From: OC GCP Questions
To: [redacted]
Subject: Immediate Termination of Principal Investigator
Date: Friday, October 30, 2015 1:00:37 PM

Good afternoon --

There is no true SOP on what needs to be done when terminating a study at a site and FDA does not have specific guidance that addresses a study closure site. 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. Generally, directions would be given to you by the study sponsor. However I can offer you the following information. Also the information that is being conveyed to the study subjects should be reviewed and approved by the IRB. I did perform a web search and you can find some helpful SOP on closing a study site.

As per 21 CFR 312.62(c), clinical investigators are required 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 (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)].

The investigator may also transfer the records to the sponsor of the study. If the records are transferred to the sponsor, and FDA wants to inspect them, it may be helpful for the sponsor to have established written standard operating procedures (SOPs) for storage of the records and for tracking who is able to access them, so that the agency can be assured that the records have not been tampered with or altered and that confidentiality of information has been maintained throughout the duration of the transfer. Again, any change in location of the study records should be communicated to both the sponsor and FDA.

Additionally, 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: Thursday, October 29, 2015 2:58 PM
To: OC GCP Questions
Subject: Immediate Termination of Principal Investigator

Good Afternoon,

We have had a recent incident of a PI being terminated from the Institution without prior notification to our research institute. There was no Sub-I on the study. Could you direct me to the appropriate resources that would enable us to write an SOP that reflects the steps necessary for notification of subjects, sponsors, and IRB's. This subject is not readily discoverable in literature. Thanks for your assistance.
[redacted]