From: Beers Block, Patricia
Sent: Tuesday, November 07, 2006 8:28 AM
To: '**[Redacted]**
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. **[Redacted]**,

In addition to the comments provided below by Kavita Dada, you should be aware that it is FDA's practice to compare copies of study records (e.g., shadow records) with original source documents. FDA regulations found at 21 CFR 312.68 (for investigational drugs) and 21 CFR 812.145 (for investigational devices) require that an investigator permit an FDA employee to have access to and copy and verify any records or reports related to an investigation. If those records are electronic records, FDA will want to have access to, copy and verify those electronic records during its inspection.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/ FDA
5600 Fishers Lane, Rm. 14B17
Rockville, MD 20857

Tel: 301-827-6473

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: CDER DRUG INFO
Sent: Monday, October 23, 2006 3:11 PM
To: '**[Redacted]** '
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. **[Redacted]**:

Thank you for writing the Division of Drug Information, in the FDA's Center for Drug Evaluation and Research.

If you are not already familiar with the FDA guidance entitled "Guidance for Industry Computerized Systems used in Clinical Trials" (http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.pdf), I would highly recommend you look over this guidance as it addresses a number of

issues related to the use of computers in clinical trials that may be of interest to you.

Another reference that was recently published by the agency as a draft guidance about which you should be familiar is the "Guidance for Industry Part 11 Electronic Records; Electronic Signatures - Scope and Application (draft)"
(http://www.fda.gov/OHRMS/DOCKETS/98fr/03d-0060-gdl0001.pdf)

This guidance, although still in draft, more closely reflects the agency's current thinking on the application of certain aspects of the Part 11 regulation. This draft guidance proposes more flexibility in the area of copies of records, record retention, audit trails and validation.

All that being said, I am forwarding your inquiry regarding the audit to the Division of Good Clinical Practices for an accurate response. As soon as I receive the answer, I will respond to you directly.

Best regards,

KCD
Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration

This communication is consistent with 21CFR10.85(k) and constitutes and informal communication that represents our best judgment at this time but does not constitute and advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, October 17, 2006 6:08 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: Our research site has a question in regards to our electronic medical records system. Our system is CFR Part 11 compliant in regards to the stated regulations. My comment is we do not let sponsors go directly into our EMR system as we cannot limit the access to just those patients that are involved in the particular trial. We simply print out any records from the EMR system and create a "shadow hard copy chart" of which then we add specific source documents for the particular study visits and protocol required procedures for the sponsor

to review at standard monitoring visits. There is a basic trust that a site is providing full adequate records whether hard copy without an existing EMR system or a shadow chart of an exising EMR system plus study specific source documentation. A question that a sponsor posed to me is if we ever received an audit by the FDA would we let the FDA go directly into our EMR system versus just looking at the "shadow hard copy chart"? So my question is: Would the FDA mandate looking at the specific research record that was utilized during the study AND the actual EMR chart at the site if an audit occured for a particular study?