From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, March 29, 2005 8:39 AM
To: [redacted]
Subject: RE: Electronic Medical Record

Dear [redacted],

Thank you for inquiring about this matter. Please accept my apologies for the delay in replying to your query. As you may have discovered after reading the draft guidance entitled "Computerized Systems Used in Clinical Trials" (see the second entry on http://www.fda.gov/oc/gcp/draft.html), FDA has broadened the methods by which one can keep information about the creation, modification, and deletion of electronic records and electronically captured data. In other words, FDA is permitting the use of methods other than computer-generated, time-stamped audit trails to keep track of changes to electronic records and electronic data. On page 7 of this draft guidance, you will find some examples of methods for tracking changes to electronic records. These include (but are not limited to):

- computer-generated , time-stamped electronic audit trails
- signed and dated printed version so f electronic records that identify what, when and by whom changes to the electronic records were made
- signed and dated printed standard electronic file formatted versions (e.g., pdf, xml, sgml) of electronic records that identify what, when and by whom changes were made to the electronic record
- procedural controls that preclude unauthorized personnel from creating, modifying, or deleting electronic records or the data contained therein.

Of course, other methods are acceptable provided that appropriate security measures exist that ensure electronic record integrity. Because clinical data are critical, and the records related to the clinical trial must be adequate and accurate, it is important to keep track of all changes made to information in the electronic records that document activities related to the conduct of the trial.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

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.

-----Original Message-----
From: [redacted]
Sent: Thursday, March 10, 2005 4:30 PM
To: gcpquestions@oc.fda.gov
Subject: Electronic Medical Record

Dear Pat,

We are [redacted] and have recently developed an electronic medical record database [redacted] for [redacted]. Initially, the plan was to use it in conjuction with the hard-copy medical record. Increasingly, however, information in the electronic medical record is not co-recorded in the hard-copy medical record. The problem with this is that the electronic medical record doesn't have and audit trail or some other components as outlined in the 'guidance for industry computerised systems used in clinical trials' document we found on your website. Our question is, if we meet the recommendations made in this document, does that mean we are compliant with FDA regulations and would this enable us to use the information collected in our electronic medical record as source documentation for our clinical trials data?

[redacted]