From: OC GCP Questions
To: [redacted]
Subject: adverse event leading to subject drop out during investigation
Date: Friday, November 06, 2015 7:17:14 AM

Good morning --

Please see the link below for FDA's guidance document on Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials.
http://www.fda.gov/downloads/regulatoryinforamtion/guidances/ucm126489.pdf It states--

FDA law and regulations recognize that a complete and accurate risk/benefit profile of an investigational product depends upon the data from every subject's experience in the clinical trial. For example, if a subject's data could be withdrawn from a study, a sponsor would not have access to data on adverse events experienced by the subject and would be unable to evaluate whether changes to the protocol or the informed consent documents are needed to ensure the rights, safety, and welfare of other trial subjects. Please see the entire guidance as it address scenarios as to when data can be used after a subject withdraws from a study and when informed consent is needed to access medical records after withdraw.

Generally information is not collected when a subject completes or withdraws from a trial. However, it must be different for collecting adverse events. I would have to defer to CDER OMP as they wrote the guidance on adverse events and are considered the experts. You can contact them directly at the email address below.

CDEROMP@fda.hhs.gov

Additionally the sponsor can contact the FDA review division and/or the regulatory project manager that is overseeing your IND to receive a clear understand of AE collection after the subject withdraws from the study.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.go v 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, November 05, 2015 4:57 PM
To: OC GCP Questions
Subject: adverse event leading to subject drop out during investigation

Dear Sir / Madame,

A study subject has declined to continue to receive the experimental drug therapy (i.e., study intervention) due to adverse events but agreed to participate in follow-up, including study specific follow-up assessments.
The question has been asked if the subject meets the criteria for 21 CFR 312.33(b)(4), as a subject who dropped out during the course of the investigation due to adverse events. Some of the study team members believe that as the subject is still participating in the clinical follow-up, the subject is still participating in the study. The subject did not receive the full course of the investigational therapy.

Thank you for any insight you can provide,

[redacted]