From: OC GCP Questions
To: [redacted]
Subject: Essential Document Binder
Date: Wednesday, July 19, 2017 8:35:00 AM
Attachments: [redacted]

Good morning –

FDA regulations do not specifically address study "binders or thumb drive/stick". However, FDA's regulations require investigators 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..." See below.

If your study is being conducted under an IND, the regulations pertaining to Investigator recordkeeping and record retention will apply. These regulations can be found at 21 CFR 312.62, which you can access at the following web link: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62

If not already in place, as you state, 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 (i.e. - study binders/thumb sticks), to assure that the records have not been tampered with or altered and that confidentiality of information has been maintained.

The guidances listed below might be helpful to you.

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

Kind regards,

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U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Monday, July 17, 2017 5:55 PM

To: OC GCP Questions
Subject: Essential Document Binder

Is it acceptable to maintain essential/regulatory binder documents on a thumb drive/stick? If investigator site will maintain all or most documents on a stick, should they create a SOP or just document process and place in a binder?