From: OC GCP Questions
To: [redacted]
Subject: HOW TO CORRECT THE MEDICAL CHARTS
Date: Friday, February 20, 2015 12:15:47 PM

Good morning ---

I can speak only to what is expected by FDA for study related documents. Your subject line states "medical charts.

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 http://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.

For more complicated corrections, a note to file might be appropriate. Document your corrections with a note to file, including how you followed up with the subject.

You also may want to develop a standard operating procedure (SOP) for all study staff to follow with regard to corrections. This will minimize inconsistencies. Make sure that the corrections you describe are in line with your institution's policies and procedures.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs. 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

From: [redacted]
Sent: Friday, February 20, 2015 8:36 AM
To: OC GCP Questions
Subject: HOW TO CORRECT THE MEDICAL CHARTS

Dear GCP experts:

I am providing training a study site and the sub investigator commented to me an issue: a CRA requested to her to perform some corrections to an entire sheet of her medical notes. The CRA commented to her not to cross this sheet and add the initials, because she commented that this kind of correction looks so ugly, instead of this the CRA requested to her to add an addendum referring to this page and emphasizing the new information. I commented to the investigator, that this kind of correction could cause confusion for other revisers and the source documents will be no consistent because there will be different information in different pages.

Could you please confirm to me if the CRA request is acceptable or not?

[redacted]