From: OC GCP Questions
To: [redacted]
Subject: RE: Informed Consent
Date: Friday, July 18, 2014 9:20:00 AM

Dear [redacted],

Your first issue has what might be conflicting statements. You first say you are asking them for "extra blood samples" and then asking if they can be considered as left-over samples. If the blood bank would be drawing samples in addition to those they draw to test for diseases to ensure the safety of their blood supply, those samples would not be considered left-over samples. If you are saying that they will supply what remains of their samples after they perform their testing, then they would be considered left-over samples. They seem to be stating that they collect a "blood bag sample pouch" from which their test samples are drawn. Even though I have given blood many times I am unaware of that set-up but assume some blood is diverted to a sample pouch rather than directly into sampling tubes. If that is what the "blood bag sample pouch" is, then whatever remains in that pouch would also be considered a left-over sample if it would otherwise be discarded.

Sorry if my response is confusing but the terminology used and the phrasing of the sentences makes it unclear as to exactly what you are stating. If, from my discussion above, you decide that the samples are left-over samples, you can use them in your study without informed consent from the individuals donating the blood **if all other conditions in the guidance document referenced are met**.

For you second question, if you are prospectively collecting samples from blood donors and not using a sample that could be considered a left-over sample, you will need to have them sign a study-specific informed consent document. The blood bank's consent form will not suffice. When I have donated blood in the past, the blood bank provided me with a separate, study-specific informed consent form to sign in addition to the regular donor consent when they were performing experimental testing beyond the customary approved testing for safety purposes on the samples they drew.

Hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.
Sincerely yours,
Jean Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US FDA
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Wednesday, July 16, 2014 3:08 PM
To: OC GCP Questions
Subject: Informed Consent

We are currently executing a sample collection protocol for an HIV study in which a full IDE 21 CFR 812 is required. We want to obtain prospective samples from blood banks. We have several questions:

1. Can the blood banks provide us extra blood samples from their subject's draw without an informed consent and consider this leftover unidentified samples? See below for our question and a blood banks response. If we review the guideline referenced it states that the FDA will NOT exercise enforcement discretion if the study requires an IDE.
    - we are requiring collection of two tubes (1 serum, 1 EDTA plasma) Is this standard for the blood banks to draw off two matrices? We routinely collect EDTA and serum from our blood bag sample pouch – for this project, the samples will be considered leftover unidentified specimens because they will be obtained from leftover blood in the sample pouch that would otherwise be discarded. In accordance withhttp://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm078384.htm , informed consent will not be required for the use of these specimens.
2. If we need an informed consent, must the informed consent meet the requirements of 21 CFR 50 or can we accept the informed consent used at the blood banks' center (assuming IRB review and approval)? When we review the blood bank's informed consent, all the required elements of 21 CFR 50 are not met.

Many thanks for your assistance.

Kind regards,
[redacted]