From: OC GCP Questions
To: [redacted]
Subject: Site Study Closure
Date: Thursday, October 18, 2018 9:06:25 AM
Attachments: [redacted]

Good morning –

The goal is to always minimize risk to the study subjects. What you describe below should have been outlined in the protocol and the informed consent especially because the IP is a medical device.

In general –

A sponsor should continue to collect data on a subject experiencing an ongoing adverse event beyond the last visit (and record the data in the CRF) if the information that would be obtained is pertinent to the investigation (e.g., could contribute useful information about the safety profile of a medical device). Factors to consider include whether the event is serious and the extent to which the event is already characterized. If the event is serious, the investigator should generally continue to follow the patient, and should always follow if the event is also unexpected. For non-serious events there may be less reason to continue to follow, particularly for events already listed in the Investigator Brochure.

Generally, the protocol should provide for follow-up of some types of adverse events until they are resolved (or clinically stable if not expected to resolve). The investigator should seek clarification from the sponsor if necessary. If the sponsor has specific concerns, they should discuss them with the review division.

It is not usually necessary to collect information on an adverse event that occurs after study completion. The follow-up period provided for in the protocol is generally considered adequate to capture adverse events that may be related to the test article. However, if an investigator believes an event occurring after the patient has completed the trial may be related to the test article, the investigator should inform the sponsor. The sponsor should evaluate as it would any other event reported by the investigator.

The sponsor can contact the revision division in CDRH that handled the IDE.

Additional information on IDE specifics, they can visit the following site:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm

As suggested earlier, if I have not adequately answered your question, you may contact CDRH directly at DICE@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Wednesday, October 17, 2018 3:55 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Re: Site Study Closure

If all sites for a device study have been closed by the Sponsor and then, the Sponsor identifies a safety concern with the device, what options does the Sponsor have to ensure that the study subjects are made aware of the issue?

Thank you.

[redacted]