From: OC GCP Questions
To: [redacted]
Subject: Sec. 312.62 Investigator record keeping and record retention.
Date: Wednesday, November 25, 2015 9:19:02 AM

Good morning –

FDA's regulations do not prohibit the off-site storage of study records. 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 and/or biologics and 21 CFR 812.145 for studies involving investigational devices www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.145]. 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. 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. Any change in location of the study records should be communicated to the study sponsor and well documented.

That said, it might be problematic if the study records are stored outside the US. As stated, if an FDA inspection occurred at your site, FDA would want to see the original study documents.

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

Kind regards,

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

From: [redacted]
Sent: Tuesday, November 24, 2015 12:02 PM
To: OC GCP Questions
Subject: Sec. 312.62 Investigator record keeping and record retention.

Good Morning:

My question today is in regards to the Investigator Responsibilities for record keeping and record retention, as per 21 CFR 312.62.

Sec. 312.62 Investigator recordkeeping and record retention.

(a) *Disposition of drug.* An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use

by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59.

(b) *Case histories.* An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

(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.

Currently, we have a Sponsor that is telling us that they will be storing all of our case histories, ICFs and all regulatory documents in Denmark; the site is located in Florida, USA. My concern with this is that these files are the Investigator's responsibility and that if the Investigator was selected for an inspection and something had happened or did happened during transport, he/she would be held responsible.

Is the Sponsor allowed to demand that they Archive and retain all study documents on behalf of the Clinical Trial Investigator?

Your response is greatly appreciated.

Kind Regards,

[redacted]