From: OC GCP Questions
To: [redacted]
Subject: BOX folder
Date: Friday, March 30, 2018 12:38:00 PM

Good afternoon –

FDA's regulations concerning clinical trials do not specifically address physical security measures except for the storage of controlled substances. This is discussed in the investigational new drug (IND) regulations, 21 CFR § 312.69, which states:

If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

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.

You might want to review the guidance documents below relating to electronic clinical trial records.

Part 11 -Electronic Records - www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Computerized Systems Used in Clinical Investigations - www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations - www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

To answer your question regarding 100% verification -- it depends on the type and complexity of the study being monitored. As you are probably aware, 100% verification is not always the answer. The CRO will have to decide what monitoring plan best fits your specific study to ensure that the subjects are protected, the integrity of the data is maintained, and that there is compliance with applicable regulations. Let's say they choose verification with 1 out of every 5 subjects and they find issues at that site, then they would want to change your monitoring plan to correct problems and ensure compliance.

I have pulled some key points from FDA's monitoring guidance. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

They are listed below.

Sponsors of clinical investigations are required to provide oversight to ensure adequate protection of the rights, welfare, and safety of human subjects and the quality and integrity of the resulting data. The regulations are not specific about how sponsors are to conduct monitoring of clinical investigations and, therefore, are compatible with a range of approaches to monitoring.

The primary focus of monitoring should be on the processes that are critical to protecting human subjects, maintaining the integrity of study data, and compliance with applicable regulations. The findings should be used to correct investigator and site practices that could result in inadequate human subject protection and/or poor data quality.

There is a growing consensus that risk-based approaches to monitoring, such as focusing on the most critical data elements, are more likely to ensure subject protection and overall study quality, and will permit sponsors to monitor the conduct of clinical investigations more effectively than routine visits to all clinical sites and 100% data verification. FDA strongly encourages sponsors to tailor monitoring plans to the needs of the trial.

No single approach to monitoring is appropriate or necessary for every clinical trial. FDA recommends that each sponsor design a monitoring plan that is tailored to the specific human subject protection and data integrity risks of the trial. The monitoring plan should identify the various methods intended to be used and the rationale for their use.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----

From: [redacted]

Sent: Thursday, March 29, 2018 7:35 PM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: BOX folder

Hello,

Would a BOX folder qualify as a secure place to house regulatory and copies of blinded subject source documents since only users can be assigned to the folder by unique email address?

A CRO states that they will not be doing 100% source document verification (SDV). What is the minimum that they are required to review? Most of my studies perform 100% SDV.

Thank you for your time

[redacted]