From: OC GCP Questions
To: [redacted]
Subject: Study Exit Question Based on Interim Analysis Futility
Date: Tuesday, February 10, 2015 11:46:51 AM

Good morning --

FDA regulations do not specifically mention sample collection. However, FDA regulation under 312.23 (6)(g) describes what should be in outlined in the protocol. "A description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk."

Specifics related to blood draws and specimen collection should be outlined in the study protocol. In addition, the case report forms (CRFs) for the study subjects should contain information as to what specimens were sent for analysis, the date(s) they were both collected and sent, and any study-specific information regarding handling of the specimens and their transmittal to the laboratory and/or receipt of the results.

When thinking about blood draws, one should consider if there could be any negative effects to the subjects or study. One concern may be whether having additional samples drawn could increase risks to subjects. Another concern may be the scientific soundness of the study which could be affected if multiple samples from the same subject were included in the study. The IRB should agree to the protocol specifics on collection of blood samples.

That said, the following information is based on the limited information in your email. If the study is not officially terminated because subjects are coming in for their exit visits, blood draws may be taken. However if the study is terminated prior to their exit visits, blood draws may not be taken for study purposes. It is best to review the study protocol.

Additionally, we strongly recommend that the sponsor contact the appropriate review division within the Center where the IND application was filed to discuss the appropriate IND reporting and closeout requirements.

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 You might find some helpful information in this guidance document.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional information.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

-----Original Message-----
From: [redacted]
Sent: Monday, February 09, 2015 11:03 AM
To: OC GCP Questions

Subject: Study Exit Question Based on Interim Analysis Futility

To Whom It May Concern:

As a result of the interim analysis futility, a decision has been made by the Sponsor to prematurely discontinue the study. Subjects will be exited at their next regularly scheduled visit. A blood draw was part of the exit visit procedures. Given the futility of the study, can the subjects still provide the blood sample and then be exited?

Thank you for the guidance.