**From:** OC GCP Questions
**To:** [redacted]
**Subject:** monitoring IP storage temperature
**Date:** Thursday, October 30, 2014 2:52:30 PM

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Good afternoon:

The manufacturer/sponsor of the investigational product generally determines (via controlled studies) the appropriate storage conditions for the investigational product and when and how often temperature monitoring of study drug should occur. The study protocol usually states the conditions/controls under which the investigational product should be stored in an effort to preserve the quality, strength, purity and identity of the product. If excursions are permissible, this should be described in the study protocol.

I can point you to the ICH E6: Good Clinical Practice: Consolidated Guidance (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf ), which is official guidance recognized by FDA, does address storage temperatures in the following sections

5.13.2 The sponsor should determine, for the investigational product(s), acceptable storage temperatures, storage conditions (e.g., protection from light),
storage times, reconstitution fluids and procedures, and devices for product infusion, if any. The sponsor should inform all involved parties (e.g., monitors,
investigators, pharmacists, storage managers) of these determinations.

5.14.3 The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of
investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

FDA regulations do not specifically address how often IP temperatures should be checked. When the regulations are silent, sites and institutions are free to develop their own standard operating procedures to address a specific situation or issue.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA



-----Original Message-----
From: [redacted]
Sent: Thursday, October 30, 2014 2:17 PM
To: OC GCP Questions
Subject: monitoring IP storage temperature

This is a question regarding the monitoring of Investigation Product (IP) storage temperature by an investigator site on a phase 3 study prior to being dispensed to children and adolescents.

The label requires the IP to be stored at 59-77 degrees Fahrenheit.

The temperature inside the locked metal drawer where the IP is stored is not assessed. The minimum-maximum digital temperature monitoring device, used to record the IP storage temperature, is located on a cabinet on another wall approx. 10 feet away from where the IP is stored inside the locked metal drawer.

Is the current method sufficent to document IP temperature monitoring or should the actual temperature be assessed inside the locked metal drawer?

Thank you.