From: OC GCP Questions
To: [redacted]
Subject: Retention of Blood Samples from a completed PK Study
Date: Thursday, March 20, 2014 4:39:11 PM

Good afternoon:

Thank you for your inquiry to FDA's Office of Good Clinical Practice. As far as I am aware, there is no specific guidance as to how specimens for clinical trials should be maintained or how long they should be stored. In general, sponsors are responsible for any and all procedures involved in the collection, maintenance, distribution and destruction of specimens. Any destruction/disposal of specimens would be subject to applicable state or local laws for disposal of biological waste. You may also check with the FDA review division that is overseeing your specific study.

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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From: [Redacted]
Sent: Thursday, March 20, 2014 10:51 AM
To: OC GCP Questions
Subject: Retention of Blood Samples from a completed PK Study

Dear Sirs;

I have a situation that I hope you can help me with. I am part of a small business which is in the process of developing our first pharmaceutical product. We have conducted a pharmacokinetic (PK) study on healthy normal individuals which is now complete. The final study report has already been submitted to the Division as an update to our open IND. The clinical supplies are being retained in accordance with the regulations but we need to

determine the disposition of the blood samples.

I cannot locate any regulations or guidances which indicate the length of time that these samples need to be retained after the completion of the study. However, the laboratory that conducted the analysis of the samples is indicating that we need to retain the samples for an extended period of time. Specifically, they are indicating five (5) years post approval of the NDA is expected. I believe that they are misinterpreting the blood sample retention to be the same as clinical trial material sample retention. However, I want to make sure that there is not something that I have missed in my search for information before I dispose of these samples.

Can you please provide clarification on this matter?

Best Regards
[Redacted]