From: OC GCP Questions
To: [redacted]
Subject: Record retention- investigator vs. Investigative Site
Date: Tuesday, January 28, 2014 6:33:34 AM

Good morning:
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.).

I am not aware of any FDA guidance specific to physical security. In general, FDA expects that reasonable steps would be taken to maintain control of the study records, the privacy and confidentiality of study subjects, and the confidentiality, completeness and accuracy of study records.

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: Monday, January 27, 2014 8:04 PM
To: OC GCP Questions
Subject: Record retention- investigator vs. Investigative Site

Dear FDA,

We are seeking clarity on 21 CFR 312.62 Investigator recordkeeping and record retention.

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."

Our understanding is that FDA uses the term “investigator” to refer to “Investigator is an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the investigational device is administered, dispensed to, or used involving a subject. In the event of an investigation being conducted by a team of individuals, "investigator" refers to the responsible leader of that team.”

In most instances we/ industry interprets this as the principal investigator (PI) and the person who is listed in Box 1 of/ signs the FDA 1572 Form. One of the agreements on that form is “I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68”.

The language in our clinical trial agreements (CTA) is structured to make the Investigative Site responsible for the document retention since the PIs are many times not the owners of the Investigative Sites. In smaller organizations we assume that the PI has a contract with the site to perform the PI duties, but the PI does not have ownership of the office facilities, that is the Investigative Site and the Site then has that responsibility. In the example of a large institution (such as a University or Hospital), the PI may be an employee, but again, does not have responsibility for document retention, that is the Institution/Investigative Site’s responsibility. It is expected that the PI should be aware of the document retention policy.

1. To whom specifically does 21 CFR 312.62 apply?
2. Is it per the regulation if the language in the CTA, when signed my someone other than the principal investigator (e.g. the responsible officer of a university or hospital), commits the signatory to retain the records (the records that are produced as the result of an applicable clinical trial conducted by a principal

investigator)?

Your time and guidance is greatly appreciated,
[redacted]