From: Toth-Allen, Jean
Sent: Tuesday, June 06, 2006 10:52 AM
To: [purged]
Subject: RE: specific guideline/regulation request

Dear [purged]:

Thank you for your inquiry concerning data integrity. Please excuse my delay in responding.

While FDA regulations regarding both non-clinical studies (21 CFR Part 58) and clinical studies (21 CFR Part 312 for pharmaceuticals and Part 812 for devices) specify that records need to be complete, accurate, and current, they do not include any specifics in this regard. Specifics are, however, found in the ICH guidance on good clinical practice which FDA has endorsed. While this guidance is written specifically to cover pharmaceutical studies, FDA believes the general information contained therein is applicable to all studies. This document, available at http://www.fda.gov/cder/guidance/959fnl.pdf, states at 4.9.3:

Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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: Friday, May 26, 2006 12:10 PM
To: OC GCP Questions
Subject: specific guideline/regulation request

Hello,

I would like to request the specific guideline(s)/regulations that deal with data integrity: cross-outs, initial and dates, no blank data, sloppy/ambiguous data. I'm having some difficulty locating this issue via my reference guide.

Thank you very much!

[purged]