From: OC GCP Questions
To: [redacted]
Subject: Request from Sponsor for Source Documents
Date: Thursday, April 16, 2015 10:28:35 AM

Good morning –

Generally original (source) study records are kept at the clinical investigator site.

FDA's regulations do not require a delegation of authority log. This log, however, is among the documents listed in the ICH E6 Good Clinical Practice (GCP) document which is official FDA guidance. FDA investigators inspecting a clinical site will not always review the delegation of authority log as it is not a regulatory requirement. If the study is clearly in good control and data verification - whether against data submitted by the sponsor or a check of source versus case report form data - indicates no problems, there is no need to verify that personnel delegated study responsibilities are qualified to do so, which is the main purpose for reviewing a delegation log

However you mention that you are working on closing out the study. Below is general information on record retention of study records.

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.

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.).

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. (See the document, “Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance”, sections 5.5.6 and 5.5.10, at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf). As noted, certain applicable regulatory requirements for FDA-regulated research are found in the citations provided. 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 legal counsel handling the sale of assets should be consulted about the ownership of the records and the responsibilities for complying with the regulatory requirements concerning the records.

Additionally, 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. Confidentiality of information is important.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hh.gov should you have

additional questions.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, April 14, 2015 1:31 PM
To: OC GCP Questions
Subject: Request from Sponsor for Source Documents

I am writing in regard to an ongoing clinical trial that I am managing site enrollment for. Enrollment has been met, and I am working on closing out the study. Recently, the sponsor requested that our site send original study logs to them (e.g. screening log, accountability log, Roles, Responsibilities, and Signatures Log, etc.).

The request for originals seemed a bit strange to me, so I contact my IRB, and they confirmed that this is not our policy and the originals should be kept on site. I am curious to know if you have any guidance on this issue that may help me to better understand what the proper good clinical practices are regarding this matter.

Thank you.

[redacted]