QA-605– Temperature Monitoring

1. **PURPOSE:**
   The purpose of this SOP is to describe the procedures to be followed for temperature monitoring of Investigational Products (IP) and biological substances stored at UTRGV for research.

2. **SCOPE:**
   This SOP applies to Investigators and research personnel at UTRGV who store and monitor IP, vaccines, specimens or anything else related to research that is temperature controlled.

   The Investigational Pharmacy Temperature Monitoring SOP will supersede this SOP for test articles being stored in the investigational pharmacy. The Biobanking Temperature Monitoring SOP will supersede this SOP for specimens being stored in the biobank.

3. **RESPONSIBLE INDIVIDUALS:** The Principal Investigator (PI), Research Manager and designated study personnel are responsible for temperature monitoring any temperature-controlled research materials stored at UTRGV and for reporting any excursions immediately.

4. **RELATED TERMS AND DEFINITIONS:**
   Investigational Products (IP)
   National Institute of Standards and Technology (NIST)
   Note to File (NTF)
   Personal Protection Equipment (PPE)

   Please reference the Standard Operating Procedures Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT:**
   Temperature monitoring logs are required to be maintained for all temperature-controlled research materials.

6. PROCEDURES:

6.1 Assigned research personnel will perform daily temperature monitoring during normal business hours Monday through Friday at any UTRGV location where research specimens or IP is being stored.

6.2 If the area 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.

6.3 Traceable Refrigerator/ Freezer Thermometers will be affixed to the outside of all refrigerators/freezers.

- The traceable thermometers will be calibrated and re-certified at least once annually using instruments traceable to National Institute of Standards and Technology (NIST).
- A 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.
- The ethylene glycol in 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 PPE, such as disposable gloves, should be employed.

6.4 Ambient 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 or specimens are stored.

6.5 <u>Manual Temperature Monitoring</u>

Temperatures will be documented daily on a separate temperature log for each storage location.

- Each refrigerator/freezer must be assigned a unique identifier.
- The thermometer mounted on the outside of each designated refrigerator or freezer must be assigned a corresponding identifier.
- Minimum and maximum temperatures for refrigerator shall be read and manually recorded on a temperature log once daily and the memory reset each time.
- A temperature log will be kept outside of 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

6.6 Automatic Temperature Monitoring

If the sponsor or institution is willing to provide a fully automated temperature monitoring system, that is acceptable as long as the following criteria are met:

- The automated system is equipped with an alarm system for temperature excursions.
- There is a back-up plan in place for automated system failure.
- The reports from the automated system are available in such a way that researchers can access the temperature logs at any time.
- The reports from the automated system are either searchable for any desired time period/never deleted or fully downloadable/printable.
- If the reports are downloadable or printable, they must be done so once a week and filed in a way that is accessible to the researchers who need them.

6.7 Historical temperature logs for all refrigerators/freezers will be maintained in a central location.

6.8 The research manager or department designee will report any temperature excursions immediately to the study PI and research coordinator.

6.9 The PI or study coordinator will inform the study sponsor (if applicable) to request confirmation that the product is fit for continued use. This should be in writing via email with a copy of the relevant temperature data.

6.10 Study staff will follow any study specific procedures for reporting temperature excursions detailed in the protocol and/or other manuals or guidance documents.

6.11 If the temperature fails to return within normal limits, the research manager or research personnel may move the supplies to an alternative area and notify the sponsor immediately.

- If the study is investigator initiated, sequester drug and notify the PI immediately.

6.12 Research personnel will document all actions taken in a Note to File and place a copy in the files of each study affected.

6.13 In the event of a clinic power failure, all refrigerators and freezers will switch to emergency power generators.

7 REFERENCES:

- ICH GCP E6. Section 4.6 Investigational Product(s)
- UTRGV DM-502
- UTRGV QA-604

8 FORMS OR ATTACHMENTS:

None