From: OC GCP Questions
To: [redacted]
Subject: Investigational Product Temperature Monitoring
Date: Saturday, January 31, 2015 10:20:38 AM

Good morning:

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)).

Again the temperature storage requirements of the investigational product (IP) should be outlined in the protocol. Generally when temperature storage and controls are unknown, it is best to ask the study sponsor or the FDA review division that is overseeing your study.

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

From: [redacted]
Sent: Thursday, January 29, 2015 3:11 PM
To: OC GCP Questions
Subject: Investigational Product Temperature Monitoring

Good afternoon,

We are the coordinating center for a multi-site study (5 sites total) for a Phase II study. The Principal Investigator here holds the IND and is considered to be the "sponsor". Most of the sites will lock up the study medication in the site PIs office (our monitor is checking the location at the Site Initiation Visits). The study medication is to be stored at 50° to 86° Fahrenheit. Because this is considered an "ambient" temperature range, do we need to ask the sites to maintain a temperature log? If so, is the temperature to be recorded on weekends when staff would not normally be on site?

Thank you in advance for considering this question.

Kind regards,
[redacted]