From:	OC GCP Questions
To:	[redacted]
Subject:	GCP Investigator Site
Date:	Thursday, May 03, 2018 6:55:00 AM
Attachments:	[redacted]

Good morning –

Those responsible for clinical trial data (records) should have a full understanding of the issues, obligations, and requirements related to data management and ownership. The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial. Any transfer of ownership of the data should be reported to the appropriate authority(ies), as required by the applicable regulatory requirements.

The record 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.).

FDA regulations that apply to record retention is under 312.62 applies to the clinical investigator. Specially 312.62(c) states—

(c) 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.

Reasonable steps must be taken to maintain control of study records, study subject privacy and confidentiality, and the confidentiality, completeness, and reliability of study records.

Responsibility for the records and transfer of the records to a different party should be clearly defined in an agreement between the parties. FDA needs to be assured that the records have not been tampered with or altered and that confidentiality of information has been maintained throughout the duration of the transfer and storage.

The sponsor should notify FDA of the transfer of records. It appears you have taken the steps that are necessary at your site. If a FDA inspection occurred at your site, you most likely will be notified prior to the inspection. At that time, you could communicate to FDA that the sponsor now has the trial source documentation. It would seem that the past study records would demonstrate the roles of the previous investigators. However, maintaining a contact list of previous investigators does violate FDA regulations.

On a side note, please note that FDA's regulations do not prohibit the off-site storage of study records or storage of records to a second party. Specifics for storage of study records, and delivery when needed, would be the subject of written legal contracts between the research site and the storage facility, or the clinical investigator. It may also be helpful to establish written standard operating procedures (SOPs) for storage of the records and for tracking who is able to access them, so that the Agency can be assured that the records have not been tampered with or altered and that confidentiality of information has been maintained throughout the duration of the transfer and storage. As previously stated confidentiality of information is important.

Kind regards,

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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, May 02, 2018 9:17 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: GCP Investigator Site

Hello, I work for a CRO that has recently (last year) closed a clinical investigator site and no longer employs any clinical investigators at the company. We have retained all study trial documentation as required. There are a couple of questions we have regarding archival and support for regulatory inspections.

1. A Sponsor has requested that all trial source documentation be transferred to their archival location. We will be maintaining a certified copy of all documentation, but do we need to notify the regulatory authorities of this transfer of ownership? If so, what is the contact for this communication?
2. As the legal ownership of the clinical trial site, we are prepared to support any regulatory inspection requirements for study documentation, SOPs, facility data, etc., but since we no longer have any clinical investigators on staff, we would not be able to answer questions related to their roles in study conduct. What is needed in these cases? Would you recommend maintaining a contact list of the previous investigators?

Thank you for your assistance!

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[redacted]

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