From: OC GCP Questions
To: [redacted]
Subject: Retention of the logs of the study after the COV
Date: Thursday, September 24, 2015 8:10:32 AM

Good morning --

The relevant US FDA regulations on record retention for clinical trials documents are as follows:

For drug and biologic studies, 21 CFR 312.62(c) states: "Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified."

For device studies, 21 CFR 812.140(d) states: "Retention period. An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol."

As you will note, the retention period is dependent on whether the data will be used to support a marketing application with FDA. The sponsor is usually the only party totally knowledgeable about the status of its investigational product (e.g., whether it has been approved for marketing, whether the sponsor no longer intends to seek marketing approval, etc.). Therefore, it is best to check with the study sponsor regarding the status of the investigational product and the need to retain the study records. You should check with each of the study sponsors before discarding any study files. FDA regulations do not specifically address what documents need to be maintained at time of destruction.

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

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: Thursday, September 24, 2015 8:05 AM
To: OC GCP Questions
Subject: Retention of the logs of the study after the COV

Dear sir/madam,

I would like to ask you about the retention of the logs (Subject Screening log, Monitoring visit log and Site Delegation list) of the Trial Master File after the site close-out visit. These logs are located in the files both of Investigator and the Sponsor. Who should keep the originals and who the

copies? It is not explained in GCP.

Thank you in advance,

[redacted]