

Standard Operating Procedures for Clinical Research at USF Health CRC			
	TEMPERATURE MONITORING		
SOP#: 605	Effective Date: 01/01/2015	Version: 1.0	Page: Page 1 of 3

PURPOSE: The purpose of this SOP is to describe the procedures to be followed for temperature monitoring of investigational products and biological substances stored in the CRC for research studies. The following procedure must be followed in order to avoid the risk that unstable.

SCOPE: This SOP applies to Investigators and research personnel who use the CRC to store and monitor investigational products, vaccines and specimens in the CRC.

RESPONSIBILITIES: The CRC Manager and designated study personnel are responsible for temperature monitoring of study medications stored in the CRC and for reporting any excursions immediately to the appropriate PI and study team who will determine if the protocol requires sponsor notification.

DEFINITIONS:

Investigational Products (IP): A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

National Institute of Standards and Technology (NIST): A non-regulatory federal agency within the U.S Department of Commerce. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

PROCEDURE:

1. The CRC Manager, or assigned research personnel, will perform daily temperature monitoring during normal business hours Monday- Friday for the following storage locations in the CRC.
 - Thermo Scientific Minus 80 freezer
 - Kenmore refrigerator 2-8 degrees Celsius or 36-46 degrees Fahrenheit
 - Frigidaire refrigerator 2-8 degrees Celsius or 36-46 degrees Fahrenheit
 - Thermo Scientific minus 20 degrees Celsius freezer or minus 4 degrees Fahrenheit
 - Secured cabinets for ambient IP 15-25 degrees Celsius or 59-77 degrees Fahrenheit
2. When the clinic is closed on weekends, holidays or during mandatory evacuations, the staff will read the minimum and maximum temperatures on the next business day morning and record the results on the Temperature Log.

Standard Operating Procedures for Clinical Research at USF Health CRC			
	TEMPERATURE MONITORING		
SOP#: 605	Effective Date:01/01/2015	Version: 1.0	Page: Page 2 of 3

PROCEDURE (cont.):

3. Traceable Refrigerator/ Freezer Thermometers will be affixed to the outside of all of the refrigerators/freezers noted above.
 - 3.1. The traceable thermometers will be calibrated and re-certified at least once annually using instruments traceable to NIST.
 - 3.2. The thermometer sensor that contains a vial of ethylene glycol will be placed in a location that is representative of the average temperature of the unit, and away from a source of incoming refrigerated air or near the freezer to avoid misrepresentative temperature readings.
 - 3.3. Ethylene glycol in the vial that contains the temperature sensor is mildly toxic. If the vial is broken and ethylene glycol leaks, research personnel will clean the spill using disposable paper towels and water. Proper personal protection, such as disposable gloves, should be employed.
4. Ambient drug storage will be monitored by a calibrated thermometer provided by the sponsor. If not provided, it may be measured by the same Thermometer referenced above or may be measured by wall thermostat located in the same room where the study drug is stored.
5. Temperatures will be documented daily on a separate temperature log for each storage location.
 - 5.1. Each refrigerator/freezer is assigned a unique letter and with the same thermometer mounted on the outside of each designated refrigerator or freezer.
 - 5.2. Minimum and maximum temperatures for medication refrigerators shall be read and manually recorded on a temperature log once daily and the memory reset each time.
 - 5.3. A temperature log will be kept outside of the each refrigerator/ freezer door and will contain the following documentation clearly written in ink:
 - Location identification
 - Date
 - Time
 - Results
 - Initials of person responsible
 - Comments if necessary
6. Historical temperature logs for all refrigerators/freezers will be maintained in a central location in the CRC.
 - 6.1. The traceable thermometers will be calibrated and re-certified at least once annually using instruments validated against NIST certified device. Refer to SOP #604: *Equipment Maintenance and Calibration*.

Standard Operating Procedures for Clinical Research at USF Health CRC			
	TEMPERATURE MONITORING		
SOP#: 605	Effective Date: 01/01/2015	Version: 1.0	Page: Page 3 of 3

7. The CRC Manager or research designee will report any temperature excursions immediately to the study PI and research coordinator. He/she will inform all the trial sponsors whose supplies are stored in that are to request confirmation that the product is fit for continued use. This should be in writing via email with a copy of the relevant graph.
8. Study staff will follow any study specific procedures for reporting temperature excursions provided by the sponsor detailed in the pharmacy clinical trial file.
9. If the temperature fails to return within normal limits, the CRC manager or research personnel may move the supplies to an alternative area in the CRC, Byrd Institute or Eye Institute and notify the sponsor immediately.
10. Research personnel will document all actions taken in a file note and place a copy in the files of each study affected.
11. In the event of a clinic power failure, all refrigerators and freezers will switch to the emergency power generators.

ICH GCP E6, Section 4.6 Investigational Product(s)			
Approval Date	Effective Date	Review/Revision Date	
REFERENCES:	01/01/2015		
RELATED POLICIES:	SOP #103: Responsibilities of the Research Team		
APPENDICES:	Appendix LL: Temperature Log		
REVISION HISTORY: Keep a running history of all revision dates.			