From: OC GCP Questions
To: [redacted]
Subject: Study site closing procedures questions???
Date: Wednesday, September 20, 2017 8:03:00 AM
Attachments: [redacted]

Good morning –

FDA regulations on storage of study documents are not that specific. In general, FDA expects that reasonable steps would be taken to maintain control of the study records, the privacy and confidentiality of study subjects, and the confidentiality, completeness and accuracy of study records.

Those responsible for clinical trial data (records) should have a full understanding of the issues, obligations, and requirements related to data management and ownership. The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial.

Record retention for drug and biologic studies, 21 CFR 312.62(c) states: "Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified."

Additionally, the following is the provision in § 312.57(c): A sponsor shall retain the records and reports required by this part for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.

As you will note, the retention period is dependent on whether the data will be used to support a marketing application with FDA. The sponsor is usually the only party totally knowledgeable about the status of its investigational product (e.g., whether it has been approved for marketing, whether the sponsor no longer intends to seek marketing approval, etc.). Therefore, it is best to check with the study sponsor regarding the status of the investigational product and the need to retain the study records.

Kind regards,

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From: [redacted]
Sent: Tuesday, September 19, 2017 1:11 PM
To: OC GCP Questions
Subject: Study site closing procedures questions???

Hello
I am looking for information on how to close a clinical research study site.

I am the Exec Dir of a Phase II, III and IV research study site that is closing operations.
We are working with Study Sponsors to close according to individual study protocols and we are transferring some studies to an affiliate of ours.

It looks like we will be able to manage all of the study subjects without any problems in accordance with the study sponsors and the IRB.

My big concern is how do I handle records storage after we go out of business?
There won't be any staff or funds.

Any other information or resources you can provide will be helpful and greatly appreciated.

Thank you
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