From: OC GCP Questions
To: [redacted]
Subject: Document Storage question concerning privacy
Date: Friday, November 22, 2019 9:51:03 AM
Attachments: [redacted]

Good morning –

Thank you for your email. I am assuming that you are the sponsor. Please see the information below. If you are the sponsor, you may accept the records from clinical investigator sites that want to send you the records as long as the information below is met.

As per 21 CFR 312.62(c), clinical investigators are required retain records for a period of two 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 two years after the investigation is discontinued and FDA is notified. If investigational records are transferred off-site to a third party (i.e. Contract Research Organization (CRO), etc.) or back to the sponsor, the sponsor and FDA should be notified by the associated clinical investigator in the form of a final report. A sponsor of an investigational drug study shall retain the records and reports for two years after an approved marketing application or until two years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified [21 CFR 312.57(c)].

Again under 21 CFR 312, sponsors and investigators are required to retain records and reports required by this part for 2 years after a marketing application is approved for the drug; or if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use id discontinued and FDA has been notified. In the ICH E6(R2) Guidance for Industry entitled Good Clinical Practice Consolidated Guidance (see https://www.fda.gov/media/93884/download), you will find suggestions in Section 8 for what "essential" documents should be retained by the sponsor and investigator. As noted in this guidance, essential documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with standards of GCP and will applicable regulatory requirements. Filing these documents in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor and monitor. These documents are the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authorities) as part of the process to confirm the validity of the trail conduct and integrity of data collected.

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 investigational products, the privacy and confidentiality of study subjects, and the confidentiality, completeness and accuracy of study records.

FDA's primary concern is the rights, safety and welfare of the subjects enrolled in all clinical investigations.

The guidance below should be helpful to you.

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

FDA does not have responsibility for the implementation of HIPAA. HIPPA is the responsibility of the Office of Civil Rights. You may wish to consult the Health Insurance Portability and Accountability Act (HIPPA). For questions regarding issues pertaining to HIPAA, you may contact OCR directly at OCRPrivacy@hhs.gov. Here also is a link to OCR's general website for HIPAA www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at www.hhs.gov/ocr/privacy/hippa/faq.index.htmlYou may also wish to discuss your question with other inhouse legal staff, including any Privacy Officer, within your organization.

Kind regards,

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

From: [redacted]
Sent: Thursday, November 21, 2019 4:16 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Document Storage question concerning privacy

Hello-

We have a site that is dissolving as a business. They would like to return their regulatory binders and subject source documents from a few studies that they conducted for us. Those studies are now complete, and they were unblinded. However, are there any data privacy or HIPAA regulations that we need to be aware before accepting those files?

Thank you-

[redacted]