From: OC GCP Questions
To: [redacted]
Subject: Site closure in clinical trial due to PI retirement
Date: Friday, October 17, 2014 11:52:51 AM

Good afternoon --

You should work with the sponsor of your study and the reviewing IRB if you decided to close your site.

I am not aware of a specific FDA guidance document that provides details about how to close out a study. However, the following information is found in the "Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance" (April 1996 ICH):

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.

Any or all of the documents addressed in this guidance may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

(See section 8.1, at http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf).

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.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

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

Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [re.a.te..]
Sent: Thursday, October 16, 2014 4:45 PM
To: OC GCP Questions
Subject: Site closure in clinical trial due to PI retirement

Dear Sir/Madam,

I am a CRA in a clinical study.I would like to ask you about the site closure in clinical trial due to PI retirement. What it should be done in a case that a PI in a clinical trial is going to retire and he/she doesn't have good relations and cooperation with the other doctors in his/her clinic in order to transfer his/her responsibilities to a new PI? It would be preferable for the safety of the participating subjects in this clinical study to close out the site. Could you give us your advice about this case?

Thank you in advance,

[redacted]