IASIS HEALTHCARE	**POLICY TITLE**: Temperature Monitoring
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 2.0.1 ☐ Addendum to Corporate Policy ☐ Form Available In I-REPP System
SECTION (as applicable): Clinical Research	**POLICY OWNER**: Tedd Adair, Vice President of Clinical Operations and Chief Clinical Officer
ORIGINATION DATE: 01/01/2011	**FINAL APPROVAL DATE**: April 30, 2016

POLICY:

When monitoring temperature in investigational product (IP) storage areas, to protect the safety of research participants and data validity by ensuring that investigational products are stored according to manufacturer's requirements with regard to temperature.

SCOPE:

This procedure applies to all study investigational products stored in any IASIS facility.

DEFINITIONS:

Not Applicable

PROCEDURE:

Instrument:

- The instrument used to measure temperature in IP storage areas is NIST calibrated.
- The certificate of NIST calibration is kept on file in the office Quality Assurance binder.
- The instrument is considered study-related equipment and is maintained and calibrated according to relevant Guideline's.
- The instrument is located as close as possible to the IP being stored.

Monitoring temperature:

- The *Temperature Monitoring Log* and *Stored IP & Storage Requirements Log* (attached) are used to record IP stored in the area, storage requirements, temperature ranges, and other related information as indicated. If there are no storage requirements for the IP, "none" is written in the "temperature requirement" columns for that product.

- In room temperature storage areas, high and low temperature readings since the previous assessment are recorded every business day.
- In refrigerated storage areas, high and low temperature readings since the previous assessment are recorded every business day.
- If the instrument used to measure highs and lows does not record the date and time of the highs and lows, this section of the form is left blank. However, it is essential that the instruments be "cleared" after each daily assessment to ensure that the highs and lows recorded reflect values that occurred since the previous day's assessment.
- At the time of the daily assessment, the high and low readings are compared against the storage requirements of the IP stored in that area during the given time interval to determine whether temperature ranges met requirements.

Action:

- If the temperature deviates from the storage requirements of the IP stored in the area during the time interval from the previous assessment to the current assessment, the study coordinator for the relevant studies is contacted immediately.
- The study coordinator puts on hold the administration/use of relevant IP and contacts the sponsor/manufacturer for instructions.
- The study coordinator records and follows these instructions and documents the actions taken where indicated on the *IP Storage Deviation Form* (attached) to demonstrate that the instructions were followed.

Responsibility:

- The study coordinator is responsible for ensuring that all information is recorded on the "temperature log" every business day and for ensuring that the "stored drugs log" is kept current for the relevant studies he/she is coordinating.
- The person recording temperature ranges is responsible for notifying the study coordinator if the ranges deviate from storage requirements.

The study coordinator is responsible for putting on hold the administration/use of relevant IP and following sponsor/manufacturer's instructions regarding actions to take in response to the IP storage deviation.

FORM REFERENCES:

Not Applicable

REFERENCES:

Food and Drug Administration Title 21 Part 312

TEMPERATURE MONITORING LOG

Location of measurement instrument: ☐ Room temperature IP storage area
☐ Refrigerator for IP storage

Assessment Date & Time	Monitor's Initials	High Temperature	Low Temperature	Meet Requirements?
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***
___/___/___ __ __:__ __	_______	______℃ or °F ___/___/___ __ __:__ __	______℃ or °F ___/___/___ __ __:__ __	☐ Yes ☐ No***

***Notify study coordinator ASAP if temperature ranges deviate from the storage requirements of the IP stored in the area during the time interval from the previous assessment to the current assessment; study coordinator contacts sponsor/manufacturer ASAP for instructions and documents instructions and actions.

STORED INVESTIGATIONAL PRODUCT
& STORAGE REQUIREMENTS LOG

Location: ☐ Room temperature IP storage area
☐ Refrigerator for IP storage

Protocol #	Study coordinator	Date IP in Storage Area	Date IP out of Storage Area	Temperature Requirement

INVESTIGATIONAL PRODUCT STORAGE DEVIATION FORM

DEVIATION

Protocol #: _____

Study Coordinator: _____

Description of Deviation: _____

_____

_____

INSTRUCTIONS

Date & Time of Sponsor/Manufacturer Contact: ____/____/____ ___ ___:___ ___

Name of Person Giving Instructions: _____

Title of Person Giving Instructions: _____

Instructions: _____

_____

_____

ACTIONS

Actions Taken & Dates: _____

_____

_____

_____

_____

Review/Revised Date:	Title:	Description of Change or Location of Change in Document:
04/30/2016	Tedd Adair, VP Clinical Operations & CCO	Scheduled review; converted to ISO Policy Template