From: OC GCP Questions
To: [redacted]
Subject: Recent Audit for a site and clarification requested for medical records
Date: Wednesday, January 31, 2018 11:22:00 AM
Attachments: [redacted]

Good morning –

FDA regulations are not that detailed but every effort should be used to minimize inconsistencies in recording/documenting clinical trial information. We often say when the regulations are silent, sites and institutions are free to develop their own standard operating procedures to address a specific issue or problem.

You might be interested in the guidance link below.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Tuesday, January 30, 2018 1:47 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Recent Audit for a site and clarification requested for medical records

To Whom It May Concern,

There was a recent site Audit and the auditor's findings included "**Inconsistent data between source documents/ certified EMR copies filed in the subjects' charts and the eCRF. "**

The site's standard process is to review medical history and concomitant medications with the subjects during the screening visit to confirm and clarify all medical procedures/surgeries performed and medications taken previously and currently. Site staff utilizes the site's medical history consult form (source template) during the screening visit and enters this information confirmed by the subject during the visit into EDC. The EMR records are utilized as a reference point for site staff to gather medical history information for the subjects but the subjects verbal consent on their own medical history takes precedence over the medical history documented in the EMR records. For example, if a medication such as Lisinopril has a start date of Jan 2017 listed on the certified EMR record and the subject denies taking this medication, then the site would NOT enter this medication into EDC nor would they record on the

subjects medical history intake form (source template) since the subject gave a verbal consent of NOT taking the medication. In addition, if the subject were to confirm that he or she took the medication Mar 2017 instead of Jan 2017, then once again the site would take the subjects start date of Mar 2017 instead of the EMR recorded start date of Jan2017 and record the subjects verbal consent start date of Mar 2017 on medical history intake form (source template) and enter in to EDC. The same format would follow for past medical hx/procedures/surgeries. The site has a general note to file documenting their process but it is not detailed enough.

To confirm the site utilizes the EMR records to gather medical history data and background information of the subject and at the screening visit the site staff will cross reference medical history documented in the EMR records with the subject and record the subjects verbal consent of their own medical history on their source template worksheet for (medical intake form). The data captured on this form is the data to be entered into EDC NOT the data documented on the EMR records. Can you please confirm if this method is acceptable per FDA regulations. What corrective action should be implemented for the site. I feel the site needs to implement a SOP to better clarify their process.

Thank you,

[redacted]

[redacted]

[redacted]

[redacted]