From: OC GCP Questions
To: [redacted]
Subject: Record retention- investigator vs. Investigative Site
Date: Thursday, January 30, 2014 11:55:57 AM

Good morning –
The clinical trial documents can be stored off-site, however, the clinical investigator is still responsible for the documents. As stated previously
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.

FDA's Bioresearch Monitoring (BIMO) program is a comprehensive program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA regulated research. The BIMO Program was established to assure the quality and integrity of data submitted to the agency in support of new product approvals, as well as, to provide for protection of the rights and welfare of the thousands of human subjects involved in FDA regulated research. In general, during an inspection FDA usually reviews original records or certified copies of records. For example, during an inspection of a clinical investigator (CI), the FDA investigator will evaluate the CI's practices and procedures to determine compliance with applicable regulations. When the inspection occurs as a result of FDA's receipt of a marketing application/submission, it will include a comparison of the data submitted by the sponsor to FDA with source documents at the CI's site (i.e., where original source data are recorded; also known as supporting data) and case report forms (CRFs) in the CI's files. If it is a "for cause" or surveillance inspection of an on-going study, data comparison will generally involve only source documents and case report forms, because there may not always be data supplied by the sponsor. Source documents may include office records, hospital records, laboratory reports, records of consultations, etc. In this case, original source records will be reviewed. If an FDA inspection occurred at the CI site, the CI would be responsible for making sure the records were accessible at his site for an inspection.

If study documents are stored off-site, the CI should obtain the approval of the sponsor of the study. The sponsor should notify FDA as to where the records are stored. Again FDA does not object to off-site storage of study records. If the study records are going to be transferred off-site, it is best to document this transfer and keep the documentation for your records.

Kind regards,

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

From: [Redacted]
Sent: Wednesday, January 29, 2014 2:19 PM
To: OC GCP Questions
Subject: RE: Record retention- investigator vs. Investigative Site

Thank you for the thorough reply. Your assistance with a little more clarification is appreciated:

So my interpretation would be that in an instance where the language in the CTA is structured to make the Investigative Site responsible for the document retention and someone with the proper authority signs the CTA, along with the principal investigator, that the record retention responsibilities are essentially being transferred to the site/ institution at that time. Is this correct?

Is there any regulatory requirement that, even if the records retention responsibilities are transferred, that the principal investigator must retain the control over and/ or access to these documents? For example, would it be permissible for the documents to be sent to off-site storage with the "owner" being the site/ institution (or even the sponsor) such that the PI doesn't have the authority to access the records or call them out of storage?

Kind regards,
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