From: OC GCP Questions
To: [redacted]
Subject: Site Study Closure
Date: Wednesday, October 17, 2018 8:02:33 AM
Attachments: [redacted]

Good morning –

It depends because it is unclear why the sponsor wants to close-out the site. Is the non-compliance at the site? 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.
FDA regulations state -

For drug studies, 21 CFR 312.56 Review of ongoing investigations.

(a) The sponsor shall monitor the progress of all clinical investigations being conducted under its IND.

(b) A sponsor who discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or the requirements of this part or other applicable parts shall promptly either secure compliance or discontinue shipments of the investigational new drug to the investigator and end the investigator's participation in the investigation. If the investigator's participation in the investigation is ended, the sponsor shall require that the investigator dispose of or return the investigational drug in accordance with the requirements of 312.59 and shall notify FDA.

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.

For device studies please see 21 CFR812.36.

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."

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.

Some sponsors/CROs may have SOPs that require a site to maintain IRB oversight throughout the data query process, and do not perform a close out visit until all data queries have been completed at that site.

Additionally, OGCP strongly recommends that the sponsor contact the appropriate review division within the Center for Devices (CDRH) where the IDE application was filed to discuss the appropriate IDE reporting and closeout requirements or CDRH directly at DICE@fda.hhs.gov .

Kind regards,

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Office of Good Clinical Practice

Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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From: S[redacted]
Sent: Tuesday, October 16, 2018 3:21 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Site Study Closure

To Whom It May Concern:

Could you comment on the following scenario:

If a device study site is closed by the Sponsor, including notification of the site's IRB, after all of the site's subjects have either completed or early exited the study and there is a subsequent safety concern with the device, what options are there for the Sponsor to take to ensure the subjects at the closed site are notified of the issue? Should a Sponsor keep the site open with their IRB until all subjects at the other study sites have fully completed the study?

Thank you.

[redacted]