From: OC GCP Questions
To: [redacted]
Subject: Query regarding patient sample collection
Date: Sunday, August 10, 2014 12:32:40 PM

Good afternoon –

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. If a bioresearch monitoring (BIMO) inspection was conducted at the site, FDA investigators would expect to see the original copies of protocol-specified laboratory results in each subject's study file and look to reconcile the dates on the results with the information in the CRFs. While FDA regulations do not address the chain of custody of study specimens, should there be any concerns about laboratory results for one or more study subjects, FDA would look for documentation of specimen collection, handling, shipment, etc. in search of potential causes of noted or suspected discrepancies.

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.

Typical collection studies include a simple blood draw. Thus may be done by a phlebotomist, nurse,etc. as part of their routine processes - however they would have to follow the protocol requirements (e.g. types of collection tube, timing of the blood draw).

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: Friday, August 08, 2014 7:48 AM
To: OC GCP Questions
Subject: Query regarding patient sample collection

Dear Sir/Ma'am,

I am a student at [redacted], currently studying clinical research and regulatory affairs. I have been studying various guidelines such as ICH, MHRA and FDA guidelines on clinical trials. I have a query regarding patient sample collection, for which I could not find a suitable answer in any of the guidelines. If there is a siuation wherein a patient has to provide blood/tissue/urine samples, but for some reason the first time the sample is taken it is not sufficient, what is the requirement for collection of additional samples? This is taking into account the fact that some fixed amount of sample that will be needed is provided by the investigator in the patient information sheet and in the protocol, but due to unforseen circumstances more sample is required. Is there any ethical restriction on taking blood from a patient again? Will a protocol deviation or protocol amendment form have to be made? What would be the legal method of obtaining the sample again from the patient?

I look forward to your response,

Thank you,

Sincerely

[redacted]