From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, June 02, 2005 11:09 AM
To: [redacted]
Subject: RE: electronic records

Dear [redacted],

Your inquiry was referred to our office for a direct reply. If I understand your question correctly, you are asking whether the organization that originally collected clinical data by, for example, recording information onto paper records and later transferring this data to electronic records, needs to comply with any FDA regulations or guidances. The quick answer to your question is "yes". THe following information explains which regulations and guidances are relevant to your question.

The regulations governing good clinical practice (e.g., 21 CFR 312; 21 CFR 812) do require that information and observations related to the conduct of a clinical trial be accurately and adequately recorded, and that this information be able for FDA inspection and copying. While it is always desirable to keep the original record of an observation, sometimes this is impractical and it makes more sense to copy the original record and substitute the copy for the original record as the "source document". In the instance you describe below, the "original" information would be that information that was recorded on paper by the collecting site; the copy would be any electronic record created by transcribing information from the paper record to the e-record.

There is no explicit regulatory requirement that the original record must be kept. However, the regulations (e.g., 21 CFR 312.62(b)) do require that the investigator prepare and maintain adequate and accurate case histories. The pertinent regulatory description of a case history is as follows:

"...Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses` notes..."

Therefore all information related to the conduct of the clinical trial must be kept as they are part of the case history. Fortunately, because the regulations do not expressly require the original note, a copy can be substituted for the original record as a "source document" under certain circumstances. Namely, a copy of an original record can serve as a source document if the copy is certified after verification as accurate and complete, containing all of the original attributes and information as the original. It is important to accurately describe in either study related records (e.g., SOPs) and/or the study protocol the methods that will be used to preserve all of the original attributes and information of the original. These procedures should describe the methods that will be used for documenting the verification and certification of copies to permit their authentication as source documents.

The ICH E6 GCP consolidated guidance (http://www.fda.gov/cder/guidance/959fnl.pdf) addresses this in the definitions of source data and source documents. I've included them below and put the pertinent text in bold italic:

1.51 Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

Source data are contained in source documents (original records or certified copies).

1.52 Source Documents: 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 complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

Another guidance that addresses the use of computerized systems in clinical trials is FDA's guidance entitled "Guidance for Industry: Computerized Systems Used in Clinical Trials" (http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.pdf links to the version finalized in April 1999; http://www.fda.gov/OHRMS/DOCKETS/98fr/2004d-0440-gdl0001.pdf links to the redrafted version of this guidance issued for comment on September 2004). This document provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA. This guidance further explains FDA's position on the use of computerized systems and electronic data.

Hopefully the comments I provided above answer your questions. However if I've made incorrect assumptions, please let me know and we can discuss this further.

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: 301-827-3340

-----Original Message-----
From: [redacted]
Sent: Wednesday, May 04, 2005 2:57 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [redacted]

E-Mail: [redacted]

Comments: An increasing number [redacted] are implementing the use of electronic medical records and/or research databases. As a result, these [redacted] are considering transferring data from the medical record (without identifying information)into a data management system (eCRF type)with other

contracted agencies (e.g. CROs), eliminating the need for using a traditional paper or electronic CRF. Are there any requirements/guidelines that would apply here for the agency transferring the data? Are they required to comply with regulations regarding testing/validation, audit trails, etc. or is it sufficient that the "receiving" agency is in compliance? For example, the audit trail at the receiving agency would likely only include information from the time it was received, but not necessarily what may have taken place before the data transfer.