From: OC GCP Questions
To: [redacted]
Subject: GCP Questions - investigator record retention requirements
Date: Thursday, July 24, 2014 1:50:24 PM

Good afternoon [redacted] –

This is our standard statement for record retention for FDA-regulated trials.

The relevant US FDA regulations on record retention for clinical trials are as follows:

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."

For device studies, 21 CFR 812.140(d) states: "Retention period. An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol."

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. You should check with each of the study sponsors before discarding any study files.

If investigational records are transferred off-site to a third party (i.e. Contract Research Organization (CRO),sponsor etc.), the sponsor and FDA should be notified by the associated clinical investigator in the form of a final report. A sponsor of an investigational drug study shall retain the records and reports for two years after an approved marketing application or until two years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified [21 CFR 312.57(c)].

If a sponsor closed the study (scenarios #1/3), the sponsor should have notified FDA. Therefore no future correspondence to FDA is necessary. The notification of the study close should have been sent to the FDA review division overseeing the study. I believe that scenario #2 would be the same as the sentence above as no subjects were enrolled prior to the study being closed.

We strongly recommend that the sponsor contact the appropriate review division within the Center where the IND application was filed to discuss the appropriate IND reporting and closeout requirements.

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, July 23, 2014 6:11 PM
To: OC GCP Questions
Cc: **[redacted]**
Subject: GCP Questions - investigator record retention requirements

Hello Doreen and team,

A sponsor recently closed a phase I/II trial of a new oncology compound. The study was conducted in the U.S. in patients with advanced solid tumors. Our regulatory consultants recently provided us with differing opinions as to their interpretation of GCPs requirements around investigator record retention responsibilities. We will appreciate your insight and guidance based on the following 3 scenarios and associated questions:

Scenario #1:
A clinical investigator received IRB approval for a sponsor's study, but the sponsor closed the study before all start-up activities at the site were completed (eg., not all essential regulatory documents were collected and no site initiation visit performed) and no investigational drug had been shipped.
Q#1: What are the GCP record retention requirements for this investigator?
Q#2: Is the Sponsor required to submit new investigator information to FDA given that the Sponsor had a signed a 1572 and received IRB approval (but never formally activated the study)?

Scenario #2:
A clinical investigator received IRB approval for a sponsor's study, completed all start-up activities and received investigational study drug, but never enrolled to the study prior to the sponsor closing the study to further enrollment.
Q#1: What are the GCP record retention requirements for this investigator?
Q#2: Is the Sponsor required to submit new investigator information to FDA given that the Sponsor had received IRB approval and received investigational drug?

Scenario #3:
A clinical investigator received IRB approval for a sponsor's study, completed all start-up activities (including a Site Initiation Visit), but had not yet received investigational study drug (and therefore never enrolled to the study), prior to the sponsor closing the study. Presumably, this will follow the same requirements as in Scenario #1, but please let us know.
Q#1: What are the GCP record retention requirements for this investigator?
Q#2: Is the Sponsor required to submit new investigator information to FDA given that the Sponsor had a signed a 1572, received all essential regulatory documents, received IRB approval, but never received investigational drug?

We look forward to your reply. Many thanks in advance.

Best regards,
[redacted]