as the temperature range and clear the memory of the thermometer. Each night, at the end of the shift, please document the current temperature as well as the temperature range and clear the memory of the thermometer. The refrigerator temperature should remain between 36-46 degree Fahrenheit ranges. The Freezer range should be -58 to 5 degree Fahrenheit ranges. If the temperature falls below or above that range please notify the supervisor and document on the back of this form.

Month/Year: \_\_\_\_\_ Location/Contents Description: \_\_\_\_\_

\*R = Refrigerator | \*F = Freezer

Morning Temperature		Low-High Range		Time	Staff Initials	End of Day Temperature		Low-High Range		Time	Staff Initials
R	F	R	F			R	F	R	F		

Supervisor Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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**Attachment B****Vaccine Storage Troubleshooting Record**Reference Link: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Take action if temp is out of range. The refrigerator temperature should remain between 36-46 degree Fahrenheit ranges. The Freezer range should be -58 to 5 degree Fahrenheit ranges.

1. Label exposed vaccine "do not use" and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out of range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify you vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the Action Taken and Results.

Practice Location: \_\_\_\_\_

 Refrigerator Freezer

Person Completing Report: Name: _____ Title: _____ Date: _____	Date and Time of Event: Date: _____ Time: _____	Storage Unit Temperature Temperature When Discovered: _____ Minimum Temp: _____ Maximum Temp: _____
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**Description of Event** (If multiple related events occurred, list each date, time, and length of time out of storage):

Please include in your description:

- General Description
- Estimated length of time between event and last documented acceptable temperature reading
- Inventory of affected vaccines, including lot #'s
- What else was in the storage unit at the time of event?
- Any Problems Prior to Event?

**Action Taken:**

Please include in your description:

- When were the affected vaccines placed in proper storage conditions?
- Who was contacted regarding the incident (supervisor, state/local health dept, manufacturer - list all)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

**Results:**

Please include in your description:

- What happened to the vaccine?
- Was it able to be used?
- If not, was it returned to the distributor?