From: Beers Block, Patricia
Sent: Wednesday, June 07, 2006 1:38 PM
To: [purged]
Subject: RE: Source document question

Dear Ms. Del Conte,

I'm a bit confused by your e-mail message so I think it might be best for me to explain: 1) what is considered source data/source document, and 2) how these documents can be used. If you still need more information about source documents, then by all means let me know and I'll address your specific question(s).

Although the regulations don't specifically make reference to the term source document, the ICH E6 Good Clinical Practice Consolidated Guidance (see section 1.52; http://www.fda.gov/cder/guidance/959fnl.pdf), defines source documents as:

> "original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and compete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medicao-technical departments involved in the clinical trial)."

So, you can see from this definition that, a source document can any record where original observations/data are recorded and/or certified copies of these original documents. For example, when using paper to record information, the source document is that piece of paper where an original observation or figure obtained from a measurement (e.g., a body temperature reading obtained from a thermometer) is recorded. The paper document can be part of a hospital medical chart where many observations/recordings about a subject are originally recorded; a sponsor-provided case report form; a form designed by the clinical testing facility; a bound notebook; or any other record that will be preserved (as the original paper or as a certified copy of the original paper).

This definition also introduces the concept of "certified" copies or transcriptions. What this means is that a copy of the "original" record can be relied upon to meet regulatory obligations in the same manner as the original record provided the copying process has been "verified" as producing a copy that contains all of the attributes and meaning of the original document. Perhaps a useful example to consider is that of making a photocopy of the original

document. If you verify through a validated process (such as visually comparing information that's present on the original document with the photocopy) that the photocopying process captured all of the attributes (e.g., ink color, stamped information) and content of the original record on the photocopy itself, you can rely on the photocopy to meet your regulatory requirements. Based on the ICH definition of source document, this photocopy would be considered equivalent to the original record.

You apply the same concepts when using electronic records. The first recording of information on an electronic record constitutes the creation of an "original" or source document. When you then convert the source e-document to a pdf version of the record, using a process that has been proven to capture all of the source document attributes and information, (e.g., by verifying the content through a visual comparison of all of the data/information that was on the original paper record with the pdf electronic version of that record), you now have a copy that can be relied upon as if it was the "original" document.

I hope this information is helpful. Please let me know if I can provide any additional information about all of this.

Sincerely,

Patricia M. Beers Block
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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.

From: [purged]
Sent: Tuesday, May 23, 2006 4:19 PM
To: OC GCP Questions
Subject: Source document question

Hello-

I have a question regarding using a copy of the CRF as the source document. We are currently working with a sponsor that said it was OK to copy the CRF and without change, use as the source document. From a legal and FDA view, is this acceptable? Is seems that there should be aditional informatin on the source that is not captured in the CRF to support the information obtained. Thank you for your time.

Regards,

[purged]