

January 30, 2013

RESEARCH STANDARD OPERATING PROCEDURES (SOP) Investigational Drug Storage and Access

1. **PURPOSE:** To establish a procedure for proper storage, temperature monitoring, and access for all medication dispensed by the Research Pharmacy.

2. **POLICY:** It is STVHCS policy that the Research Pharmacy is responsible for maintaining proper storage conditions for investigational drugs. Only the ACOS for Research and the Chief of Pharmacy have the authority to authorize access to the research pharmacy. Only the Police Service has the authority to assign and/or delete electronic card reader access and pin numbers to the research pharmacy as well as the ability to perform audits on the door access as necessary to ensure security of the research pharmacy.

3. **ACTION:**

a. **Procedures:**

(1) **Storage:**

(a) All medications will be stored according to the manufacturers recommendations either located in the study protocol or the package insert.

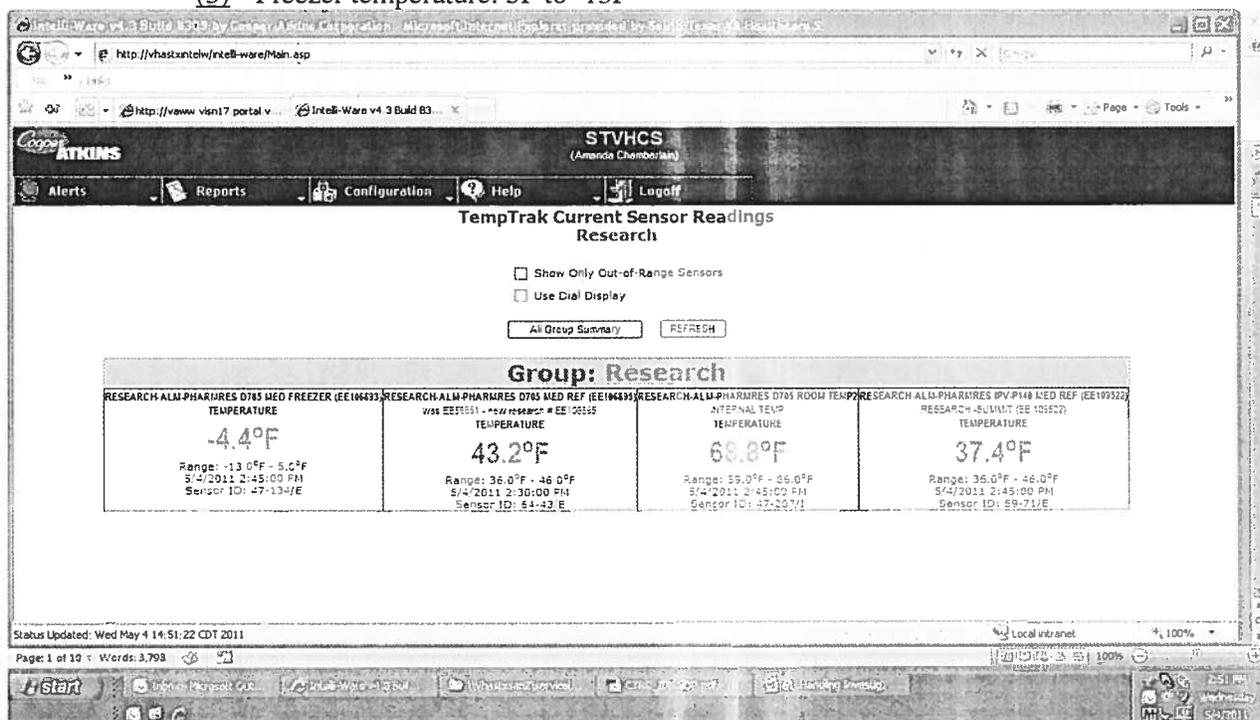
(b) All medications maintained in the research pharmacy are continuously monitored by the TempTrak Monitoring System as detailed in *Pharmacy Policy Memorandum TempTrak Remote Temperature Monitoring Policy*.

