From: OC GCP Questions
To: [redacted]
Subject: question regarding a 1572
Date: Tuesday, September 16, 2014 10:54:39 AM

Importance: High

Good morning –

Please see FDA's guidance on the 1572 form.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

From the scenario that you describe I don't believe the second site needs to be listed on the 1572 form.

If study documents are stored off-site, the CI should obtain the approval of the sponsor of the study. The sponsor should notify FDA as to where the records are stored. FDA does not object to off-site storage of study records. If the study records are going to be transferred off-site, it is best to document this transfer and keep the documentation for your records. Again, please note that FDA's regulations do not prohibit the off-site storage of study records. Specifics for storage of study records, and delivery when needed, would be the subject of written legal contracts between the research site and the storage facility. It may also be helpful to establish written standard operating procedures (SOPs) for storage of the records and for tracking who is able to access them, so that the Agency can be assured that the records have not been tampered with or altered and that confidentiality of information has been maintained throughout the duration of the transfer and storage. Confidentiality of information is important.

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

Kind regards,

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Office of Good Clinical Practice
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From: [redacted]
Sent: Monday, September 15, 2014 12:11 PM
To: OC GCP Questions
Subject: question regarding a 1572
Importance: High

Good morning FDA.

I appreciate all assistance regarding the proper, standardized way to fill out a 1572. I have spent a

lot of time looking online to find the answer, but to no avail.

My question is this: if we are conducting research for study XYZ at a site (ex: Main Street) but, due to space limitations, are housing only lab kits, screen failed study binders, etc. at a different site (ex: Smith Street) for study XYZ does this second site (Smith Street) need to be on the 1572, or can we simply provide the sponsor with a letter stating where supplies for study XYZ will be kept?

Once a study closes we provide sponsors with a letter notifying them where the documents are being housed. This second location (Smith Street, for storage purposes) will not house study drug, labs specimens, etc. It will only house lab kits and screen failed source binders.

Any advice on this regulation would be greatly appreciated!

[redacted]