From: OC GCP Questions
To: [redacted]
Subject: Question re: Site Termination of Contract
Date: Thursday, July 19, 2018 8:39:00 AM
Attachments: [redacted]
Importance: High

Good morning –

The relevant US FDA regulation on record retention for clinical trial for an IND is 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."

If an FDA Bioresearch Monitoring (BIMO) inspection of the research site were to occur, however, FDA investigators would expect to see the original records or certified copies of such. Therefore, the only requirement would be that stored records be made available for inspection when needed [See 21 CFR 312.68 www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.68 for studies involving investigational drugs

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.

For the data itself, generally that would be given to the sponsor. Any data collected during the course of the study would be turned over to the sponsor. However, has stated the records would need to be retained as outlined above.

The reviewing IRB should be notified that you are terminating the research with the sponsor. FDA does not comment on clinical study agreements or legal issues.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

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 18, 2018 1:37 PM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question re: Site Termination of Contract
Importance: High

Dear Madam or Sir:

We have a unique issue that we would like guidance on. We are a dedicated clinical research site that is a very small, stand-alone, business. We have been owned money by a huge conglomerate under a Clinical Study Agreement that has been in breach for some time. After the continuing failure of this huge company to pay us, we have initiated termination procedures, as per our contract. This failure to pay us has also hurt another small business that provided services to our site for this study.

All patients in the study have completed visits, so there is no patient safety issue. What is the FDA's position on what we should do with the data collected once the contract is terminated? It is unfair for our tiny business to be forced to work without payment. I do not think that some sponsors care about the burden they place on small business who have obligations to make payroll, pay payroll taxes, rent, insurance, ect., then suffer when we are not paid. We would truly appreciate any opinion that the FDA could give us in this matter.

Kind regards, [redacted]