From: OC GCP Questions
To: [redacted]
Subject: Withdrawal of Consent
Date: Thursday, March 31, 2016 10:32:55 AM

Good afternoon –

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 For example, if a subject's data could be withdrawn from a study, a sponsor would not have access to data on adverse events experienced by the subject and would be unable to evaluate whether changes to the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 if you are the sponsor you can contact the FDA review division and/or the regulatory project manager that is overseeing your study 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.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Thursday, March 31, 2016 9:46 AM
To: OC GCP Questions
Subject: Withdrawal of Consent

Good day. If a subject withdraws consent on March 15, 2016 and expires on March 16, 2016, is this a reportable SAE?

Kind regards,

[redacted]

[redacted]

[redacted]