From: OC GCP Questions
To: [redacted]
Subject: Question Concerning Back Dating of Study Documents
Date: Tuesday, January 02, 2018 10:45:00 AM
Attachments: [redacted]

Good morning --

Back dating is considered a serious violation that could be considered falsifying the document and could call in to question the integrity of the study data.

The steps described in ICH E6 4.9.3 represent an acceptable method to make changes or corrections in study documents. The FDA recognized ICH E6: Good Clinical Practice: Consolidated Guidance, available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf, does include the following recommendations:

Section 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 (see section 5.18.4(n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections."

Generally, the change should be crossed out with a single line, initialed, dated in real time, and explained by writing “error” without obscuring the original document.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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: [redacted]
Sent: Saturday, December 30, 2017 3:42 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Question Concerning Back Dating of Study Documents

I need some input.
An inspector or auditor notices the investigator site’s principal investigator (PI) acknowledging site

monitor's follow-up letters by placing an initial and date on the document. The date of the PI is several weeks or months from the date stated on the actual letter. The inspector or auditor has access to the electronic Portable Document Format (PDF), opens the properties (creation date/metadata/audit trail) and notes that the PDF creation date is very close to the PI's signature for 75% of the follow-up letters. The inspector or auditor interviews the PI and staff and confirms that the letters were in fact sent several weeks/months after the letter date. This was also confirmed by the email containing the letters. What regulations or practices are at play here?

[redacted]