From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, November 30, 2005 2:51 PM
To: [redacted]
Subject: RE: Source Documentation

Dear [redacted],

Thank you for the clarification. The use of a paper and electronic record hybrid system is especially helpful when a company first decides to utilize electronic data capture systems. Transitioning from a paper to a totally electronic record environment can be challenging to people. Using a hybrid system as the first step can help employees gain confidence in using and relying on an electronic system/records.

When considering the use of computerized systems, its important that source data and study records factually and accurately document how a study was conducted, and that these records/data be preserved in a manner that successfully preserves them for later reference (either in a paper or electronic format).

The process you describe below seems reasonable and if properly implemented should meet the regulatory requirements for creating and preserving study records.

If you have specific questions about using computers in a clinical setting, I suggest you look at the FDA guidance document entitled "Computerized Systems Used in Clinical Trials". This document was first published in 1999 and was recently revised (and is available as a draft guidance) in 2004. Here is the url for this guidance: http://www.fda.gov/oc/gcp/guidance.html; it's the 5th posting on this web page.

I hope this information is helpful to you. Please let me know if you have any additional questions about the use of computerized systems in clinical trials.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD
20857
Telephone: 301-827-6473

-----Original Message-----
From: [redacted]
Sent: Wednesday, November 30, 2005 9:04 AM
To: 'OC GCP Questions'
Subject: RE: Source Documentation

Good morning Patricia,

The scenario you describe is what the [redacted]. The [redacted] group will create the e-CRF based on the protocol. They want to make a paper copy of each screen for each e-CRF module and bind these copies into a source workbook. The site will record source data onto this workbook and later enter the information into the e-CRF.

At the end of the trial, the e-CRF screen source workbook would be archived at the site as part of the patient's record. An electronic copy of the data entered into the e-CRF will also be provided to the site at study closure, for archiving.

Kind Regards,
[redacted]

-----Original Message-----
From: Beers Block, Patricia [mailto:PBeersblock@OC.FDA.GOV] On Behalf Of OC GCP Questions
Sent: Wednesday, November 30, 2005 7:49 AM
To: [redacted]
Subject: RE: Source Documentation

Good Morning [redacted],

I want to be certain I understand the process [redacted] to use before answering your question. Do [redacted] for the e-CRF screen shot printout to be used as the document onto which direct entries (e.g., source data) are recorded? Will this information/data then be transcribed to the e-CRF? What are your plans for the source data/record? Will the completed screen shot printout be preserved somehow?

It would be most helpful if you could clarify [redacted] for me. Thanks so much. I look forward to any clarification you can provide on this.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
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Rockville, MD
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-----Original Message-----
From: [redacted]
Sent: Friday, November 25, 2005 2:45 PM
To: 'OC GCP Questions'
Subject: Source Documentation

Hi Patricia,

Hope you are well and enjoying Thanksgiving. It's been a while since I had a question for you!

A [redacted] to provide the sites in [redacted] study with e-CRF screen shot printouts to be used as a source document template. [redacted] have not been willing to accept this although it has never been clearly explained to me why not. Can you provide me with the FDAs opinion on this matter?

Kind Regards,

[redacted]