From: GC GCP Questions
To: [redacted]
Subject: [redacted] Document
Date: Wednesday, February 07, 2018 8:53:00 AM
Attachments: [redacted]

Good morning –

Certainly, any information documenting corrections needs to be legible, so efforts to ensure legibility when space is limited would be acceptable provided it is clear what information goes with each correction. If corrections are made by the same person, at the same time and for the same reason, then use of a vertical strike would appear to be a way to efficiently use limited space in order to assure legibility. Having an SOP for how errors will be corrected would help ensure consistency and may help address concerns that may arise when brackets or other methods are used due to limited space.

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/DrugsGuidanceComplianceRegulatoryInformation/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.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
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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: Wednesday, February 07, 2018 7:17 AM
To: GC GCP Questions <gcp-questions@fda.hhs.gov>
Subject: Regarding correction in document

Respected sir,

Kindly find attached herewith a sample copy of document in which i have made correction with a single vertical strike and i have made sign with date for correction.
My question is if multiple entries are corrected on same page and on same time but with a single vertical strike then is this method of correction is acceptable?

Awaiting for your reply.

Many thanks in advance

[redacted]