From: OC GCP Questions
To: [redacted]
Subject: Optional Procedures in a Clinical Trial
Date: Friday, August 15, 2014 9:48:03 AM

Good morning –

Generally if the subject signed a study-specific informed consent document then additional measures for extra draws would not be needed. However I can offer the following additional information for consideration.

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.

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

Kind regards,.

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, August 14, 2014 2:33 PM
To: OC GCP Questions
Subject: Optional Procedures in a Clinical Trial

Good Afternoon,

I have a question about Optional Procedures in clinical trials.

Many protocols have optional blood collection for biomarkers or tissue collected for banking.

If a subject gives consent for the optional blood collections, does the study staff have the option to collect them or not? (I am not referring to the occasional missed sample, but for most of the samples for all subjects in a trial)I have been asked this question recently and I am unable to find anything specifically addressing it in my institution's policies or in the FDA Guidance's.

Thank you.
[redacted]