From: OC GCP Questions
Sent: Friday, December 11, 2015 3:44 PM
To: [redacted]
Subject: RE: Source documentation worksheets provided by sponsor

Dear [redacted]:

Many institutions and sites are going to a fully electronic record system. If the protocol states that the site should be using electronic records, it is not necessary to keep hard copies if the original files can be accessed electronically. However, if the protocol requires hard copies, whatever is specified in the protocol would be necessary.

Please note that there are no restrictions on which documents are maintained electronically or signed with e-signatures. If a site were to have a bioresearch monitoring (BIMO) inspection, the FDA investigator would look for the site's procedures for creating certified copies or validating e-signatures if they are used and determine if they were followed since there are no specific procedures identified in the regulations.

I've listed below a few FDA guidance documents that you may find helpful:

FDA's Guidance for Industry – Computerized Systems Used in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

FDA's Guidance for Industry -- Part 11, Electronic Records; Electronic Signatures --Scope and Application found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

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

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Tuesday, December 08, 2015 8:49 PM
To: OC GCP Questions
Subject: Source documentation worksheets provided by sponsor

Dear GCP Help Desk,

Would you please provide guidance on whether a sponsor may MANDATE that a site utilize sponsor-provided worksheets, even when electronic medical records are available to provide every end point required in the study? It seems that requiring a site to manually transcribe data from the electronic medical record to a sponsor-provided paper form only creates possible conflicting data due to transcription errors, and therefore would not be desirable.

Also, if a site has an SOP specifying that they will utilize electronic medical records as the primary (and only) source data document when those records are available, is that sufficient to meet all FDA requirements? Or may the sponsor (who is insisting that the site use paper worksheets) cite them for failure to follow sponsor guidelines?

Thank you,
[redacted]