From: OC GCP Questions
To: [redacted]
Subject: Making corrections
Date: Friday, December 11, 2015 11:58:33 AM

Good morning --

Please see ICH E6, Good Clinical Practice, Consolidated Guidance, section 4.9.3:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

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.

During an inspection, FDA's inspector would expect to see original entries and corrections, and (as indicated above) the date(s) the corrections were made, who made them, and the explanation why the correction was necessary.

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

Kind regards,

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Office of Good Clinical Practice

Office of the Commissioner, 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.

-----Original Message-----
From: [redacted]
Sent: Friday, December 11, 2015 11:43 AM
To: OC GCP Questions
Subject: Making corrections

What is proper way to make correction on paper crf's

Thank you