From: OC GCP Questions
To: [redacted]
Subject: WAIVER FOR CLOSE OUT VIST
Date: Monday, March 16, 2015 11:00:58 AM

Good morning --

You should check with the sponsor of the study. I am not sure how a study can be closed without a close out visit. Please see the information below.

Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the appropriate files.

The activities a sponsor, CRO and investigator/site follow for a close out visit and any data query follow-up are usually addressed in Standard Operating Procedures (SOPs) of the sponsor, CRO, and site. The clinical investigator must ensure that any requirements to maintain IRB oversight per the regulations are met, and additionally, that any pertinent SOPs are followed.

Clinical investigators are responsible for the control of the investigational drug as per 21 CFR 312.61 and to maintain adequate records concerning the disposition of the drug under 21 CFR 312.62(a). The regulations state that if the investigation is terminated or discontinued, the investigator will return or provide the sponsor the disposition of the unused supplies of the drug as per 21 CFR 312.59. In addition to supplying the sponsor with routine progress reports during the investigational study (21 CFR 312.64(a)), the clinical investigator is required to provide the sponsor with adequate information in the form of a final report shortly after the completion of the investigator's participation in the study (21 CFR 312.64(c)).

As per 21 CFR 312.62(c), clinical investigators are required to retain records for a period of two 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 two years after the investigation is discontinued and FDA is notified. If investigational records are transferred off-site to a third party (e.g., CRO), the sponsor and FDA should be notified by the associated clinical investigator in the form of a final report.

When study enrollment and subject follow-up have been completed at a given site, the clinical investigator will often (usually for FDA-regulated studies) send the required final report to the IRB, thus closing out the study at the site.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Saturday, March 14, 2015 2:15 PM

To: OC GCP Questions
Subject: WAIVER FOR CLOSE OUT VIST

Dear GCP experts:

A site to whom I am providing training has pending to receive a close out visit 1.5 years. The database is closed sinve Nov 2013, and the investigator's binder is pending to be reconciled by the CRA. The site would like to close the delegation log and archive the essential documents. Is it possible to close a site in case that the COV.

Regards

[redacted]