From: OC GCP Questions
To: [redacted]
Subject: Biological samples in clinical trials
Date: Thursday, March 09, 2017 10:11:00 AM
Attachments: [redacted]

Good morning –

I can point you to the ICH E6: Good Clinical Practice: Consolidated Guidance (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)).

The manufacturer/sponsor of the investigational product generally determines (via controlled studies) the appropriate storage conditions for the investigational product. 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.

FDA's regulations on records about disposition of the investigational drug state, "An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59."

312.59 states -- The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug in accordance with 312.57.

312.61 states -- Control of the investigational drug.
An investigator shall administer the drug only to subjects under the investigator's personal supervision or under the supervision of a subinvestigator responsible to the investigator. The investigator shall not supply the investigational drug to any person not authorized under this part to receive it.

312.69 states -- Handling of controlled substances.
If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

As you can see, the regulations are very general to allow sponsors and study sites the necessary flexibility to account for the supplies of investigational product that were received, administered,

returned, and the final disposition (e.g., destruction) of any unused investigational articles. Please note that the records maintained at the site need to be adequate to show "disposition of the drug, including dates, quantity, and use by subjects.

As far as I am aware, there are not any guidances as to how specimens for clinical trials should be maintained or how long they should be stored. In general, sponsors are responsible for any and all procedures involved in the collection, maintenance, distribution and destruction of specimens. Any destruction/disposal of specimens would be subject to applicable state or local laws for disposal of biological waste.

I hope this information is helpful.

Kind regards,

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

From: [redacted]
Sent: Thursday, March 09, 2017 8:48 AM
To: OC GCP Questions
Subject: Biological samples in clinical trials

Dear all,

I would like to know if there is a guidance or reference for biological sample handling in clinical trials encompassing for example (storage, confidentiality, destruction, future use among others).

Best Regards,
[redacted]