From: OC GCP Questions
To: [redacted]
Subject: RE: IRB Records
Date: Thursday, March 16, 2017 1:58:00 PM
Attachments: [redacted]

[redacted]

Thank you for your question.

The regulation that you cite in your email, 21 CFR 56.115, is the FDA regulation which addresses IRB requirements for record keeping. These regulations discuss what records need to be stored and not how they are stored. As you are aware, these regulations are not specific as to the security measures to be taken to keep the records safe. When the regulations are silent, IRBs and institutions are free to develop their own procedures and practices as long as the applicable regulatory requirements for record retention are met.

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.

IRBs and institutions typically have SOPs for record retention and storage that incorporate best practices for things such as limited access, protection of privacy, etc. 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.

The following regulations address the investigator requirements for record retention related to IRBs: 21 CFR 312.62 for drug investigations and 21 CFR 812.140(a) for device investigations. While these regulations and requirements are specific to the investigators (and are in some ways different from IRB requirements for what records are to be kept), they also do not identify security measures to be taken for storing the records. Again, your institution may have SOPs to address investigator records storage.

Other sources of information include the Guidance for IRBs and Clinical Investigators 1998 Update and IEC E6 Section 8.

Additionally, there are also a number of professional societies that may provide workshops

on clinical studies which include advice with regard to maintenance of study records. These include the Association of Clinical Research Professional - ACRP, the Society of Clinical Research Associates - SoCRA, the Drug Information Association - DIA, and the Regulatory Affairs Professionals Society - RAPS.

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

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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.

From: [redacted]
Sent: Wednesday, March 15, 2017 8:07 AM
To: OC GCP Questions
Subject: IRB Records

Good morning,

Could you please tell me if there is anything in the regulations regarding storing IRB records using double locks? The only reference I can find is 56.115 but this isn't very helpful. Our IRB records do not contain patient identifiable information however there is proprietary information.

Also are the regulations for storing IRB records different for Investigators since their records would contain both patient identifiable information as well as proprietary information?

Thanks