**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Regulatory questions
**Date:** Thursday, February 23, 2017 6:50:00 AM
**Attachments:** [redacted]

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Good morning –

FDA regulations do not specifically address study "binders". 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 your study is being conducted under an IND, the regulations pertaining to the Sponsor recordkeeping and record retention will apply. These regulations can be found at 21 CFR 312.57, which you can access at the following web link: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.57

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 (i.e. - study binders), to assure that the records have not been tampered with or altered and that confidentiality of information has been maintained. Also, just a thought but you might want to consider obtaining documentation that the files were sent and returned to the CRO in case they are misplaced or lost and the site cannot retrieve the original study information.

Please see the links below to a few guidance documents that might be helpful to you.

ICH-E6 Good Clinical Practice --
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

A Risk-Based Approach to Monitoring --
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

Additionally delegation logs are not addressed in the FDA regulations related to the conduct of clinical trials (21 CFR Part 312 for drugs and biologics and Part 812 for medical devices). Such a log is also not specified in the list of essential documents in the ICH good clinical practice (GCP) guidance document (ICH E6), though signature sheets are included there. Appropriate delegation of clinical trial responsibilities is addressed in the FDA guidance regarding clinical investigator responsibility (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf).

The guidance document states:

*It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory*

*violations resulting from failure to adequately supervise the conduct of the clinical study. The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task.*

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

Kind regards,

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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.

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**From:** [redacted]
**Sent:** Wednesday, February 22, 2017 5:51 PM
**To:** OC GCP Questions
**Subject:** Regulatory questions

Hello,

My company has, within the last year, added a Regulatory Department, and while we are relatively caught up on the ins and outs, have had a few moments where we aren't quite sure of the best practice for certain situations. One of us has a background in Business Management and one as a Coordinator, so we do have experience in this or related fields, and have a support staff of coordinators around us. We've used several of the available PDF's to answer these questions, and to see where our IRB's request slightly different information than the standard, but for other topics, there doesn't seem to be an accepted Best Practice.

I was wondering if you had any documents for Best Practices concerning topics of Maintaining site Delegation of Authority Logs versus using sponsor-provided delegation logs, formatting of regulatory binders, what documents can be maintained in a site-level format and not individually upkept for each individual study at all times (we have a large staff, minimal space, and numerous open studies, so finding ways to limit the amount of site-specific items we have to reproduce for every study is imperative) or similar documents.

I know from speaking with our coordinators that our department has a lot of leeway for how we set up our binders, and how we format essential documentation (Training logs, Delegation Logs, Financial Disclosures), and that in many cases, we do not have to follow the recommended formatting provided by our sponsors, but I want to make sure I know the requirements and specific

regulations before we start changing everything, to make sure we don't overstep or omit necessary items.

Any information you can provide would be greatly appreciated.

Thank you,

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