From: OC GCP Questions
To: [redacted]
Subject: After consent withdrawal
Date: Tuesday, April 07, 2015 12:42:42 PM

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 For example, if a subject's data could be withdrawn from a study, a sponsor would not have access to data on adverse events experienced by the subject and would be unable to evaluate whether changes to the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 as 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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, April 06, 2015 4:36 PM
To: OC GCP Questions
Subject: After consent withdrawal

Hello,
We are doing several clinical trials with an endpoint of survival. If a subject withdraws consent, I know we can use any public records regarding survival to determine a subject's outcome. We can

also use data collected prior to the subject's withdrawal. What we need a bit of advice with involves a particular incident. A subject's legal representative withdrew consent. The following day, the site study coordinator sent an SAE (resulting in death) to the CRO handling our pharmacovigilance reporting and database. Our data management team is concerned about having data collected after consent was withdrawn, yet some of us feel it is more important to correctly report SAEs. Can you advise on this?

Additionally, as the Sponsor, we feel it is our obligation to report all SAEs we become aware of. Since death in itself defines an SAE, if the subject or their legal representative withdrew consent, we likely would be unable to completely fill out the information required in an SAE report for deaths we become aware of. It would then be probable that the event would be "death" as well as the outcome of the event, as we would not be able to use the subject's medical records to determine the actual cause of death, or SAE term. Can you provide any guidance on this scenario?

Any assistance would be deeply appreciated. Please feel free to call me if my questions are unclear.

Thank you,
[redacted]