From: OC GCP Questions
To: [redacted]
Subject: Investigator Site Question
Date: Wednesday, February 28, 2018 9:26:00 AM
Attachments: [redacted]

Good morning –

FDA regulations do not require that an investigative site have an organizational chart or site security plan.

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.

If not already in place, it may be helpful to establish written standard operating procedures (SOPs) for storage of study records and for tracking who is able to access them, to assure that the records have not been tampered with or altered and that confidentiality of information has been maintained.

Kind regards,

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U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Wednesday, February 28, 2018 8:13 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Investigator Site Question

Good day. Are there any specific regulations that require/suggest that an Investigational Site have Organizational Chart or Site security plan in place?