(c) The TempTrak Monitoring System has been programmed with the following temperature ranges:

(1) Room temperature: 59F to 86F

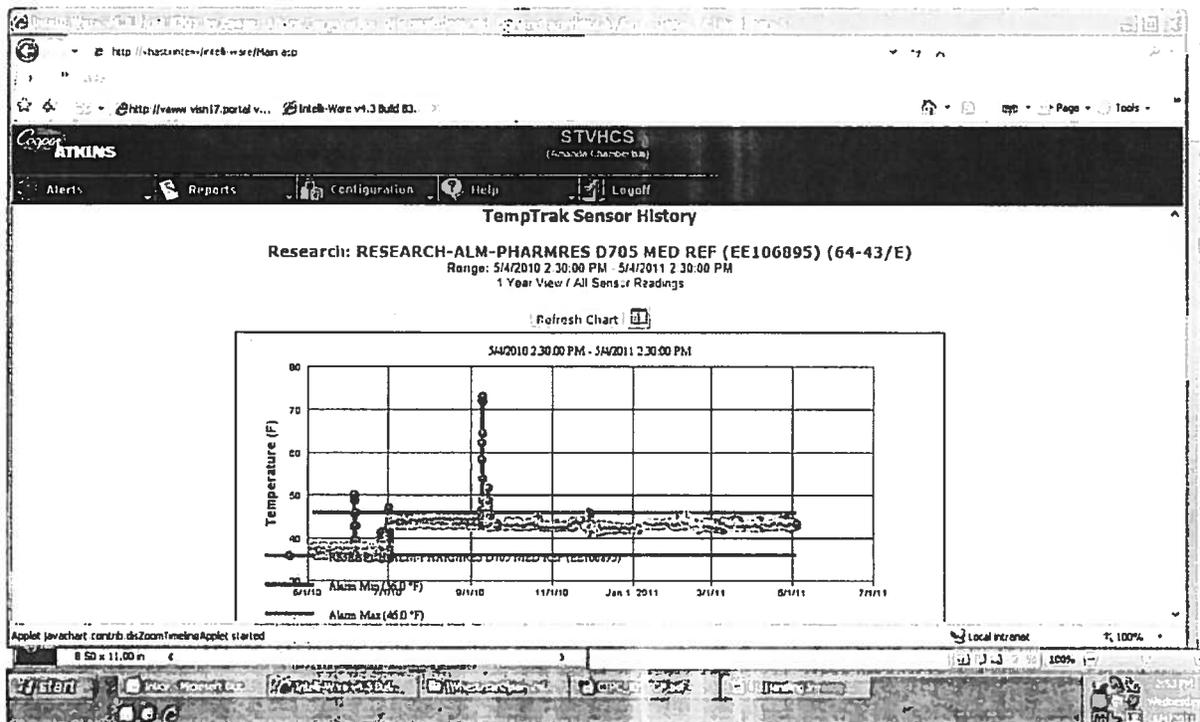
(2) Refrigerated temperature: 36F to 46F

(3) Freezer temperature: 5F to -13F



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- (d) The TempTrak Monitoring System records temperature readings from monitored systems every fifteen minutes.
- (e) The system will notify the research pharmacist directly both via email and pager to report any temperature deviations.
- (f) Temperature readings for TempTrak monitored systems, up to 1 year, will be printed out when requested by study monitors.



(2) Access

- (a) Business hours for the Research Pharmacy are 08:00 to 16:30, Monday through Friday. The research pharmacy is equipped with controlled access via an electronic card reader and pin number unique to each individual granted access. Access to the research pharmacy is limited only to research pharmacy personnel.
- (b) The main entry door to the research pharmacy will be unlocked by an authorized pharmacist upon arrival. Keys to the dead bolt of the research pharmacy will be provided only to the ACOS for Research, research pharmacist, relief research pharmacist and other authorized pharmacist.
- (c) The main door will remain unlocked until 16:30 PM or whenever the last pharmacist leaves for the day. After that time, the main door to the research pharmacy be dead bolted or otherwise locked.
- (d) On the last day of employment with research or pharmacy service, the ACOS for Research or the Chief of Pharmacy will authorize the police service to delete personnel access codes to the research pharmacy.

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4. **REFERENCES:** VHA Handbook 1108.04 Investigational Drugs and Supplies, Research SOP Handling of Investigational Drugs and Devices, TempTrak Remote Temperature Monitoring Policy.

5. **RESPONSIBILITY:** ACOS for Research and Development (151) and Chief, Pharmacy Service (119)

6. **RESCISSIONS:** Research Service SOP for Investigational Drug Storage and Access dated May 13,2011

7. **RECERTIFICATION:** May 2016


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